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THE GOVERNMENT PRINTING WORKS

PUBLICATIONS DIVISION

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**MASADA BUILDING at 196 PROES STREET, PRETORIA
(i.e. CORNER OF PAUL KRUGER AND PROES STREETS)**
with effect from **3 May 2005**.

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GENERAL NOTICE ALGEMENE KENNISGEWING

NOTICE 226 OF 2006

MEDICINES CONTROL COUNCIL

CONDITIONS OF REGISTRATION OF A MEDICINE IN TERMS OF THE PROVISIONS OF SECTION 15(7) OF THE MEDICINES AND RELATED SUBSTANCES ACT, 1965 (ACT No. 101 OF 1965)

1. The applicant shall ensure that the medicine is manufactured and controlled in terms of current Good Manufacturing Practices as determined by Council.
2. The manufacture of this medicine is subject to regular investigation and inspections by the inspectors appointed in terms of Section 26 of the Act, to assess compliance with current Good Manufacturing Practices.
3. The information in the package insert shall be updated on a regular basis to conform to the package insert recently approved by Council.
4. The applicant must comply with all the legal requirements of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965).
5. The registration of this medicine shall be subject to regular review regarding its quality, safety and efficacy, and the registration of this medicine may be varied subject to issues Council may deem fit.
6. The first two production batches must be fully validated in terms of the detailed process validation protocol submitted at the time of application for registration, and the validation report must be submitted within a month after completion of the validation.
7. The registration dossier is subject to review at intervals as determined by Council.
8. A post-registration inspection must be conducted in the first production batch of the locally manufactured product.
9. A post-registration inspection must be conducted on the first production batch manufactured by each local manufacturer.
10. A post-registration inspection must be conducted on the first production batch of the imported product.
11. Marketing of the product may only commence following a satisfactory post-registration inspection report.
12. One sample of every batch, together with four copies of the protocol for testing of the bulk lot and filling lot, and six copies of the certificate of release issued by a competent authority in the country in which the product was manufactured, must be submitted to the Council for lot release purposes.
13. The expiry date allocated shall be modified by adding a statement that the virus strains are currently recommended for South African usage in the specific year.
14. The strains of the master seed viruses must be approved by the Department of Health for each year.

KENNISGEWING 226 VAN 2006

MEDISYNEBEHEERRAAD

VOORWAARDES VIR DIE REGISTRASIE VAN 'N MEDISYNE IN TERME VAN DIE BEPALINGS VAN ARTIKEL 15(7) VAN DIE WET OP BEHEER VAN MEDISYNE EN VERWANTE STOWWE, 1965 (WET NO. 101 VAN 1965)

1. Die applikant sal verseker dat die medisyne vervaardig en beheer word ooreenkomstig huidige Goele Vervaardigingspraktyke soos bepaal deur die Medisynebeheerraad.
2. Die vervaardiging van hierdie medisyne is onderhewig aan gereelde ondersoeke en inspeksies deur Inspekteurs, aangestel ingevolge Artikel 26 van die Wet, om die nakoming van Goele Vervaardigingspraktyke te bepaal.
3. Die Inligting soos vervat in die voubiljet moet op 'n gereelde grondslag opgedateer word in ooreenstemming met 'n voubiljet wat onlangs deur die Raad goedgekeur is.
4. Die applikant moet voldoen aan alle wetlike vereistes van die Wet op Medisyne en Verwante Stowwe, 1965 (Wet No. 101 van 1965).
5. Die registrasie van hierdie medisyne is onderhewig aan gereelde hersiening rakende kwaliteit, veiligheid en effektiwiteit, en die registrasie van hierdie medisyne kan gewysig word onderhewig aan kwessies soos goedgealink deur die Raad.
6. Die eerste twee produksielote moet ten volle gevaldeur word ooreenkomstig die breedvoerige prosesvalidasie protokol wat ingedien is ten tye van die aansoek om registrasie, en die validasieverslag moet binne die bestek van een maand na die voltooiing van die validasie ingedien word.
7. Die registrasie-aansoek is onderhewig aan hersiening met tussenposes soos deur die Raad bepaal.
8. 'n Na-registrasie-inspeksie moet op die eerste produksielot van die plaaslike vervaardigde produk uitgevoer word.
9. 'n Na-registrasie-inspeksie moet op die eerste produksielot van elke plaaslike vervaardiger uitgevoer word.
10. 'n Na-registrasie-inspeksie moet op die eerste produksielot van die Ingevoerde produk uitgevoer word.
11. Bemerking van die produk mag slegs in aanvang neem nadat 'n bevredigende na-registrasie-inspeksieverslag gedien het.
12. Een monster van elke lot moet tesame met vier kopleë van die protokolle vir die toets van die massalot en die vullot sowel as ses kopleë van die vrystellingsertifikaat wat uitgereik is deur die verantwoordelike beheerliggaam in die land waar die produk vervaardig word, ingedien word by die Raad vir lotvrystellingsdoeleindes.
13. Die vervaldatum toegeken, sal gewysig word deur 'n verklaring by te voeg dat die virusstamme tans vir Suid-Afrikaanse gebruik gedurende die gespesifiseerde jaar aanbeveel word.
14. Die stamme van die oorspronklike saadvirusse moet elke jaar deur die Departement van Gesondheid goedgekeur word.

MRF 15 (MBR 15)

Registration number: 01/2.1/14

Name of medicine: ALFAXAN-CD RTU Anaesthetic Injection

Dosage form: INJECTION

Active ingredients: EACH 1,0 ml SOLUTION CONTAINS:
ALFAXOLONE 10,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: KYRON LABORATORIES (PTY) LTD

Manufacturer: JUROX, RUTHERFORD, NEW SOUTH WALES,
AUSTRALIA

Packer: JUROX, RUTHERFORD, NEW SOUTH WALES,
AUSTRALIA

Laboratory: FPRC: JUROX, RUTHERFORD, NEW SOUTH WALES,
AUSTRALIA
FPRC/FPRR: KYRON LABORATORIES, BENROSE, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A04/21.9/02

Name of medicine: RILEXINE 75

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
CEPHALEXIN MONOHYDRATE EQUIVALENT TO
CEPHALEXIN 75,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: VIRBAC RSA (PTY) LTD

Manufacturer: VIRBAC SA, CARROS-CEDEX, FRANCE

Packer: VIRBAC SA, CARROS-CEDEX, FRANCE
VIRBAC RSA, CENTURION, RSA

Laboratory: FPRC: VIRBAC SA, CARROS-CEDEX, FRANCE
INSPECTORATE M&L, ORMONDE,
JOHANNESBURG, RSA
FPRC/FPRR: VIRBAC RSA, CENTURION, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A04/21.9/03

Name of medicine: RILEXINE 300

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
CEPHALEXIN MONOHYDRATE EQUIVALENT TO
CEPHALEXIN 300,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: VIRBAC RSA (PTY) LTD

Manufacturer: VIRBAC SA, CARROS-CEDEX, FRANCE

Packer: VIRBAC SA, CARROS-CEDEX, FRANCE
VIRBAC RSA, CENTURION, RSA

Laboratory: FPRC: VIRBAC SA, CARROS-CEDEX, FRANCE
INSPECTORATE M&L, ORMONDE,
JOHANNESBURG, RSA
FPRC/FPRR: VIRBAC RSA, CENTURION, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A04/21.9/04

Name of medicine: RILEXINE 600

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
CEPHALEXIN MONOHYDRATE EQUIVALENT TO
CEPHALEXIN 600,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: VIRBAC RSA (PTY) LTD

Manufacturer: VIRBAC SA, CARROS-CEDEX, FRANCE

Packer: VIRBAC SA, CARROS-CEDEX, FRANCE
VIRBAC RSA, CENTURION, RSA

Laboratory: FPRC: VIRBAC SA, CARROS-CEDEX, FRANCE
INSPECTORATE M&L, ORMONDE,
JOHANNESBURG, RSA
FPRC/FPRR: VIRBAC RSA, CENTURION, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 93/16.1/3

Name of medicine: SYNULOC PRED LC

Dosage form: INFUSION

Active ingredients: EACH SYRINGE CONTAINS:
AMOXYCILLIN TRIHYDRATE EQUIVALENT TO
AMOXYCILLIN 200,0 MG
POTASSIUM CLAVULANATE EQUIVALENT TO
CLAVULANIC ACID 50,0 MG
PREDNISOLONE 10,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: PFIZER LABORATORIES (PTY) LTD

Manufacturer: PFIZER ITALIANA S.p.A, LATINA, ITALY

Packer: PFIZER ITALIANA S.p.A, LATINA, ITALY

Laboratory: FPRC: PFIZER ITALIANA S.p.A, LATINA, ITALY
FPRR: PFIZER LABORATORIES, PIETERMARITZBURG,
RSA

Shelf-life: 18 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 35/7.1/0179

Name of medicine: DINATRIX

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
INDAPAMIDE 2,5 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: PHARMACARE LIMITED

Manufacturer: LENNON LTD, KORSTEN PORT ELIZABETH

Packer: LENNON LTD, KORSTEN PORT ELIZABETH

Laboratory: FPRC/FPRR: LENNON LTD, KORSTEN PORT ELIZABETH
PHARMACARE LTD, KORSTEN, PORT ELIZABETH

Shelf-life: 48 months packed in Securitainers
36 months packed in Blisters

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 36/21.5.1/0105

Name of medicine: METICORTEN 20 MG TABLETS

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
PREDNISONONE 20,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: SCHERING-PLOUGH (PTY) LTD

Manufacturer: SCHERING-PLOUGH, ISANDO, RSA

Packer: SCHERING-PLOUGH, ISANDO, RSA

Laboratory: FPRC/FPRR: SCHERING-PLOUGH, ISANDO, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 36/24/0176

Name of medicine: POTIDE

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
POTASSIUM CHLORIDE 600,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: SANDOZ (PTY) LTD

Manufacturer: NOVARTIS, SPARTAN, KEMPTON PARK, RSA

Packer: NOVARTIS, SPARTAN, KEMPTON PARK, RSA

Laboratory: FPRC/FPRR: NOVARTIS, SPARTAN, KEMPTON PARK, RSA
FPRR: SANDOZ, SPARTAN, KEMPTON PARK, RSA

Shelf-life: 24 months packed in Blisters
60 months packed in HDPE securitainers

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 36/20.1.1/0221

Name of medicine: BETAMYCIN 250 MG

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
ERYTHROMYCIN STEARATE EQUIVALENT TO
ERYTHROMYCIN 250,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: BE-TABS PHARMACEUTICALS (PTY) LTD

Manufacturer: KOPRAN LTD, KHALAPUR, RAIGAD, INDIA

Packer: KOPRAN LTD, KHALAPUR, RAIGAD, INDIA

Laboratory: FPRC: KOPRAN LTD, KHALAPUR, RAIGAD, INDIA
FPRR: BE-TABS PHARMACEUTICALS, ROODEPOORT, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 36/20.1.1/0241

Name of medicine: PHARMACARE AMIKACIN 100 MG/2 ML

Dosage form: INJECTION

Active ingredients: EACH 2,0 ml SOLUTION CONTAINS:
AMIKACIN SULPHATE EQUIVALENT TO
AMIKACIN 100,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: PHARMACARE LIMITED

Manufacturer: BODENE, KORSTEN, PORT ELIZABETH
PHARMA-Q, INDUSTRIA, JOHANNESBURG

Packer: BODENE, KORSTEN, PORT ELIZABETH
PHARMA-Q, INDUSTRIA, JOHANNESBURG

Laboratory: FPRC: BODENE, KORSTEN, PORT ELIZABETH
PHARMA-Q, INDUSTRIA, JOHANNESBURG
FPRR: PHARMACARE LTD, KORSTEN, PORT ELIZABETH

Shelf-life: 48 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 36/20.1.1/0242

Name of medicine: PHARMACARE AMIKACIN 500 MG/2 ML

Dosage form: INJECTION

Active ingredients: EACH 2,0 ml SOLUTION CONTAINS:
AMIKACIN SULPHATE EQUIVALENT TO
AMIKACIN 500,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: PHARMACARE LIMITED

Manufacturer: BODENE, KORSTEN, PORT ELIZABETH
PHARMA-Q, INDUSTRIA, JOHANNESBURG

Packer: BODENE, KORSTEN, PORT ELIZABETH
PHARMA-Q, INDUSTRIA, JOHANNESBURG

Laboratory: FPRC: BODENE, KORSTEN, PORT ELIZABETH
PHARMA-Q, INDUSTRIA, JOHANNESBURG
FPRR: PHARMACARE LTD, KORSTEN, PORT ELIZABETH

Shelf-life: 48 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 36/7.1.3/0291

Name of medicine: P & U ENALAPRIL MALEATE 2,5 MG

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
ENALAPRIL MALEATE 2,5 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: PHARMACIA S.A. (PTY) LTD

Manufacturer: DEXCEL LTD, OR AKIVA, ISRAEL

Packer: DEXCEL LTD, OR AKIVA, ISRAEL

Laboratory: FPRC: DEXCEL LTD, OR AKIVA, ISRAEL
PERIO PRODUCTS, JERUSALEM, ISRAEL
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
KHULULEKANI LABORATORY SERVICES,
MIDRAND, RSA
FPRR: PHARMACIA, MIDRAND, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 36/7.1.3/0292

Name of medicine: P & U ENALAPRIL MALEATE 5 MG

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
ENALAPRIL MALEATE 5,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: PHARMACIA S.A. (PTY) LTD

Manufacturer: DEXCEL LTD, OR AKIVA, ISRAEL

Packer: DEXCEL LTD, OR AKIVA, ISRAEL

Laboratory: FPRC: DEXCEL LTD, OR AKIVA, ISRAEL
PERIO PRODUCTS, JERUSALEM, ISRAEL
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
KHULULEKANI LABORATORY SERVICES,
MIDRAND, RSA
FPRR: PHARMACIA, MIDRAND, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 36/7.1.3/0293

Name of medicine: P & U ENALAPRIL MALEATE 10 MG

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
ENALAPRIL MALEATE 10,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: PHARMACIA S.A. (PTY) LTD

Manufacturer: DEXCEL LTD, OR AKIVA, ISRAEL

Packer: DEXCEL LTD, OR AKIVA, ISRAEL

Laboratory: FPRC: DEXCEL LTD, OR AKIVA, ISRAEL
PERIO PRODUCTS, JERUSALEM, ISRAEL
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
KHULULEKANI LABORATORY SERVICES,
MIDRAND, RSA
FPRR: PHARMACIA, MIDRAND, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 36/7.1.3/0294

Name of medicine: P & U ENALAPRIL MALEATE 20 MG

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
ENALAPRIL MALEATE 20,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: PHARMACIA S.A. (PTY) LTD

Manufacturer: DEXCEL LTD, OR AKIVA, ISRAEL

Packer: DEXCEL LTD, OR AKIVA, ISRAEL

Laboratory: FPRC: DEXCEL LTD, OR AKIVA, ISRAEL
PERIO PRODUCTS, JERUSALEM, ISRAEL
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
KHULULEKANI LABORATORY SERVICES,
MIDRAND, RSA
FPRR: PHARMACIA, MIDRAND, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 36/2.8/0379

Name of medicine: MYBUCOD

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
IBUPROFEN 200,0 MG
PARACETAMOL 350,0 MG
CODEINE PHOSPHATE 10,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: PHARMACARE LIMITED

Manufacturer: LENNON LTD, KORSTEN, PORT ELIZABETH
SAD SELF MEDICATION, WILSONIA,
EAST LONDON

Packer: LENNON LTD, KORSTEN, PORT ELIZABETH
SAD SELF MEDICATION, WILSONIA,
EAST LONDON

Laboratory: FPRC: LENNON LTD, KORSTEN, PORT ELIZABETH
SAD SELF MEDICATION, WILSONIA,
EAST LONDON
FPRR: PHARMACARE, KORSTEN, PORT ELIZABETH

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 36/7.1.3/0382

Name of medicine: DIOVAN 40

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
VALSARTAN 40,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: NOVARTIS SOUTH AFRICA (PTY) LTD

Manufacturer: NOVARTIS PHARMA STEIN,
SCHAFFHAUSERSTRASSE, STEIN, SWITZERLAND

Packer: NOVARTIS PHARMA STEIN,
SCHAFFHAUSERSTRASSE, STEIN, SWITZERLAND
NOVARTIS, SPARTAN, KEMPTON PARK, RSA

Laboratory: FPRC: NOVARTIS PHARMA STEIN,
SCHAFFHAUSERSTRASSE, STEIN, SWITZERLAND
INSPECTORATE M&L, ORMONDE,
JOHANNESBURG, RSA
FPRC/FPRR: NOVARTIS, SPARTAN, KEMPTON PARK, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 36/2.2/0524

Name of medicine: SANDOZ-ZOPICLONE 3,75

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
ZOPICLONE 3,75 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: SANDOZ (PTY) LTD

Manufacturer: NOVARTIS SA, SPARTAN, KEMPTON PARK, RSA

Packer: NOVARTIS SA, SPARTAN, KEMPTON PARK, RSA

Laboratory: FPRC/FPRR: NOVARTIS SA, SPARTAN, KEMPTON PARK, RSA
FPRR: SANDOZ, SPARTAN, KEMPTON PARK, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR, 15)

Registration number: 37/13.4.2/0040

Name of medicine: TRETODERM 10

Dosage form: CAPSULE

Active ingredients: EACH CAPSULE CONTAINS:
ISOTRETINOIN 10,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: HEXAL PHARMA (SA) (PTY) LTD

Manufacturer: SWISS CAPS, KIRCHBERG, SWITZERLAND

Packer: DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, RSA
PHARMA-Q, INDUSTRIA WEST, GAUTENG, RSA

Laboratory: FPRC: SWISS CAPS, KIRCHBERG, SWITZERLAND
PHARMA-Q, INDUSTRIA WEST, GAUTENG, RSA
CONSULTING CHEMICAL LABORATORIES, STAR
STREET, BOKSBURG, RSA
ANALYTICON, KEMPTON PARK, RSA
FPRR: HEXAL PHARMA, WESTMEAD, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 37/13.4.2/0041

Name of medicine: TRETODERM 20

Dosage form: CAPSULE

Active ingredients: EACH CAPSULE CONTAINS:
ISOTRETINOIN 20,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: HEXAL PHARMA (SA) (PTY) LTD

Manufacturer: SWISS CAPS, KIRCHBERG, SWITZERLAND

Packer: DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, RSA
PHARMA-Q, INDUSTRIA WEST, GAUTENG, RSA

Laboratory:FPRC: SWISS CAPS, KIRCHBERG, SWITZERLAND
PHARMA-Q, INDUSTRIA WEST, GAUTENG, RSA
CONSULTING CHEMICAL LABORATORIES, STAR
STREET, BOKSBURG, RSA
ANALYTICON, KEMPTON PARK, RSA
FPRR: HEXAL PHARMA, WESTMEAD, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 37/5.4/0106

Name of medicine: DAS-OXYBUTYNNIN HCL 5 MG

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
OXYBUTYNNIN HYDROCHLORIDE 5,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: STRIDES SA (PTY) LTD

Manufacturer: ROTTENDORF PHARMA GmbH,
ENNIGERLOH, GERMANY

Packer: ROTTENDORF PHARMA GmbH,
ENNIGERLOH, GERMANY
DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, RSA
PHARMA NATURA, WYNBERG, SANDTON, RSA

Laboratory: FPRC: ROTTENDORF PHARMA GmbH,
ENNIGERLOH, GERMANY
COLUMBIA PHARMACEUTICALS, BARDENE,
BOKSBURG, RSA
INSTITUTE FOR PHARMACEUTICAL SERVICES,
BOKSBURG, RSA
SYNTHON, NIJMEGEN, THE NETHERLANDS
FPRR: STRIDES, ARCADIA, PRETORIA, RSA

Shelf-life: 36 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 37/34/0145

Name of medicine: DILUENT FOR RISPERDAL CONSTA

Dosage form: INJECTION

Active ingredients: EACH 1,0 ml SOLUTION CONTAINS:
SODIUM CARBOXYMETHYLCELLULOSE 22,5 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: JANSSEN PHARMACEUTICA (PTY) LTD

Manufacturer: VETTER PHARMA FERTIGUNG GmbH,
RAVENBERG, GERMANY

Packer: CILAG AG, SCHAFFHAUSEN, SWITZERLAND

Laboratory: FPRC: JANSSEN PHARMACEUTICA NV, BEERSE,
BELGIUM
FPRR: JANSSEN PHARMACEUTICA, HALFWAY HOUSE,
RSA

Shelf-life: 36 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 37/1.2/0157

Name of medicine: CIPLA-FLUOXETINE ORAL SOLUTION

Dosage form: SOLUTION

Active ingredients: EACH 5,0 ml SOLUTION CONTAINS:
FLUOXETINE HYDROCHLORIDE EQUIVALENT TO
FLUOXETINE 20,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: CIPLA MEDPRO (PTY) LTD

Manufacturer: CIPLA LTD, SATARA, INDIA
CIPLA LTD, VIKHROLI, BOMBAY, INDIA

Packer: CIPLA LTD, SATARA, INDIA
CIPLA LTD, VIKHROLI, BOMBAY, INDIA

Laboratory: FPRC: CIPLA LTD, SATARA, INDIA
CIPLA LTD, VIKHROLI, BOMBAY, INDIA
FPRR: CIPLA MEDPRO, ROSENPARK, BELLVILLE, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 37/34/0158

Name of medicine: MYFORTIC 180

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
MYCOPHENOLATE SODIUM EQUIVALENT TO
MYCOPHENOLATE 180,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: NOVARTIS SOUTH AFRICA (PTY) LTD

Manufacturer: NOVARTIS PHARMA STEIN,
SCHAFFHAUSERSTRASSE, STEIN, SWITZERLAND

Packer: NOVARTIS PHARMA STEIN,
SCHAFFHAUSERSTRASSE, STEIN, SWITZERLAND
NOVARTIS, SPARTAN, KEMPTON PARK, RSA

Laboratory: FPRC: NOVARTIS PHARMA STEIN,
SCHAFFHAUSERSTRASSE, STEIN, SWITZERLAND
INSPECTORATE M&L, ORMONDE,
JOHANNESBURG, RSA
FPRC/FPRR: NOVARTIS, SPARTAN, KEMPTON PARK, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 37/34/0159

Name of medicine: MYFORTIC 360

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
MYCOPHENOLATE SODIUM EQUIVALENT TO
MYCOPHENOLATE 360,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: NOVARTIS SOUTH AFRICA (PTY) LTD

Manufacturer: NOVARTIS PHARMA STEIN,
SCHAFFHAUSERSTRASSE, STEIN, SWITZERLAND

Packer: NOVARTIS PHARMA STEIN,
SCHAFFHAUSERSTRASSE, STEIN, SWITZERLAND
NOVARTIS, SPARTAN, KEMPTON PARK, RSA

Laboratory: FPRC: NOVARTIS PHARMA STEIN,
SCHAFFHAUSERSTRASSE, STEIN, SWITZERLAND
INSPECTORATE M&L, ORMONDE,
JOHANNESBURG, RSA
FPRC/FPRR: NOVARTIS, SPARTAN, KEMPTON PARK, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 37/2.6.5/0188

Name of medicine: CLOZAPINE-HEXAL 25

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
CLOZAPINE 25,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: HEXAL PHARMA (S.A.) (PTY) LTD

Manufacturer: HEXAL AG, HOLZKIRCHEN, GERMANY

Packer: HEXAL AG, HOLZKIRCHEN, GERMANY
DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, RSA
PHARMA Q, INDUSTRIA WEST, RSA

Laboratory: FPRC: HEXAL AG, HOLZKIRCHEN, GERMANY
PHARMA Q, INDUSTRIA WEST, RSA
CONSULTING CHEMICAL LABORATORIES,
STAR STREET, BOKSBURG, RSA
ANALYTICON, KEMPTON PARK, RSA
FPRR: HEXAL PHARMA, WESTMEAD, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 37/2.6.5/0189

Name of medicine: CLOZAPINE-HEXAL 50

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
CLOZAPINE 50,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: HEXAL PHARMA (S.A.) (PTY) LTD

Manufacturer: HEXAL AG, HOLZKIRCHEN, GERMANY

Packer: HEXAL AG, HOLZKIRCHEN, GERMANY
DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, RSA
PHARMA Q, INDUSTRIA WEST, RSA

Laboratory: FPRC: HEXAL AG, HOLZKIRCHEN, GERMANY
PHARMA Q, INDUSTRIA WEST, RSA
CONSULTING CHEMICAL LABORATORIES,
STAR STREET, BOKSBURG, RSA
ANALYTICON, KEMPTON PARK, RSA
FPRR: HEXAL PHARMA, WESTMEAD, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 37/2.6.5/0190

Name of medicine: CLOZAPINE-HEXAL 100

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
CLOZAPINE 100,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: HEXAL PHARMA (S.A.) (PTY) LTD

Manufacturer: HEXAL AG, HOLZKIRCHEN, GERMANY

Packer: HEXAL AG, HOLZKIRCHEN, GERMANY
DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, RSA
PHARMA Q, INDUSTRIA WEST, RSA

Laboratory: FPRC: HEXAL AG, HOLZKIRCHEN, GERMANY
PHARMA Q, INDUSTRIA WEST, RSA
CONSULTING CHEMICAL LABORATORIES,
STAR STREET, BOKSBURG, RSA
ANALYTICON, KEMPTON PARK, RSA
FPRR: HEXAL PHARMA, WESTMEAD, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 37/2.6.5/0191

Name of medicine: HEXAL-CLOZAPINE 25 MG TABLETS

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
CLOZAPINE 25,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: HEXAL PHARMA (S.A.) (PTY) LTD

Manufacturer: HEXAL AG, HOLZKIRCHEN, GERMANY

Packer: HEXAL AG, HOLZKIRCHEN, GERMANY
DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, RSA
PHARMA Q, INDUSTRIA WEST, RSA

Laboratory: FPRC: HEXAL AG, HOLZKIRCHEN, GERMANY
PHARMA Q, INDUSTRIA WEST, RSA
CONSULTING CHEMICAL LABORATORIES,
STAR STREET, BOKSBURG, RSA
ANALYTICON, KEMPTON PARK, RSA
FPRR: HEXAL PHARMA, WESTMEAD, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 37/2.6.5/0192

Name of medicine: HEXAL-CLOZAPINE 50 MG TABLETS

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
CLOZAPINE 50,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: HEXAL PHARMA (S.A.) (PTY) LTD

Manufacturer: HEXAL AG, HOLZKIRCHEN, GERMANY

Packer: HEXAL AG, HOLZKIRCHEN, GERMANY
DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, RSA
PHARMA Q, INDUSTRIA WEST, RSA

Laboratory: FPRC: HEXAL AG, HOLZKIRCHEN, GERMANY
PHARMA Q, INDUSTRIA WEST, RSA
CONSULTING CHEMICAL LABORATORIES,
STAR STREET, BOKSBURG, RSA
ANALYTICON, KEMPTON PARK, RSA
FPRR: HEXAL PHARMA, WESTMEAD, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number:	37/2.6.5/0193
Name of medicine:	HEXAL-CLOZAPINE 100 MG TABLETS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CLOZAPINE 100,0 MG
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	HEXAL PHARMA (S.A.) (PTY) LTD
Manufacturer:	HEXAL AG, HOLZKIRCHEN, GERMANY
Packer:	HEXAL AG, HOLZKIRCHEN, GERMANY DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, RSA PHARMA Q, INDUSTRIA WEST, RSA
Laboratory:	FPRC: HEXAL AG, HOLZKIRCHEN, GERMANY PHARMA Q, INDUSTRIA WEST, RSA CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA ANALYTICON, KEMPTON PARK, RSA FPRR: HEXAL PHARMA, WESTMEAD, RSA
Shelf-life:	24 months
Date of registration:	25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 37/2.2/0211

Name of medicine: DAS-MIDAZOLAM 5 MG/5 ML

Dosage form: INJECTION

Active ingredients: EACH 5,0 ml AMPOULE CONTAINS:
MIDAZOLAM 5,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: STRIDES S.A. (PTY) LTD

Manufacturer: PHARMA HAMELN GmbH, HAMELN, GERMANY
NYCOMED AUSTRIA GmbH, LINZ, AUSTRIA

Packer: PHARMA HAMELN GmbH, HAMELN, GERMANY
NYCOMED AUSTRIA GmbH, LINZ, AUSTRIA
DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, RSA
PHARMA NATURA, WYNBERG, SANDTON, RSA

Laboratory: FPRC: PHARMA HAMELN GmbH, HAMELN, GERMANY
NYCOMED AUSTRIA GmbH, LINZ, AUSTRIA
INSTITUTE FOR PHARMACEUTICALS SERVICES,
BARDENE, BOKSBURG, RSA
FPRR: SYNTHON BV, NIJMEGEN, THE NETHERLANDS
STRIDES, ARCADIA, PRETORIA, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 37/2.2/0212

Name of medicine: DAS-MIDAZOLAM 15 MG/3 ML

Dosage form: INJECTION

Active ingredients: EACH 3,0 ml AMPOULE CONTAINS:
MIDAZOLAM 15,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: STRIDES S.A. (PTY) LTD

Manufacturer: PHARMA HAMELN GmbH, HAMELN, GERMANY
NYCOMED AUSTRIA GmbH, LINZ, AUSTRIA

Packer: PHARMA HAMELN GmbH, HAMELN, GERMANY
NYCOMED AUSTRIA GmbH, LINZ, AUSTRIA
DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, RSA
PHARMA NATURA, WYNBERG, SANDTON, RSA

Laboratory: FPRC: PHARMA HAMELN GmbH, HAMELN, GERMANY
NYCOMED AUSTRIA GmbH, LINZ, AUSTRIA
INSTITUTE FOR PHARMACEUTICALS SERVICES,
BARDENE, BOKSBURG, RSA
FPRR: SYNTHON BV, NIJMEGEN, THE NETHERLANDS
STRIDES, ARCADIA, PRETORIA, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 37/2.2/0213

Name of medicine: DAS-MIDAZOLAM 50 MG/10 ML

Dosage form: INJECTION

Active ingredients: EACH 10,0 ml AMPOULE CONTAINS:
MIDAZOLAM 50,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: STRIDES S.A. (PTY) LTD

Manufacturer: PHARMA HAMELN GmbH, HAMELN, GERMANY
NYCOMED AUSTRIA GmbH, LINZ, AUSTRIA

Packer: PHARMA HAMELN GmbH, HAMELN, GERMANY
NYCOMED AUSTRIA GmbH, LINZ, AUSTRIA
DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, RSA
PHARMA NATURA, WYNBERG, SANDTON, RSA

Laboratory: FPRC: PHARMA HAMELN GmbH, HAMELN, GERMANY
NYCOMED AUSTRIA GmbH, LINZ, AUSTRIA
INSTITUTE FOR PHARMACEUTICALS SERVICES,
BARDENE, BOKSBURG, RSA
FPRR: SYNTHON BV, NIJMEGEN, THE NETHERLANDS
STRIDES, ARCADIA, PRETORIA, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 37/7.1.3/0225

Name of medicine: CO-DIOVAN 160 PLUS

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
VALSARTAN 160,0 MG
HYDROCHLOROTHIAZIDE 25,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: NOVARTIS SOUTH AFRICA (PTY) LTD

Manufacturer: NOVARTIS PHARMA STEIN,
SCHAFFHAUSERSTRASSE, STEIN, SWITZERLAND

Packer: NOVARTIS PHARMA STEIN,
SCHAFFHAUSERSTRASSE, STEIN, SWITZERLAND
NOVARTIS, SPARTAN, KEMPTON PARK, RSA

Laboratory: FPRC: NOVARTIS PHARMA STEIN,
SCHAFFHAUSERSTRASSE, STEIN, SWITZERLAND
INSPECTORATE M&L, ORMONDE,
JOHANNESBURG, RSA
FPRC/FPRR: NOVARTIS, SPARTAN, KEMPTON PARK, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 37/34/0254

Name of medicine: NEUMEGA STERILE WATER FOR INJECTION

Dosage form: INJECTION

Active ingredients: EACH VIAL CONTAINS:
WATER FOR INJECTIONS 1,0 ml

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: WYETH S.A. (PTY) LTD

Manufacturer: GENSLASICOR PHARMACEUTICALS, IRVINE, USA

Packer: GENSLASICOR PHARMACEUTICALS, IRVINE, USA

Laboratory: FPRC: GENSLASICOR PHARMACEUTICALS, IRVINE, USA
PHARMA-Q, INDUSTRIA, RSA
SOUTH AFRICAN BUREUA OF STANDARDS,
PRETORIA, RSA
FPRR: WYETH, MIDRAND, RSA

Shelf-life: 36 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 37/10.2.1/0273

Name of medicine: ATROVENT 20 HFA

Dosage form: METERED DOSE INHALER

Active ingredients: EACH METERED DOSE CONTAINS:
IPRATROPIUM BROMIDE EQUIVALENT TO
IPRATROPIUM BROMIDE ANHYDROUS 0,02 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: INGELHEIM PHARMACEUTICALS (PTY) LTD

Manufacturer: BOEHRINGER INGELHEIM PHARMA, INGELHEIM
AM RHEIN, GERMANY

Packer: BOEHRINGER INGELHEIM PHARMA, INGELHEIM
AM RHEIN, GERMANY

Laboratory: FPRC: BOEHRINGER INGELHEIM PHARMA, INGELHEIM
AM RHEIN, GERMANY
AVENTIS PHARMA, WALTLOO, PRETORIA
ANALYTICON, KEMPTON PARK, RSA
FPRR: INGELHEIM PHARMACEUTICALS, RANDBURG

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15

Registration number: 37/15.2/0275

Name of medicine: DEXAGEL

Dosage form: GEL

Active ingredients: EACH 1,0 g GEL CONTAINS:
DEXAMETHASONE SODIUM
PHOSPHATE 0,985 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: SOFLENS (PTY) LTD

Manufacturer: DR MANN PHARMA, BERLIN, GERMANY

Packer: DR MANN PHARMA, BERLIN, GERMANY
COLUMBIA PHARMACEUTICALS, BARDENE,
BOKSBURG, RSA

Laboratory: FPRC: DR MANN PHARMA, BERLIN, GERMANY
CONSULTING CHEMICAL LABORATORIES,
STAR STREET, BOKSBURG, RSA
FPRR: SOFLENS, RIVONIA, SANDTON, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 37/13.4.2/0292

Name of medicine: ISOTRETINOIN-HEXAL 10

Dosage form: CAPSULE

Active ingredients: EACH CAPSULE CONTAINS:
ISOTRETINOIN 10,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: HEXAL PHARMA (SA) (PTY) LTD

Manufacturer: SWISS CAPS, KIRCHBERG, SWITZERLAND

Packer: DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, RSA
PHARMA-Q, INDUSTRIA WEST, GAUTENG, RSA

Laboratory: FPRC: SWISS CAPS, KIRCHBERG, SWITZERLAND
PHARMA-Q, INDUSTRIA WEST, GAUTENG, RSA
CONSULTING CHEMICAL LABORATORIES, STAR
STREET, BOKSBURG, RSA
ANALYTICON, KEMPTON PARK, RSA
FPRR: HEXAL PHARMA, WESTMEAD, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 37/13.4.2/0293

Name of medicine: ISOTRETINOIN-HEXAL 20

Dosage form: CAPSULE

Active ingredients: EACH CAPSULE CONTAINS:
ISOTRETINOIN 20,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: HEXAL PHARMA (SA) (PTY) LTD

Manufacturer: SWISS CAPS, KIRCHBERG, SWITZERLAND

Packer: DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, RSA
PHARMA-Q, INDUSTRIA WEST, GAUTENG, RSA

Laboratory: FPRC: SWISS CAPS, KIRCHBERG, SWITZERLAND
PHARMA-Q, INDUSTRIA WEST, GAUTENG, RSA
CONSULTING CHEMICAL LABORATORIES, STAR
STREET, BOKSBURG, RSA
ANALYTICON, KEMPTON PARK, RSA
FPRR: HEXAL PHARMA, WESTMEAD, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number:	37/26/0359
Name of medicine:	VINELBA 10
Dosage form:	INJECTION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: VINORELBINE TARTRATE EQUIVALENT TO VINORELBINE 10,0 MG
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	TEMA MEDICAL (PTY) LTD
Manufacturer:	PIERRE FABRE MEDICAMENT PRODUCTION, IDRON, FRANCE
Packer:	PIERRE FABRE MEDICAMENT PRODUCTION, IDRON, FRANCE TECHNIKON LABORATORIES, FLORIDA, RSA
Laboratory:	PIERRE FABRE MEDICAMENT PRODUCTION, IDRON, FRANCE TECHNIKON LABORATORIES, FLORIDA, RSA KQATSA, PRETORIA, RSA INSPECTORATE M&L, ORMONDE, JOHANNESBURG TEMA MEDICAL, SANDTON, RSA
Shelf-life:	36 months
Date of registration:	7 MAY 2004

MRF 15 (MBR 15)

Registration number:	37/26/0360
Name of medicine:	VINELBA 50
Dosage form:	INJECTION
Active ingredients:	EACH 5,0 ml SOLUTION CONTAINS: VINORELBINE TARTRATE EQUIVALENT TO VINORELBINE 50,0 MG
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	TEMA MEDICAL (PTY) LTD
Manufacturer:	PIERRE FABRE MEDICAMENT PRODUCTION, IDRON, FRANCE
Packer:	PIERRE FABRE MEDICAMENT PRODUCTION, IDRON, FRANCE TECHNIKON LABORATORIES, FLORIDA, RSA
Laboratory:	PIERRE FABRE MEDICAMENT PRODUCTION, IDRON, FRANCE TECHNIKON LABORATORIES, FLORIDA, RSA KQATSA, PRETORIA, RSA INSPECTORATE M&L, ORMONDE, JOHANNESBURG TEMA MEDICAL, SANDTON, RSA
Shelf-life:	36 months
Date of registration:	7 MAY 2004

MRF 15 (MBR 15)

Registration number:	37/2.2/0375
Name of medicine:	DAS-ZOPICLONE 7,5 MG
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ZOPICLONE 7,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	STRIDES S.A. (PTY) LTD
Manufacturer:	DRAGENOPHARM, TITTMONING, GERMANY
Packer:	DRAGENOPHARM, TITTMONING, GERMANY MPF BV, HEERENVEEN, THE NETHERLANDS PHARMA NATURA, WYNBERG, SANDTON, GAUTENG, RSA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, GAUTENG, RSA
Laboratory:	FPRC: DRAGENOPHARM, TITTMONING, GERMANY SYNTHON BV, NIJMEGEN, THE NETHERLANDS COLUMBIA PHARMACEUTICALS, BARDENE, BOKSBURG, GAUTENG, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES, BARDENE, BOKSBURG, RSA FPRR: STRIDES, ARCADIA, PRETORIA, RSA
Shelf-life:	24 months
Date of registration:	25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 37/10.2.1/462

Name of medicine: IPVENT RESPULES

Dosage form: INHALATION

Active ingredients: EACH 2,0 ml SOLUTION CONTAINS:
IPRATROPIUM BROMIDE 0,50 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: CIPLA MEDPRO (PTY) LTD

Manufacturer: CIPLA LTD, VIKHROLI, MUMBAI, INDIA

Packer: CIPLA LTD, VIKHROLI, MUMBAI, INDIA

Laboratory: FPRC: CIPLA LTD, VIKHROLI, MUMBAI, INDIA
FPRR: CIPLA MEDPRO, ROSENPARK, BELLVILLE, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 37/34/0469

Name of medicine: IMUSPORIN-25

Dosage form: CAPSULE

Active ingredients: EACH CAPSULE CONTAINS:
CYCLOSPORINE 25,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: CIPLA-MEDPRO (PTY) LTD

Manufacturer: CIPLA LTD, KURKUMBH, MAHARASHTRA, INDIA

Packer: CIPLA LTD, KURKUMBH, MAHARASHTRA, INDIA

Laboratory: FPRC: CIPLA LTD, KURKUMBH, MAHARASHTRA, INDIA
FPRR: CIPLA-MEDPRO, ROSENPARK, BELLVILLE, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 37/34/0470

Name of medicine: IMUSPORIN-50

Dosage form: CAPSULE

Active ingredients: EACH CAPSULE CONTAINS:
CYCLOSPORINE 50,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: CIPLA-MEDPRO (PTY) LTD

Manufacturer: CIPLA LTD, KURKUMBH, MAHARASHTRA, INDIA

Packer: CIPLA LTD, KURKUMBH, MAHARASHTRA, INDIA

Laboratory: FPRR: CIPLA LTD, KURKUMBH, MAHARASHTRA, INDIA
FPRC: CIPLA-MEDPRO, ROSENPARK, BELLVILLE, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number:	37/34/0471
Name of medicine:	IMUSPORIN-100
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: CYCLOSPORINE 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CIPLA-MEDPRO (PTY) LTD
Manufacturer:	CIPLA LTD, KURKUMBH, MAHARASHTRA, INDIA
Packer:	CIPLA LTD, KURKUMBH, MAHARASHTRA, INDIA
Laboratory:	FPRC: CIPLA LTD, KURKUMBH, MAHARASHTRA, INDIA FPRR: CIPLA-MEDPRO, ROSENPARK, BELLVILLE, RSA
Shelf-life:	24 months
Date of registration:	25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 37/34/0472

Name of medicine: CIPLA-CYCLOSPORINE-25

Dosage form: CAPSULE

Active ingredients: EACH CAPSULE CONTAINS:
CYCLOSPORINE 25,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: CIPLA LIFE SCIENCES (PTY) LTD

Manufacturer: CIPLA LTD, KURKUMBH, MAHARASHTRA, INDIA

Packer: CIPLA LTD, KURKUMBH, MAHARASHTRA, INDIA

Laboratory: FPRC: CIPLA LTD, KURKUMBH, MAHARASHTRA, INDIA
FPRR: CIPLA LIFE SCIENCES, ROSENPARK, BELLVILLE,
RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 37/34/0473

Name of medicine: CIPLA-CYCLOSPORINE-50

Dosage form: CAPSULE

Active ingredients: EACH CAPSULE CONTAINS:
CYCLOSPORINE 50,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: CIPLA LIFE SCIENCES (PTY) LTD

Manufacturer: CIPLA LTD, KURKUMBH, MAHARASHTRA, INDIA

Packer: CIPLA LTD, KURKUMBH, MAHARASHTRA, INDIA

Laboratory: FPRC: CIPLA LTD, KURKUMBH, MAHARASHTRA, INDIA
FPR: CIPLA LIFE SCIENCES, ROSENPARK, BELLVILLE,
RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 37/34/0474

Name of medicine: CIPLA-CYCLOSPORINE-100

Dosage form: CAPSULE

Active ingredients: EACH CAPSULE CONTAINS:
CYCLOSPORINE 100,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: CIPLA LIFE SCIENCES (PTY) LTD

Manufacturer: CIPLA LTD, KURKUMBH, MAHARASHTRA, INDIA

Packer: CIPLA LTD, KURKUMBH, MAHARASHTRA, INDIA

Laboratory: FPRC: CIPLA LTD, KURKUMBH, MAHARASHTRA, INDIA
FPRR: CIPLA LIFE SCIENCES, ROSENPARK, BELLVILLE,
RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 37/3.1/0479

Name of medicine: IBUSOR 200

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
IBUPROFEN 200,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: MEDICINE DEVELOPERS INTERNATIONAL C.C.

Manufacturer: EMCURE PHARMACEUTICALS LTD, PUNE, INDIA

Packer: EMCURE PHARMACEUTICALS LTD, PUNE, INDIA

Laboratory: FPRC: EMCURE PHARMACEUTICALS LTD, PUNE, INDIA
CONSULTING CHEMICAL LABORATORIES,
STAR STREET, BOKSBURG, RSA
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
FPRR: MDI CC, MENLO PARK, PRETORIA, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 37/3.1/0480

Name of medicine: IBUSOR 400

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
IBUPROFEN 400,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: MEDICINE DEVELOPERS INTERNATIONAL C.C.

Manufacturer: EMCURE PHARMACEUTICALS LTD, PUNE, INDIA

Packer: EMCURE PHARMACEUTICALS LTD, PUNE, INDIA

Laboratory: FPRC: EMCURE PHARMACEUTICALS LTD, PUNE, INDIA
CONSULTING CHEMICAL LABORATORIES,
STAR STREET, BOKSBURG, RSA
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
FPRR: MDI CC, MENLO PARK, PRETORIA, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 37/26/0484

Name of medicine: IFOLEM 1 G

Dosage form: INJECTION

Active ingredients: EACH VIAL CONTAINS:
IFOSFAMIDE 1,0 G

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: KEY ONCOLOGICS (PTY) LTD

Manufacturer: LEMERY,S.A. de C.V., HUICHAPAN, XOCH, MEXICO

Packer: LEMERY,S.A. de C.V., HUICHAPAN, XOCH, MEXICO

Laboratory: FPRC: LEMERY,S.A. de C.V., HUICHAPAN, XOCH, MEXICO
INSTITUTE FOR PHARMACEUTICAL SERVICES,
BARDENE, BOKSBURG, RSA
FPRR: KEY ONCOLOGICS, SANDTON, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 37/1.2/0491

Name of medicine: ASPEN TRAZODONE 50 MG

Dosage form: CAPSULE

Active ingredients: EACH CAPSULE CONTAINS:
TRAZODONE HYDROCHLORIDE 50,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: PHARMACARE LIMITED

Manufacturer: LENNON LTD, KORSTEN, PORT ELIZABETH
ALPHAPHARM, BRISBANE, QUEENSLAND,
AUSTRALIA

Packer: LENNON LTD, KORSTEN, PORT ELIZABETH
GERARD LABORATORIES, DUBLIN, IRELAND

Laboratory: FPRC: LENNON LTD, KORSTEN, PORT ELIZABETH
GERARD LABORATORIES, DUBLIN, IRELAND
GENERICS LTD, POTTERS BAR, HERTFORDSHIRE,
UK
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, UNIVERSITY, POTCHEFSTROOM
FPRR: PHARMACARE LTD, KORSTEN, PORT ELIZABETH

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 37/1.2/0492

Name of medicine: ASPEN TRAZODONE 100 MG

Dosage form: CAPSULE

Active ingredients: EACH CAPSULE CONTAINS:
TRAZODONE HYDROCHLORIDE 100,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: PHARMACARE LIMITED

Manufacturer: LENNON LTD, KORSTEN, PORT ELIZABETH
ALPHAPHARM, BRISBANE, QUEENSLAND,
AUSTRALIA

Packer: LENNON LTD, KORSTEN, PORT ELIZABETH
GERARD LABORATORIES, DUBLIN, IRELAND

Laboratory: FPRC: LENNON LTD, KORSTEN, PORT ELIZABETH
GERARD LABORATORIES, DUBLIN, IRELAND
GENERIC LTD, POTTERS BAR, HERTFORDSHIRE,
UK
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, UNIVERSITY, POTCHEFSTROOM
FPRR: PHARMACARE LTD, KORSTEN, PORT ELIZABETH

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 37/7.1.3/0494

Name of medicine: CARVEDILOL – HEXAL 6,25

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
CARVEDILOL 6,25mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: HEXAL PHARMA (SA) (PTY) LTD

Manufacturer: GEA FARMACEUTISK FABRIK, FREDERIKSBERG,
DENMARK

Packer: DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, GAUTENG, RSA

Laboratory: FPRC: GEA FARMACEUTISK FABRIK, FREDERIKSBERG,
DENMARK
CONSULTING CHEMICAL LABORATORIES, STAR
STREET, BOKSBURG, RSA
ANALYTICON, KEMPTON PARK, GAUTENG, RSA
FPRR: HEXAL PHARMA, WESTMEAD, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 37/7.1.3/0495

Name of medicine: CARVEDILOL – HEXAL 12,5

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
CARVEDILOL 12,5mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: HEXAL PHARMA (SA) (PTY) LTD

Manufacturer: GEA FARMACEUTISK FABRIK, FREDERIKSBERG,
DENMARK

Packer: DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, GAUTENG, RSA

Laboratory: FPRC: GEA FARMACEUTISK FABRIK, FREDERIKSBERG,
DENMARK
CONSULTING CHEMICAL LABORATORIES, STAR
STREET, BOKSBURG, RSA
ANALYTICON, KEMPTON PARK, GAUTENG, RSA
FPRR: HEXAL PHARMA, WESTMEAD, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 37/7.1.3/0496

Name of medicine: CARVEDILOL – HEXAL 25

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
CARVEDILOL 25mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: HEXAL PHARMA (SA) (PTY) LTD

Manufacturer: GEA FARMACEUTISK FABRIK, FREDERIKSBERG,
DENMARK

Packer: DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, GAUTENG, RSA

Laboratory: FPRC: GEA FARMACEUTISK FABRIK, FREDERIKSBERG,
DENMARK
CONSULTING CHEMICAL LABORATORIES, STAR
STREET, BOKSBURG, RSA
ANALYTICON, KEMPTON PARK, GAUTENG, RSA
FPRR: HEXAL PHARMA, WESTMEAD, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 37/25/0523

Name of medicine: CISPLATIN-HEXAL 10 MG/20 ML

Dosage form: SOLUTION

Active ingredients: EACH 1,0 ml SOLUTION CONTAINS:
Cisplatin 0,5 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: HEXAL PHARMA (S.A.) (PTY) LTD

Manufacturer: EBWE ARZNEIMITTEL GESELLSCHAFT,
UNTERACH, AUSTRIA

Packer: EBWE ARZNEIMITTEL GESELLSCHAFT,
UNTERACH, AUSTRIA
DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, RSA

Laboratory: FPRC: EBWE ARZNEIMITTEL GESELLSCHAFT,
UNTERACH, AUSTRIA
CONSULTING CHEMICAL LABORATORIES,
STAR STREET, BOKSBURG, RSA
ANALYTICON, KEMPTON PARK, RSA
PHARMA Q, INDUSTRIA WEST, RSA
FPRR: HEXAL PHARMA, WESTMEAD, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 37/25/0524

Name of medicine: CISPLATIN-HEXAL 50 MG/100 ML

Dosage form: SOLUTION

Active ingredients: EACH 1,0 ml SOLUTION CONTAINS:
Cisplatin 0,5 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: HEXAL PHARMA (S.A.) (PTY) LTD

Manufacturer: EBEWE ARZNEIMITTEL GESELLSCHAFT,
UNTERACH, AUSTRIA

Packer: EBEWE ARZNEIMITTEL GESELLSCHAFT,
UNTERACH, AUSTRIA
DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, RSA

Laboratory: FPRC: EBEWE ARZNEIMITTEL GESELLSCHAFT,
UNTERACH, AUSTRIA
CONSULTING CHEMICAL LABORATORIES,
STAR STREET, BOKSBURG, RSA
ANALYTICON, KEMPTON PARK, RSA
PHARMA Q, INDUSTRIA WEST, RSA
FPRR: HEXAL PHARMA, WESTMEAD, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 37/34/0584

Name of medicine: PHYSIONEAL 40 GLUCOSE 1,36 % w/v /13,6 MG/ML

Dosage form: DIALYSIS SOLUTION

Active ingredients: EACH 1000,0 ml SOLUTION CONTAINS:
ANHYDROUS GLUCOSE 37,5 G
CALCIUM CHLORIDE DIHYDRATE 0,507 G
MAGNESIUM CHLORIDE HEXAHYDRATE 0,140 G

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: ADCOCK INGRAM CRITICAL CARE (PTY) LTD

Manufacturer: BAXTER HEALTHCARE, CASTLEBAR,
COUNTY MAYO, IRELAND
BAXTER HEALTHCARE S.p.A, SESTO FIORENTINO,
ITALY

Packer: BAXTER HEALTHCARE, CASTLEBAR,
COUNTY MAYO, IRELAND
BAXTER HEALTHCARE S.p.A, SESTO FIORENTINO,
ITALY
ADCOCK INGRAM CRITICAL CARE, AEROTON,
JOHANNESBURG, RSA

Laboratory: FPRC: BAXTER HEALTHCARE, CASTLEBAR,
COUNTY MAYO, IRELAND
BAXTER HEALTHCARE S.p.A, SESTO FIORENTINO,
ITALY
FPRC/FPRR: ADCOCK INGRAM CRITICAL CARE, AEROTON,
JOHANNESBURG, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 37/34/0585

Name of medicine: PHYSIONEAL 40 GLUCOSE 2,27 % w/v /22,7 MG/ML

Dosage form: DIALYSIS SOLUTION

Active ingredients: EACH 1000,0 ml SOLUTION CONTAINS:
ANHYDROUS GLUCOSE 62,6 G
CALCIUM CHLORIDE DIHYDRATE 0,507 G
MAGNESIUM CHLORIDE HEXAHYDRATE 0,140 G

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: ADCOCK INGRAM CRITICAL CARE (PTY) LTD

Manufacturer: BAXTER HEALTHCARE, CASTLEBAR,
COUNTY MAYO, IRELAND
BAXTER HEALTHCARE S.p.A, SESTO FIORENTINO,
ITALY

Packer: BAXTER HEALTHCARE, CASTLEBAR,
COUNTY MAYO, IRELAND
BAXTER HEALTHCARE S.p.A, SESTO FIORENTINO,
ITALY
ADCOCK INGRAM CRITICAL CARE, AEROTON,
JOHANNESBURG, RSA

Laboratory: FPRC: BAXTER HEALTHCARE, CASTLEBAR,
COUNTY MAYO, IRELAND
BAXTER HEALTHCARE S.p.A, SESTO FIORENTINO,
ITALY
FPRC/FPRR: ADCOCK INGRAM CRITICAL CARE, AEROTON,
JOHANNESBURG, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 37/34/0586

Name of medicine: PHYSIONEAL 40 GLUCOSE 3,86 % w/v /38,6 MG/ML

Dosage form: DIALYSIS SOLUTION

Active ingredients: EACH 1000,0 ml SOLUTION CONTAINS:
ANHYDROUS GLUCOSE 106,5 G
CALCIUM CHLORIDE DIHYDRATE 0,507 G
MAGNESIUM CHLORIDE HEXAHYDRATE 0,140 G

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: ADCOCK INGRAM CRITICAL CARE (PTY) LTD

Manufacturer: BAXTER HEALTHCARE, CASTLEBAR,
COUNTY MAYO, IRELAND
BAXTER HEALTHCARE S.p.A, SESTO FIORENTINO,
ITALY

Packer: BAXTER HEALTHCARE, CASTLEBAR,
COUNTY MAYO, IRELAND
BAXTER HEALTHCARE S.p.A, SESTO FIORENTINO,
ITALY
ADCOCK INGRAM CRITICAL CARE, AEROTON,
JOHANNESBURG, RSA

Laboratory: FPRC: BAXTER HEALTHCARE, CASTLEBAR,
COUNTY MAYO, IRELAND
BAXTER HEALTHCARE S.p.A, SESTO FIORENTINO,
ITALY
FPRC/FPRR: ADCOCK INGRAM CRITICAL CARE, AEROTON,
JOHANNESBURG, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 37/26/0592

Name of medicine: ETOPOSIDE LEMERY 100 MG

Dosage form: INJECTION

Active ingredients: EACH 1,0 ml SOLUTION CONTAINS:
ETOPOSIDE 20,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: KEY ONCOLOGICS (PTY) LTD

Manufacturer: LEMERY, S.A. de C.V., HUICHAPAN XOCH, MEXICO

Packer: LEMERY, S.A. de C.V., HUICHAPAN XOCH, MEXICO

Laboratory: FPRC: LEMERY, S.A. de C.V., HUICHAPAN XOCH, MEXICO
INSTITUTE FOR PHARMACEUTICAL SERVICES,
BARDENE, BOKSBURG, RSA
FPRR: KEY ONCOLOGICS, SANDTON, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 37/26/0593

Name of medicine: ETOPOSIDE LEMERY 500 MG

Dosage form: INJECTION

Active ingredients: EACH 1,0 ml SOLUTION CONTAINS:
ETOPOSIDE 20,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: KEY ONCOLOGICS (PTY) LTD

Manufacturer: LEMERY, S.A. de C.V., HUICHAPAN XOCH, MEXICO

Packer: LEMERY, S.A. de C.V., HUICHAPAN XOCH, MEXICO

Laboratory: FPRC: LEMERY, S.A. de C.V., HUICHAPAN XOCH, MEXICO
INSTITUTE FOR PHARMACEUTICAL SERVICES,
BARDENE, BOKSBURG, RSA
FPRR: KEY ONCOLOGICS, SANDTON, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 37/26/0594

Name of medicine: ETOPOSIDE LEMERY 1000 MG

Dosage form: INJECTION

Active ingredients: EACH 1,0 ml SOLUTION CONTAINS:
ETOPOSIDE 20,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: KEY ONCOLOGICS (PTY) LTD

Manufacturer: LEMERY, S.A. de C.V., HUICHAPAN XOCH, MEXICO

Packer: LEMERY, S.A. de C.V., HUICHAPAN XOCH, MEXICO

Laboratory: FPRC: LEMERY, S.A. de C.V., HUICHAPAN XOCH, MEXICO
INSTITUTE FOR PHARMACEUTICAL SERVICES,
BARDENE, BOKSBURG, RSA
FPRR: KEY ONCOLOGICS, SANDTON, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 37/7.1.3/0599

Name of medicine: QUINASPEN 5 MG

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
QUINAPRIL HYDROCHLORIDE EQUIVALENT TO
QUINAPRIL 5,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: PHARMACARE LIMITED

Manufacturer: MERCK FARMA y QUIMICA, BARCELONA, SPAIN
LENNON LTD, KORSTEN, PORT ELIZABETH

Packer: MERCK FARMA y QUIMICA, BARCELONA, SPAIN
LENNON LTD, KORSTEN, PORT ELIZABETH

Laboratory: FPRC: MERCK FARMA y QUIMICA, BARCELONA, SPAIN
LENNON LTD, KORSTEN, PORT ELIZABETH
FPRR: PHARMACARE LTD, KORSTEN, PORT ELIZABETH

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 37/7.1.3/0600

Name of medicine: QUINASPEN 10 MG

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
QUINAPRIL HYDROCHLORIDE EQUIVALENT TO
QUINAPRIL 10,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: PHARMACARE LIMITED

Manufacturer: MERCK FARMA y QUIMICA, BARCELONA, SPAIN
LENNON LTD, KORSTEN, PORT ELIZABETH

Packer: MERCK FARMA y QUIMICA, BARCELONA, SPAIN
LENNON LTD, KORSTEN, PORT ELIZABETH

Laboratory: FPRC: MERCK FARMA y QUIMICA, BARCELONA, SPAIN
LENNON LTD, KORSTEN, PORT ELIZABETH
FPRR: PHARMACARE LTD, KORSTEN, PORT ELIZABETH

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 37/7.1.3/0601

Name of medicine: QUINASPEN 20 MG

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
QUINAPRIL HYDROCHLORIDE EQUIVALENT TO
QUINAPRIL 20,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: PHARMACARE LIMITED

Manufacturer: MERCK FARMA y QUIMICA, BARCELONA, SPAIN
LENNON LTD, KORSTEN, PORT ELIZABETH

Packer: MERCK FARMA y QUIMICA, BARCELONA, SPAIN
LENNON LTD, KORSTEN, PORT ELIZABETH

Laboratory: FPRC: MERCK FARMA y QUIMICA, BARCELONA, SPAIN
LENNON LTD, KORSTEN, PORT ELIZABETH
FPRR: PHARMACARE LTD, KORSTEN, PORT ELIZABETH

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 37/7.1.3/0602

Name of medicine: QUINASPEN 40 MG

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
QUINAPRIL HYDROCHLORIDE EQUIVALENT TO
QUINAPRIL 40,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: PHARMACARE LIMITED

Manufacturer: MERCK FARMA y QUIMICA, BARCELONA, SPAIN
LENNON LTD, KORSTEN, PORT ELIZABETH

Packer: MERCK FARMA y QUIMICA, BARCELONA, SPAIN
LENNON LTD, KORSTEN, PORT ELIZABETH

Laboratory: FPRC: MERCK FARMA y QUIMICA, BARCELONA, SPAIN
LENNON LTD, KORSTEN, PORT ELIZABETH
FPRR: PHARMACARE LTD, KORSTEN, PORT ELIZABETH

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number:	37/22.1.4/0605
Name of medicine:	SUPRADYN PRONATAL
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: VITAMIN A 4000,0 iu THIAMINE HYDROCHLORIDE 1,6 mg RIBOFLAVINE 1,8 mg NICOTINAMIDE 19,0 mg CALCIUM PANTOTHENATE 10,0 mg PYRIDOXINE HYDROCHLORIDE 2,6 mg BIOTIN 200,0 ug FOLIC ACID 0,8 mg CYANOCOBALAMIN 4,0 ug ASCORBIC ACID 100,0 mg CHOLECALCIFEROL 100,0 iu α - TOCOPHEROL ACETATE 15,0 mg CALCIUM 125,0 mg COPPER 1,0 mg IRON 60,0 mg MAGNESIUM 100,0 mg MANGANESE 1,0 mg PHOSPHORUS 125,0 mg ZINC 7,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	BAYER (PTY) LTD
Manufacturer:	ROCHE PRODUCTS,WELWYN,HERTFORDSHIRE,UK
Packer:	ROCHE PRODUCTS,WELWYN,HERTFORDSHIRE,UK
Laboratory:	FPRC: ROCHE PRODUCTS,WELWYN,HERTFORDSHIRE,UK FPRC/FPRR: BAYER, ISANDO, GAUTENG, RSA
Shelf-life:	24 months
Date of registration:	25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 37/7.1.3/0613

Name of medicine: CARLOC 6,25

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
CARVEDILOL 6,25 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: CIPLA-MEDPRO (PTY) LTD

Manufacturer: CIPLA LTD, VIKHROLI, MUMBAI, INDIA

Packer: CIPLA LTD, VIKHROLI, MUMBAI, INDIA

Laboratory: CIPLA LTD, VIKHROLI, MUMBAI, INDIA
CIPLA-MEDPRO, ROSENPARK, BELLVILLE, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 37/21.12/0616

Name of medicine: SPEC-FLUTAMIDE

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
FLUTAMIDE 250,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: SPECPHARM (PTY) LTD

Manufacturer: MIPHARM S.p.A., MILAN, ITALY

Packer: MIPHARM S.p.A., MILAN, ITALY

Laboratory: FPRC: MIPHARM S.p.A., MILAN, ITALY
ANALYTICON, KEMPTON PARK, RSA
FPRR: SPECPHARM, RANDBURG, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 37/34/0649

Name of medicine: IMUSPORIN ORAL SOLUTION

Dosage form: SOLUTION

Active ingredients: EACH 1,0 ml SOLUTION CONTAINS:
CYCLOSPORINE 100,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: CIPLA-MEDPRO (PTY) LTD

Manufacturer: CIPLA LTD, VIKHROLI, MUMBAI, INDIA

Packer: CIPLA LTD, VIKHROLI, MUMBAI, INDIA

Laboratory: FPRC: CIPLA LTD, VIKHROLI, MUMBAI, INDIA
FPRR: CIPLA-MEDPRO, ROSENPARK, BELLVILLE, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 37/34/0650

Name of medicine: CIPLA-CYCLOSPORINE ORAL SOLUTION

Dosage form: SOLUTION

Active ingredients: EACH 1,0 ml SOLUTION CONTAINS:
CYCLOSPORINE 100,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: CIPLA LIFE SCIENCES (PTY) LTD

Manufacturer: CIPLA LTD, VIKHROLI, MUMBAI, INDIA

Packer: CIPLA LTD, VIKHROLI, MUMBAI, INDIA

Laboratory: FPRC: CIPLA LTD, VIKHROLI, MUMBAI, INDIA
FPRR: CIPLA LIFE SCIENCES, ROSENPAK, BELLVILLE,
RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 37/1.2/0665

Name of medicine: SEDARIN

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
PAROXETINE HYDROCHLORIDE EQUIVALENT TO
PAROXETINE 20,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: XIXI PHARMACEUTICALS (PTY) LTD

Manufacturer: ALPHAPHARM, CAROLE PARK, QUEENSLAND,
AUSTRALIA
MERCK PHARMACEUTICAL MANUFACTURING,
WADEVILLE, GERMISTON, RSA

Packer: GERARD LABORATORIES, DUBLIN, IRELAND
MERCK PHARMACEUTICAL MANUFACTURING,
WADEVILLE, GERMISTON, RSA

Laboratory: FPRC: ALPHAPHARM, CAROLE PARK, QUEENSLAND,
AUSTRALIA
MERCK PHARMACEUTICAL MANUFACTURING,
WADEVILLE, GERMISTON, RSA
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, UNIVERSITY, POTCHEFSTROOM
FPRR: XIXIA PHARMACEUTICALS, MODDERFONTEIN,
RSA

Shelf-life: 36 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 37/26/0668

Name of medicine: BUSULFEX

Dosage form: INJECTION

Active ingredients: EACH AMPOULE CONTAINS:
BUSULFAN 60,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: TEMA MEDICAL (PTY) LTD

Manufacturer: BEN VENUE LABORATORIES, BEDFORD, OHIO,
USA

Packer: BEN VENUE LABORATORIES, BEDFORD, OHIO,
USA
PIERRE FABRE MEDICAMENT, IDRON, FRANCE
TECHNIKON LABORATORIES, ROBERTVILLE,
FLORIDA, RSA

Laboratory: FPRC: BEN VENUE LABORATORIES, BEDFORD, OHIO,
USA
PIERRE FABRE MEDICAMENT, IDRON, FRANCE
TECHNIKON LABORATORIES, ROBERTVILLE,
FLORIDA, RSA
KQATSA, PRETORIA, RSA
FPRR: TEMA MEDICAL, SANDTON, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 37/21.1/0670

Name of medicine: BIOSULIN R

Dosage form: INJECTION

Active ingredients: EACH 1,0 ml SOLUTION CONTAINS:
HUMAN INSULIN 100,0 IU

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: RESMED HEALTHCARE

Manufacturer: M.J. BIOPHARM PRIVATE LTD, RAIGAD,
MAHARASHTRA, INDIA

Packer: M.J. BIOPHARM PRIVATE LTD, RAIGAD,
MAHARASHTRA, INDIA

Laboratory: FPRC: M.J. BIOPHARM PRIVATE LTD, RAIGAD,
MAHARASHTRA, INDIA
FPRR: RESMED HEALTHCARE, SPRINGFIELD
PARK, DURBAN, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 37/21.1/0671

Name of medicine: BIOSULIN N

Dosage form: INJECTION

Active ingredients: EACH 1,0 ml SUSPENSION CONTAINS:
HUMAN INSULIN 100,0 IU

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: RESMED HEALTHCARE

Manufacturer: M.J. BIOPHARM PRIVATE LTD, RAIGAD,
MAHARASHTRA, INDIA

Packer: M.J. BIOPHARM PRIVATE LTD, RAIGAD,
MAHARASHTRA, INDIA

Laboratory: FPRC: M.J. BIOPHARM PRIVATE LTD, RAIGAD,
MAHARASHTRA, INDIA
FPRR: RESMED HEALTHCARE, SPRINGFIELD
PARK, DURBAN, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 37/21.1/0672

Name of medicine: BIOSULIN L

Dosage form: INJECTION

Active ingredients: EACH 1,0 ml SUSPENSION CONTAINS:
HUMAN INSULIN 100,0 IU

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: RESMED HEALTHCARE

Manufacturer: M.J. BIOPHARM PRIVATE LTD, RAIGAD,
MAHARASHTRA, INDIA

Packer: M.J. BIOPHARM PRIVATE LTD, RAIGAD,
MAHARASHTRA, INDIA

Laboratory: FPRC: M.J. BIOPHARM PRIVATE LTD, RAIGAD,
MAHARASHTRA, INDIA
FPRR: RESMED HEALTHCARE, SPRINGFIELD
PARK, DURBAN, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 37/21.1/0673

Name of medicine: BIOSULIN 30-70

Dosage form: INJECTION

Active ingredients: EACH 1,0 ml SUSPENSION CONTAINS:
HUMAN INSULIN 100,0 IU

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: RESMED HEALTHCARE

Manufacturer: M.J. BIOPHARM PRIVATE LTD, RAIGAD,
MAHARASHTRA, INDIA

Packer: M.J. BIOPHARM PRIVATE LTD, RAIGAD,
MAHARASHTRA, INDIA

Laboratory: FPRC: M.J. BIOPHARM PRIVATE LTD, RAIGAD,
MAHARASHTRA, INDIA
FPRR: RESMED HEALTHCARE, SPRINGFIELD
PARK, DURBAN, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15

Registration number: 38/1.2/0020

Name of medicine: SERDEP-50

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
SERTRALINE HYDROCHLORIDE EQUIVALENT
TO SERTRALINE 50,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: CIPLA MEDPRO (PTY) LTD

Manufacturer: CIPLA LTD, VIKHROLI, MUMBAI, INDIA

Packer: CIPLA LTD, VIKHROLI, MUMBAI, INDIA

Laboratory: FPRC: CIPLA LTD, VIKHROLI, MUMBAI, INDIA
FPRR: CIPLA MEDPRO, ROSENPARK, BELLVILLE, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 38/5.6/0040

Name of medicine: SERC 24

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
BETAHISTINE DIHYDROCHLORIDE 24,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: SOLVAY PHARMA (PTY) LTD

Manufacturer: SOLVAY PHARMACEUTICALS B.V., OLST,
THE NETHERLANDS

Packer: SOLVAY PHARMACEUTICALS B.V., OLST,
THE NETHERLANDS

Laboratory: FPRC: SOLVAY PHARMACEUTICALS B.V., OLST,
THE NETHERLANDS
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA
SCHERING, MIDRAND, RSA
FPRR: SOLVAY PHARMA, MIDRAND, RSA

Shelf-life: 36 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 38/2.5/0049

Name of medicine: ROLAB-CARBAMAZEPINE CR 200

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
CARBAMAZEPINE 200,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: SANDOZ (PTY) LTD

Manufacturer: TARO PHARMACEUTICAL INDUSTRIES LTD,
HAIFA BAY, ISRAEL

Packer: TARO PHARMACEUTICAL INDUSTRIES LTD,
HAIFA BAY, ISRAEL
NOVARTIS, SPARTAN, KEMPTON PARK

Laboratory: FPRC: TARO PHARMACEUTICAL INDUSTRIES LTD,
HAIFA BAY, ISRAEL
FPRC/FPRR: NOVARTIS, SPARTAN, KEMPTON PARK
FPRR: SANDOZ, SPARTAN, KEMPTON PARK

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 38/26/0059

Name of medicine: BLASTOCARB 150 MG

Dosage form: INJECTION

Active ingredients: EACH 15,0 ml VIAL CONTAINS:
CARBOPLATIN 150,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: KEY ONCOLOGICS (PTY) LTD

Manufacturer: LEMERY , S.A. de C.V., XOCH, MEXICO

Packer: LEMERY , S.A. de C.V., XOCH, MEXICO

Laboratory: FPRC: LEMERY , S.A. de C.V., XOCH, MEXICO
INSTITUTE FOR PHARMACEUTICAL SERVICES,
BARDENE, BOKSBURG, RSA
FPRR: KEY ONCOLOGICS, HOUGHTON, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 38/2.5/0062

Name of medicine: ROLAB-CARBAMAZEPINE CR 400

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
CARBAMAZEPINE 400,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: SANDOZ (PTY) LTD

Manufacturer: TARO PHARMACEUTICAL INDUSTRIES LTD,
HAIFA BAY, ISRAEL

Packer: TARO PHARMACEUTICAL INDUSTRIES LTD,
HAIFA BAY, ISRAEL
NOVARTIS, SPARTAN, KEMPTON PARK

Laboratory: FPRC: TARO PHARMACEUTICAL INDUSTRIES LTD,
HAIFA BAY, ISRAEL
FPRC/FPRR: NOVARTIS, SPARTAN, KEMPTON PARK
FPRR: SANDOZ, SPARTAN, KEMPTON PARK

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 38/5.4.1/0067

Name of medicine: STALEVO 50/12,5

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
ENTACAPONE 200,0 MG
LEVODOPA 50,0 MG
CARBIDOPA MONOHYDRATE EQUIVALENT TO
CARBIDOPA 12,5 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: NOVARTIS SOUTH AFRICA (PTY) LTD

Manufacturer: ORION CORPORATION ORION PHARMA,
ESPOO, FINLAND

Packer: ORION CORPORATION ORION PHARMA,
ESPOO, FINLAND
NOVARTIS, SPARTAN, KEMPTON PARK, RSA

Laboratory: FPRC: ORION CORPORATION ORION PHARMA,
ESPOO, FINLAND
INSPECTORATE M&L, ORMONDE,
JOHANNESBURG, RSA
FPRC/FPRR: NOVARTIS, SPARTAN, KEMPTON PARK, RSA

Shelf-life: 36 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 38/5.8/0111

Name of medicine: FLUSIN SINUS TABLETS

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
PSEUDOEPHEDRINE HYDROCHLORIDE 30,0 MG
PARACETAMOL 500,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: PHARMACARE LIMITED

Manufacturer: LENNON LTD, KORSTEN, PORT ELIZABETH
SAD SELF MEDICATION, WILSONIA,
EAST LONDON

Packer: LENNON LTD, KORSTEN, PORT ELIZABETH
SAD SELF MEDICATION, WILSONIA,
EAST LONDON

Laboratory: FPRC: LENNON LTD, KORSTEN, PORT ELIZABETH
SAD SELF MEDICATION, WILSONIA,
EAST LONDON
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, UNIVERSITY, POTCHEFSTROOM
FPRR: PHARMACARE LTD, KORSTEN, PORT ELIZABETH

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 38/21.5.1/0126

Name of medicine: PANAFCORTELONE SYRUP

Dosage form: SYRUP

Active ingredients: EACH 5,0 ml SYRUP CONTAINS:
PREDNISOLONE 15,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: ADCOCK INGRAM LIMITED

Manufacturer: ADCOCK INGRAM HEALTHCARE, WADEVILLE,
GERMISTON, RSA

Packer: ADCOCK INGRAM HEALTHCARE, WADEVILLE
GERMISTON, RSA

Laboratory: FPRC/FPRR: ADCOCK INGRAM HEALTHCARE, WADEVILLE
GERMISTON, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 38/26/0134

Name of medicine: BLASTOCARB 450 MG

Dosage form: INJECTION

Active ingredients: EACH 15,0 ml VIAL CONTAINS:
CARBOPLATIN 450,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: KEY ONCOLOGICS (PTY) LTD

Manufacturer: LEMERY , S.A. de C.V., XOCH, MEXICO

Packer: LEMERY , S.A. de C.V., XOCH, MEXICO

Laboratory: FPRC: LEMERY , S.A. de C.V., XOCH, MEXICO
INSTITUTE FOR PHARMACEUTICAL SERVICES,
BARDENE, BOKSBURG, RSA
FPRR: KEY ONCOLOGICS, HOUGHTON, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 38/2.5/0135

Name of medicine: ROCARB 200 CR

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
CARBAMAZEPINE 200,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: SANDOZ (PTY) LTD

Manufacturer: TARO PHARMACEUTICAL INDUSTRIES LTD,
HAIFA BAY, ISRAEL

Packer: TARO PHARMACEUTICAL INDUSTRIES LTD,
HAIFA BAY, ISRAEL
NOVARTIS, SPARTAN, KEMPTON PARK

Laboratory: FPRC: TARO PHARMACEUTICAL INDUSTRIES LTD,
HAIFA BAY, ISRAEL
FPRC/FPRR: NOVARTIS, SPARTAN, KEMPTON PARK
FPRR: SANDOZ, SPARTAN, KEMPTON PARK

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 38/2.5/0136

Name of medicine: ROCARB 400 CR

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
CARBAMAZEPINE 400,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: SANDOZ (PTY) LTD

Manufacturer: TARO PHARMACEUTICAL INDUSTRIES LTD,
HAIFA BAY, ISRAEL

Packer: TARO PHARMACEUTICAL INDUSTRIES LTD,
HAIFA BAY, ISRAEL
NOVARTIS, SPARTAN, KEMPTON PARK

Laboratory: FPRC: TARO PHARMACEUTICAL INDUSTRIES LTD,
HAIFA BAY, ISRAEL
FPRC/FPRR: NOVARTIS, SPARTAN, KEMPTON PARK
FPRR: SANDOZ, SPARTAN, KEMPTON PARK

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 38/5.4.1/0137

Name of medicine: STALEVO 150/37,5

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
ENTACAPONE 200,0 MG
LEVODOPA 150,0 MG
CARBIDOPA MONOHYDRATE EQUIVALENT TO
CARBIDOPA 37,5 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: NOVARTIS SOUTH AFRICA (PTY) LTD

Manufacturer: ORION CORPORATION ORION PHARMA,
ESPOO, FINLAND

Packer: ORION CORPORATION ORION PHARMA,
ESPOO, FINLAND
NOVARTIS, SPARTAN, KEMPTON PARK, RSA

Laboratory: FPRC: ORION CORPORATION ORION PHARMA,
ESPOO, FINLAND
INSPECTORATE M&L, ORMONDE,
JOHANNESBURG, RSA
FPRC/FPRR: NOVARTIS, SPARTAN, KEMPTON PARK, RSA

Shelf-life: 36 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 38/5.4.1/0138

Name of medicine: STALEVO 100/25

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
ENTACAPONE 200,0 MG
LEVODOPA 100,0 MG
CARBIDOPA MONOHYDRATE EQUIVALENT TO
CARBIDOPA 25,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: NOVARTIS SOUTH AFRICA (PTY) LTD

Manufacturer: ORION CORPORATION ORION PHARMA,
ESPOO, FINLAND

Packer: ORION CORPORATION ORION PHARMA,
ESPOO, FINLAND
NOVARTIS, SPARTAN, KEMPTON PARK, RSA

Laboratory: FPRC: ORION CORPORATION ORION PHARMA,
ESPOO, FINLAND
INSPECTORATE M&L, ORMONDE,
JOHANNESBURG, RSA
FPRC/FPRR: NOVARTIS, SPARTAN, KEMPTON PARK, RSA

Shelf-life: 36 months

Date of registration: 25 NOVEMBER 2005

MRF 15

Registration number: 38/34/0143

Name of medicine: GLEEVEC

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
IMATINIB MESILATE EQUIVALENT TO
IMATINIB 100,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: NOVARTIS SOUTH AFRICA (PTY) LTD

Manufacturer: NOVARTIS PHARMA STEIN AG, STEIN,
SWITZERLAND

Packer: NOVARTIS PHARMA STEIN AG, STEIN,
SWITZERLAND
NOVARTIS, SPARTAN, KEMPTON PARK, RSA

Laboratory: FPRC: NOVARTIS PHARMA STEIN AG, STEIN,
SWITZERLAND
NOVARTIS, SPARTAN, KEMPTON PARK, RSA
INSPECTORATE M&L, ORMONDE,
JOHANNESBURG, RSA
FPRR: NOVARTIS, SPARTAN, KEMPTON PARK, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15

Registration number: 38/34/0144

Name of medicine: GLEEVEC 400

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
IMATINIB MESILATE EQUIVALENT TO
IMATINIB 400,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: NOVARTIS SOUTH AFRICA (PTY) LTD

Manufacturer: NOVARTIS PHARMA STEIN AG, STEIN,
SWITZERLAND

Packer: NOVARTIS PHARMA STEIN AG, STEIN,
SWITZERLAND
NOVARTIS, SPARTAN, KEMPTON PARK, RSA

Laboratory: FPRC: NOVARTIS PHARMA STEIN AG, STEIN,
SWITZERLAND
NOVARTIS, SPARTAN, KEMPTON PARK, RSA
INSPECTORATE M&L, ORMONDE,
JOHANNESBURG, RSA
FPRR: NOVARTIS, SPARTAN, KEMPTON PARK, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15

Registration number: 38/2.6.5/0167

Name of medicine: CLONEX 25 MG

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
CLOZAPINE 25,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: PHARMACARE LIMITED

Manufacturer: ALPHAPHARM, CAROLE PARK, QUEENSLAND,
AUSTRALIA
LENNON LTD, KORSTEN, PORT ELIZABETH

Packer: ALPHAPHARM, CAROLE PARK, QUEENSLAND,
AUSTRALIA
LENNON LTD, KORSTEN, PORT ELIZABETH
GERARD LABORATORIES, DUBLIN, IRELAND

Laboratory: FPRC: ALPHAPHARM, CAROLE PARK, QUEENSLAND,
AUSTRALIA
LENNON LTD, KORSTEN, PORT ELIZABETH
GERARD LABORATORIES, DUBLIN, IRELAND
GENERICIS LTD, POTTERS BAR,
HERTFORDSHIRE, U.K.
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, UNIVERSITY, POTCHEFSTROOM
FPRR: PHARMACARE LTD, KORSTEN,
PORT ELIZABETH

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15

Registration number: 38/2.6.5/0168

Name of medicine: CLONEX 100 MG

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
CLOZAPINE 100,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: PHARMACARE LIMITED

Manufacturer: ALPHAPHARM, CAROLE PARK, QUEENSLAND,
AUSTRALIA
LENNON LTD, KORSTEN, PORT ELIZABETH

Packer: ALPHAPHARM, CAROLE PARK, QUEENSLAND,
AUSTRALIA
LENNON LTD, KORSTEN, PORT ELIZABETH
GERARD LABORATORIES, DUBLIN, IRELAND

Laboratory: FPRC: ALPHAPHARM, CAROLE PARK, QUEENSLAND,
AUSTRALIA
LENNON LTD, KORSTEN, PORT ELIZABETH
GERARD LABORATORIES, DUBLIN, IRELAND
GENERIC LTD, POTTERS BAR,
HERTFORDSHIRE, U.K.
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, UNIVERSITY, POTCHEFSTROOM
FPRR: PHARMACARE LTD, KORSTEN,
PORT ELIZABETH

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 38/21.5.1/0187

Name of medicine: SYMBICORD TURBUHALER 320:9 UG/DOSE

Dosage form: INHALER

Active ingredients: EACH DELIVERED DOSE CONTAINS:
FORMOTEROL FUMARATE DIHYDRATE 9,0 UG
BUDESONIDE 320,0 UG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: ASTRAZENECA PHARMACEUTICALS (PTY) LTD

Manufacturer: ASTRAZENECA AB, SODERTALJE, SWEDEN

Packer: ASTRAZENECA AB, SODERTALJE, SWEDEN
ASTRAZENECA U.K., MACCLESFIELD, CHESHIRE,
UK
ASTRAZENECA, ALRODE, ALBERTON, RSA
JANSSEN PHARMACEUTICA, HALFWAY HOUSE,
RSA

Laboratory: FPRC: ASTRAZENECA AB, SODERTALJE, SWEDEN
JANSSEN PHARMACEUTICA, HALFWAY HOUSE,
RSA
CONSULTING CHEMICAL LABORATORIES, STAR
STREET, BOKSBURG, RSA
ANALYTICON, KEMPTON PARK, RSA
FPRC/FPRR: ASTRAZENECA, ALRODE, ALBERTON, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 38/7.1.3/0210

Name of medicine: ADCO-QUINARETIC 10/12,5

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
QUINAPRIL HYDROCHLORIDE EQUIVALENT TO
QUINAPRIL 10,0 MG
HYDROCHLOROTHIAZIDE 12,5 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: ADCOCK INGRAM LIMITED

Manufacturer: DELTA LTD, HAFNARFJORDUR, ICELAND

Packer: DELTA LTD, HAFNARFJORDUR, ICELAND

Laboratory: FPRC: DELTA LTD, HAFNARFJORDUR, ICELAND
FPRC/FPRR: ADCOCK INGRAM HEALTHCARE, WADEVILLE,
GERMISTON, RSA
ADCOCK INGRAM HEALTHCARE, CLAYVILLE,
OLIFANTSFONTEIN, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 38/7.1.3/0211

Name of medicine: ADCO-QUINARETIC 20/12,5

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
QUINAPRIL HYDROCHLORIDE EQUIVALENT TO
QUINAPRIL 20,0 MG
HYDROCHLOROTHIAZIDE 12,5 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: ADCOCK INGRAM LIMITED

Manufacturer: DELTA LTD, HAFNARFJORDUR, ICELAND

Packer: DELTA LTD, HAFNARFJORDUR, ICELAND

Laboratory: FPRC: DELTA LTD, HAFNARFJORDUR, ICELAND
FPRC/FPRR: ADCOCK INGRAM HEALTHCARE, WADEVILLE,
GERMISTON, RSA
ADCOCK INGRAM HEALTHCARE, CLAYVILLE,
OLIFANTSFONTEIN, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 38/34/0226

Name of medicine: EBIXA 10 MG

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
MEMANTINE HYDROCHLORIDE 10,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: H. LUNDBECK (PTY) LTD

Manufacturer: ROTTENDORF PHARMA GmbH, ENNIGERLOH,
GERMANY

Packer: MERZ + CO. GmbH & CO., REINHEIM, GERMANY

Laboratory: FPRC: MERZ + CO. GmbH & CO., REINHEIM, GERMANY
H. LUNDBECK A/S, COPENHAGEN, DENMARK
FPRR: H. LUNDBECK, NORTH RIDING, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A38/3.1/0390

Name of medicine: DISFLAM (DISPERSIBLE TABLET)

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
DICLOFENAC 46,5 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: PHARMACARE LIMITED

Manufacturer: PHARMACARE LTD, KORSTEN, PORT ELIZABETH
SAD SELF MEDICATION, WILSONIA,
EAST LONDON

Packer: PHARMACARE LTD, KORSTEN, PORT ELIZABETH
SAD SELF MEDICATION, WILSONIA,
EAST LONDON

Laboratory: PHARMACARE LTD, KORSTEN, PORT ELIZABETH
SAD SELF MEDICATION, WILSONIA,
EAST LONDON
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
RESEARCH INSTITUTE FOR PHARMACEUTICAL
SERVICES, UNIVERSITY, POTCHEFSTROOM
PHARMACARE LTD, WOODMEAD, RSA

Shelf-life: 24 months

Date of registration: 23 SEPTEMBER 2005

MRF 15 (MBR 15)

Registration number:	A38/20.2.2/0395
Name of medicine:	TERBINISIL 250
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: TERBINAFINE HYDROCHLORIDE EQUIVALENT TO TERBINAFINE 250,0 MG
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	HEXAL PHARMA (S.A.) (PTY) LTD
Manufacturer:	GEA FARMACEUTISK FABRIK, HVIDOVRE, DENMARK SALUTAS PHARMA GmbH, BARLEBEN, GERMANY ILSAN ILAC VE HAMMADDELERI SANAYI, ISTANBUL, TURKEY
Packer:	GEA FARMACEUTISK FABRIK, HVIDOVRE, DENMARK SALUTAS PHARMA GmbH, BARLEBEN, GERMANY ILSAN ILAC VE HAMMADDELERI SANAYI, ISTANBUL, TURKEY DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, RSA
Laboratory:	FPRC: GEA FARMACEUTISK FABRIK, HVIDOVRE, DENMARK SALUTAS PHARMA GmbH, BARLEBEN, GERMANY ILSAN ILAC VE HAMMADDELERI SANAYI, ISTANBUL, TURKEY CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA ANALYTICON, KEMPTON PARK, RSA FPRR: HEXAL PHARMA, WESTMEAD, RSA
Shelf-life:	24 months
Date of registration:	25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number:	A38/20.2.2/0396
Name of medicine:	TERBINISIL 125
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: TERBINAFINE HYDROCHLORIDE EQUIVALENT TO TERBINAFINE 125,0 MG
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	HEXAL PHARMA (S.A.) (PTY) LTD
Manufacturer:	GEA FARMACEUTISK FABRIK, HVIDOVRE, DENMARK SALUTAS PHARMA GmbH, BARLEBEN, GERMANY ILSAN ILAC VE HAMMADDELERI SANAYI, ISTANBUL, TURKEY
Packer:	GEA FARMACEUTISK FABRIK, HVIDOVRE, DENMARK SALUTAS PHARMA GmbH, BARLEBEN, GERMANY ILSAN ILAC VE HAMMADDELERI SANAYI, ISTANBUL, TURKEY DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, RSA
Laboratory:	FPRC: GEA FARMACEUTISK FABRIK, HVIDOVRE, DENMARK SALUTAS PHARMA GmbH, BARLEBEN, GERMANY ILSAN ILAC VE HAMMADDELERI SANAYI, ISTANBUL, TURKEY CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA ANALYTICON, KEMPTON PARK, RSA FPRR: HEXAL PHARMA, WESTMEAD, RSA
Shelf-life:	24 months
Date of registration:	25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number:	A38/20.2.2/0397
Name of medicine:	TERBANE 250
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: TERBINAFINE HYDROCHLORIDE EQUIVALENT TO TERBINAFINE 250,0 MG
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	HEXAL PHARMA (S.A.) (PTY) LTD
Manufacturer:	GEA FARMACEUTISK FABRIK, HVIDOVRE, DENMARK SALUTAS PHARMA GmbH, BARLEBEN, GERMANY ILSAN ILAC VE HAMMADDELERI SANAYI, ISTANBUL, TURKEY
Packer:	GEA FARMACEUTISK FABRIK, HVIDOVRE, DENMARK SALUTAS PHARMA GmbH, BARLEBEN, GERMANY ILSAN ILAC VE HAMMADDELERI SANAYI, ISTANBUL, TURKEY DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, RSA
Laboratory:	FPRC: GEA FARMACEUTISK FABRIK, HVIDOVRE, DENMARK SALUTAS PHARMA GmbH, BARLEBEN, GERMANY ILSAN ILAC VE HAMMADDELERI SANAYI, ISTANBUL, TURKEY CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA ANALYTICON, KEMPTON PARK, RSA FPRR: HEXAL PHARMA, WESTMEAD, RSA
Shelf-life:	24 months
Date of registration:	25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number:	A38/20.2.2/0399
Name of medicine:	TERBANE 125
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: TERBINAFINE HYDROCHLORIDE EQUIVALENT TO TERBINAFINE 125,0 MG
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	HEXAL PHARMA (S.A.) (PTY) LTD
Manufacturer:	GEA FARMACEUTISK FABRIK, HVIDOVRE, DENMARK SALUTAS PHARMA GmbH, BARLEBEN, GERMANY ILSAN ILAC VE HAMMADDELERI SANAYI, ISTANBUL, TURKEY
Packer:	GEA FARMACEUTISK FABRIK, HVIDOVRE, DENMARK SALUTAS PHARMA GmbH, BARLEBEN, GERMANY ILSAN ILAC VE HAMMADDELERI SANAYI, ISTANBUL, TURKEY DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, RSA
Laboratory: FPRC:	GEA FARMACEUTISK FABRIK, HVIDOVRE, DENMARK SALUTAS PHARMA GmbH, BARLEBEN, GERMANY ILSAN ILAC VE HAMMADDELERI SANAYI, ISTANBUL, TURKEY CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA ANALYTICON, KEMPTON PARK, RSA
FPRR:	HEXAL PHARMA, WESTMEAD, RSA
Shelf-life:	24 months
Date of registration:	25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number:	A38/20.1.2/0462
Name of medicine:	MYMOX 250
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: AMOXYCILLIN TRIHYDRATE EQUIVALENT TO AMOXYCILLIN 250,0 MG
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	UNICHEM S.A. (PTY) LTD
Manufacturer:	UNICHEM LABORATORIES LTD, BADDI, SOLAN, INDIA
Packer:	UNICHEM LABORATORIES LTD, BADDI, SOLAN, INDIA
Laboratory:	FPRC: UNICHEM LABORATORIES LTD, BADDI, SOLAN, INDIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY, POTCHEFSTROOM CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA INSTITUTE FOR PHARMACEUTICAL & CHEMICAL SERVICES, BARDENE, BOKSBURG, RSA ALLIANCE PHARMA, VILLAGE MAIN, JOHANNESBURG, RSA FPRR: UNICHEM, VAN DER HOFF PARK, POTCHEFSTROOM, RSA
Shelf-life:	24 months
Date of registration:	25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A38/20.1.2/0463

Name of medicine: MYMOX 500

Dosage form: CAPSULE

Active ingredients: EACH CAPSULE CONTAINS:
AMOXYCILLIN TRIHYDRATE EQUIVALENT TO
AMOXYCILLIN 500,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: UNICHEM S.A. (PTY) LTD

Manufacturer: UNICHEM LABORATORIES LTD, BADDI, SOLAN,
INDIA

Packer: UNICHEM LABORATORIES LTD, BADDI, SOLAN,
INDIA

Laboratory: FPRC: UNICHEM LABORATORIES LTD, BADDI, SOLAN,
INDIA
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, UNIVERSITY, POTCHEFSTROOM
CONSULTING CHEMICAL LABORATORIES,
STAR STREET, BOKSBURG, RSA
INSTITUTE FOR PHARMACEUTICAL & CHEMICAL
SERVICES, BARDENE, BOKSBURG, RSA
ALLIANCE PHARMA, VILLAGE MAIN,
JOHANNESBURG, RSA
FPRR: UNICHEM, VAN DER HOFF PARK,
POTCHEFSTROOM, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A38/20.2.2/0484

Name of medicine: TERBICIL

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
TERBINAFINE HYDROCHLORIDE EQUIVALENT TO
TERBINAFINE 250,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: PHARMACARE LIMITED

Manufacturer: GENPHARM PHARMACEUTICALS, ONTARIO,
CANADA
LENNON LTD, KORSTEN, PORT ELIZABETH

Packer: GENPHARM PHARMACEUTICALS, ONTARIO,
CANADA
LENNON LTD, KORSTEN, PORT ELIZABETH
GENERIC [UK] LTD, POTTERS BAR,
HERTFORDSHIRE, U.K.
GERARD LABORATORIES, DUBLIN, IRELAND

Laboratory: FPRC: GENPHARM PHARMACEUTICALS, ONTARIO,
CANADA
LENNON LTD, KORSTEN, PORT ELIZABETH
GENERIC [UK] LTD, POTTERS BAR,
HERTFORDSHIRE, U.K.
GERARD LABORATORIES, DUBLIN, IRELAND
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, UNIVERSITY, POTCHEFSTROOM
FPRR: PHARMACARE, KORSTEN, PORT ELIZABETH

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A38/7.1.3/0509

Name of medicine: RILACE 1,25 TABLETS

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
RAMIPRIL 1,25 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: ADCOCK INGRAM LIMITED

Manufacturer: DELTA LTD, HAFNARFJORDUR, ICELAND

Packer: DELTA LTD, HAFNARFJORDUR, ICELAND
ADCOCK INGRAM HEALTHCARE, WADEVILLE,
GERMISTON, RSA
ADCOCK INGRAM HEALTHCARE, CLAYVILLE,
OLIFANTSFONTEIN, RSA

Laboratory: FPRC: DELTA LTD, HAFNARFJORDUR, ICELAND
FPRC/FPRR: ADCOCK INGRAM HEALTHCARE, WADEVILLE,
GERMISTON, RSA
ADCOCK INGRAM HEALTHCARE, CLAYVILLE,
OLIFANTSFONTEIN, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A38/7.1.3/0510

Name of medicine: RILACE 2,5 TABLETS

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
RAMIPRIL 2,5 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: ADCOCK INGRAM LIMITED

Manufacturer: DELTA LTD, HAFNARFJORDUR, ICELAND

Packer: DELTA LTD, HAFNARFJORDUR, ICELAND
ADCOCK INGRAM HEALTHCARE, WADEVILLE,
GERMISTON, RSA
ADCOCK INGRAM HEALTHCARE, CLAYVILLE,
OLIFANTSFONTEIN, RSA

Laboratory: FPRC: DELTA LTD, HAFNARFJORDUR, ICELAND
FPRC/FPRR: ADCOCK INGRAM HEALTHCARE, WADEVILLE,
GERMISTON, RSA
ADCOCK INGRAM HEALTHCARE, CLAYVILLE,
OLIFANTSFONTEIN, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A38/7.1.3/0514

Name of medicine: XIXIPRIL 1,25

Dosage form: CAPSULE

Active ingredients: EACH CAPSULE CONTAINS:
RAMIPRIL 1,25 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: XIXIA PHARMACEUTICALS (PTY) LTD

Manufacturer: GENPHARM INC., ETOBICOKE, CANADA

Packer: GENPHARM INC., ETOBICOKE, CANADA
MERCK PHARMACEUTICAL MANUFACTURING,
WADEVILLE, GERMISTON, RSA

Laboratory: FPRC: GENPHARM INC., ETOBICOKE, CANADA
MERCK PHARMACEUTICAL MANUFACTURING,
WADEVILLE, GERMISTON, RSA
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, UNIVERSITY, POTCHEFSTROOM, RSA
FPRR: XIXIA PHARMACEUTICALS, MODDERFONTEIN,
RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A38/7.1.3/0515

Name of medicine: XIXIPRIL 2,5

Dosage form: CAPSULE

Active ingredients: EACH CAPSULE CONTAINS:
RAMIPRIL 2,5 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: XIXIA PHARMACEUTICALS (PTY) LTD

Manufacturer: GENPHARM INC., ETOBICOKE, CANADA

Packer: GENPHARM INC., ETOBICOKE, CANADA
MERCK PHARMACEUTICAL MANUFACTURING,
WADEVILLE, GERMISTON, RSA

Laboratory: FPRC: GENPHARM INC., ETOBICOKE, CANADA
MERCK PHARMACEUTICAL MANUFACTURING,
WADEVILLE, GERMISTON, RSA
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, UNIVERSITY, POTCHEFSTROOM, RSA
FPRR: XIXIA PHARMACEUTICALS, MODDERFONTEIN,
RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A38/7.1.3/0516

Name of medicine: XIXIPRIL 5

Dosage form: CAPSULE

Active ingredients: EACH CAPSULE CONTAINS:
RAMIPRIL 5,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: XIXIA PHARMACEUTICALS (PTY) LTD

Manufacturer: GENPHARM INC., ETOBICOKE, CANADA

Packer: GENPHARM INC., ETOBICOKE, CANADA
MERCK PHARMACEUTICAL MANUFACTURING,
WADEVILLE, GERMISTON, RSA

Laboratory: FPRC: GENPHARM INC., ETOBICOKE, CANADA
MERCK PHARMACEUTICAL MANUFACTURING,
WADEVILLE, GERMISTON, RSA
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, UNIVERSITY, POTCHEFSTROOM, RSA
FPRR: XIXIA PHARMACEUTICALS, MODDERFONTEIN,
RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A38/7.1.3/0517

Name of medicine: XIXIPRIL 10

Dosage form: CAPSULE

Active ingredients: EACH CAPSULE CONTAINS:
RAMIPRIL 10,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: XIXIA PHARMACEUTICALS (PTY) LTD

Manufacturer: GENPHARM INC., ETOBICOKE, CANADA

Packer: GENPHARM INC., ETOBICOKE, CANADA
MERCK PHARMACEUTICAL MANUFACTURING,
WADEVILLE, GERMISTON, RSA

Laboratory: FPRC: GENPHARM INC., ETOBICOKE, CANADA
MERCK PHARMACEUTICAL MANUFACTURING,
WADEVILLE, GERMISTON, RSA
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, UNIVERSITY, POTCHEFSTROOM, RSA
FPRR: XIXIA PHARMACEUTICALS, MODDERFONTEIN,
RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number:	A38/1.2/0520
Name of medicine:	STRATTERA 10 MG
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: ATOMOXETINE HYDROCHLORIDE EQUIVALENT TO ATOMOXETINE 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ELI LILLY (S.A.) (PTY) LTD
Manufacturer:	ELI LILLY & CO LTD, BASINGSTOKE, HAMPSHIRE,U.K. LILLY DEL CARIBE, CAROLINA, PUERTO RICO
Packer:	ELI LILLY & CO LTD, BASINGSTOKE, HAMPSHIRE,U.K. LILLY DEL CARIBE, CAROLINA, PUERTO RICO BRECON PHARMACEUTICALS, HAY-ON-WYE, HEREFORD, UK
Laboratory:	ELI LILLY & CO LTD, BASINGSTOKE, HAMPSHIRE,U.K. LILLY DEL CARIBE, CAROLINA, PUERTO RICO SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA, RSA ELI LILLY, BRYANSTON, GAUTENG, RSA
Shelf-life:	36 months
Date of registration:	3 JUNE 2005

MRF 15 (MBR 15)

Registration number: A38/1.2/0521

Name of medicine: STRATTERA 18 MG

Dosage form: CAPSULE

Active ingredients: EACH CAPSULE CONTAINS:
ATOMOXETINE HYDROCHLORIDE EQUIVALENT
TO ATOMOXETINE 18,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: ELI LILLY (S.A.) (PTY) LTD

Manufacturer: ELI LILLY & CO LTD, BASINGSTOKE,
HAMPSHIRE,U.K.
LILLY DEL CARIBE, CAROLINA, PUERTO RICO

Packer: ELI LILLY & CO LTD, BASINGSTOKE,
HAMPSHIRE,U.K.
LILLY DEL CARIBE, CAROLINA, PUERTO RICO
BRECON PHARMACEUTICALS, HAY-ON-WYE,
HEREFORD, UK

Laboratory: ELI LILLY & CO LTD, BASINGSTOKE,
HAMPSHIRE,U.K.
LILLY DEL CARIBE, CAROLINA, PUERTO RICO
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
ELI LILLY, BRYANSTON, GAUTENG, RSA

Shelf-life: 36 months

Date of registration: 3 JUNE 2005

MRF 15 (MBR 15)

Registration number:	A38/1.2/0522
Name of medicine:	STRATTERA 25 MG
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: ATOMOXETINE HYDROCHLORIDE EQUIVALENT TO ATOMOXETINE 25,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ELI LILLY (S.A.) (PTY) LTD
Manufacturer:	ELI LILLY & CO LTD, BASINGSTOKE, HAMPSHIRE, U.K. LILLY DEL CARIBE, CAROLINA, PUERTO RICO
Packer:	ELI LILLY & CO LTD, BASINGSTOKE, HAMPSHIRE, U.K. LILLY DEL CARIBE, CAROLINA, PUERTO RICO BRECON PHARMACEUTICALS, HAY-ON-WYE, HEREFORD, UK
Laboratory:	ELI LILLY & CO LTD, BASINGSTOKE, HAMPSHIRE, U.K. LILLY DEL CARIBE, CAROLINA, PUERTO RICO SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA, RSA ELI LILLY, BRYANSTON, GAUTENG, RSA
Shelf-life:	36 Months
Date of registration:	3 JUNE 2005

MRF 15 (MBR 15)

Registration number:	A38/1.2/0523
Name of medicine:	STRATTERA 40 MG
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: ATOMOXETINE HYDROCHLORIDE EQUIVALENT TO ATOMOXETINE 40,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ELI LILLY (S.A.) (PTY) LTD
Manufacturer:	ELI LILLY & CO LTD, BASINGSTOKE, HAMPSHIRE,U.K. LILLY DEL CARIBE, CAROLINA, PUERTO RICO BRECON PHARMACEUTICALS, HAY-ON-WYE, HEREFORD, UK
Packer:	ELI LILLY & CO LTD, BASINGSTOKE, HAMPSHIRE,U.K. LILLY DEL CARIBE, CAROLINA, PUERTO RICO
Laboratory:	ELI LILLY & CO LTD, BASINGSTOKE, HAMPSHIRE,U.K. LILLY DEL CARIBE, CAROLINA, PUERTO RICO SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA, RSA ELI LILLY, BRYANSTON, GAUTENG, RSA
Shelf-life:	36 months
Date of registration:	3 JUNE 2005

MRF 15 (MBR 15)

Registration number:	A38/1.2/0524
Name of medicine:	STRATTERA 60 MG
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: ATOMOXETINE HYDROCHLORIDE EQUIVALENT TO ATOMOXETINE 60,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ELI LILLY (S.A.) (PTY) LTD
Manufacturer:	ELI LILLY & CO LTD, BASINGSTOKE, HAMPSHIRE,U.K. LILLY DEL CARIBE, CAROLINA, PUERTO RICO
Packer:	ELI LILLY & CO LTD, BASINGSTOKE, HAMPSHIRE,U.K. LILLY DEL CARIBE, CAROLINA, PUERTO RICO BRECON PHARMACEUTICALS, HAY-ON-WYE, HEREFORD, UK
Laboratory:	ELI LILLY & CO LTD, BASINGSTOKE, HAMPSHIRE,U.K. LILLY DEL CARIBE, CAROLINA, PUERTO RICO SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA, RSA ELI LILLY, BRYANSTON, GAUTENG, RSA
Shelf-life:	36 months
Date of registration:	3 JUNE 2005

MRF 15 (MBR 15)

Registration number: A38/26/0528

Name of medicine: METVIX CREAM

Dosage form: CREAM

Active ingredients: EACH 1,0 g CREAM CONTAINS:
METHYL AMINOLEVULINATE HYDROCHLORIDE
EQUIVALENT TO METHYL AMINOLEVULINATE
160,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: GALDERMA LABORATORIES S.A. (PTY) LTD

Manufacturer: PENN PHARMACEUTICAL SERVICES LTD,
TREDEGAR, GWENT, U.K.

Packer: PENN PHARMACEUTICAL SERVICES LTD,
TREDEGAR, GWENT, U.K.

Laboratory: FPRC: COSI PHARMACEUTICALS, INDUSTRIA,
JOHANNESBURG, RSA
FPRR: GALDERMA LABORATORIES, BRYANSTON,
JOHANNESBURG, RSA

Shelf-life: 12 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A38/2.5/0567

Name of medicine: CIPLA – LAMOTRIGINE 25

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
LAMOTRIGINE 25,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: CIPLA LIFE SCIENCES (PTY) LTD

Manufacturer: CIPLA LTD, RAIGAD, MAHARASHTRA, INDIA

Packer: CIPLA LTD, RAIGAD, MAHARASHTRA, INDIA

Laboratory: FPRC: CIPLA LTD, RAIGAD, MAHARASHTRA, INDIA
FPRR: CIPLA LIFE SCIENCES, ROSENPARK, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A38/2.5/0568

Name of medicine: CIPLA – LAMOTRIGINE 50

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
LAMOTRIGINE 50,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: CIPLA LIFE SCIENCES (PTY) LTD

Manufacturer: CIPLA LTD, RAIGAD, MAHARASHTRA, INDIA

Packer: CIPLA LTD, RAIGAD, MAHARASHTRA, INDIA

Laboratory: FPRC: CIPLA LTD, RAIGAD, MAHARASHTRA, INDIA
FPRR: CIPLA LIFE SCIENCES, ROSENPARK, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A38/2.5/0569

Name of medicine: CIPLA – LAMOTRIGINE 100

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
LAMOTRIGINE 100,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: CIPLA LIFE SCIENCES (PTY) LTD

Manufacturer: CIPLA LTD, RAIGAD, MAHARASHTRA, INDIA

Packer: CIPLA LTD, RAIGAD, MAHARASHTRA, INDIA

Laboratory: FPRC: CIPLA LTD, RAIGAD, MAHARASHTRA, INDIA
FPRR: CIPLA LIFE SCIENCES, ROSENPARK, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A38/2.5/0570

Name of medicine: CIPLA – LAMOTRIGINE 200

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
LAMOTRIGINE 200,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: CIPLA LIFE SCIENCES (PTY) LTD

Manufacturer: CIPLA LTD, RAIGAD, MAHARASHTRA, INDIA

Packer: CIPLA LTD, RAIGAD, MAHARASHTRA, INDIA

Laboratory: FPRC: CIPLA LTD, RAIGAD, MAHARASHTRA, INDIA
FPRR: CIPLA LIFE SCIENCES, ROSEN PARK, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A38/21.1/0578

Name of medicine: APEX-METFORMIN 500 MG TABLETS

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
METFORMIN HYDROCHLORIDE 500,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: CAMOX PHARMACEUTICALS (PTY) LTD

Manufacturer: MEDREICH STERILAB LTD, VIRGONAGAR,
BANGALORE, INDIA

Packer: MEDREICH STERILAB LTD, VIRGONAGAR,
BANGALORE, INDIA

Laboratory: FPRC: MEDREICH STERILAB LTD, VIRGONAGAR,
BANGALORE, INDIA
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
INSTITUTE FOR PHARMACEUTICAL SERVICES,
BARDENE, BOKSBURG, RSA
INSPECTORATE M&L, ORMONDE, JOHANNESBURG
FPRR: CAMOX PHARMACEUTICALS, ROSEBANK, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A38/21.1/0579

Name of medicine: APEX-METFORMIN FORTE 850 MG TABLETS

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
METFORMIN HYDROCHLORIDE 850,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: CAMOX PHARMACEUTICALS (PTY) LTD

Manufacturer: MEDREICH STERILAB LTD, VIRGONAGAR,
BANGALORE, INDIA

Packer: MEDREICH STERILAB LTD, VIRGONAGAR,
BANGALORE, INDIA

Laboratory: FPRC: MEDREICH STERILAB LTD, VIRGONAGAR,
BANGALORE, INDIA
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
INSTITUTE FOR PHARMACEUTICAL SERVICES,
BARDENE, BOKSBURG, RSA
INSPECTORATE M&L, ORMONDE, JOHANNESBURG
FPRR: CAMOX PHARMACEUTICALS, ROSEBANK, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A38/10.2.2/0584

Name of medicine: SINGULAIR SPRINKLES

Dosage form: GRANULES

Active ingredients: EACH PACKET CONTAINS:
MONTELUKAST SODIUM EQUIVALENT TO
MONTELUKAST 4,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: MSD (PTY) LTD

Manufacturer: MERCK MANUFACTURING DIVISION, WEST POINT,
PA, USA

Packer: ANDERSON PACKAGING, ROCKFORD, IL, USA
MMD-HAARLEM, HAARLEM, THE NETHERLANDS
MSD, HALFWAY HOUSE, RSA

Laboratory: FPRC: MERCK MANUFACTURING DIVISION, WEST POINT,
PA, USA
FPRC/FPRR: MSD, HALFWAY HOUSE, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A38/2.5/0585

Name of medicine: ASPEN LAMOTRIGINE 25 MG

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
LAMOTRIGINE 25,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: PHARMACARE LIMITED

Manufacturer: GENPHARM PHARMACEUTICALS INC, ONTARIO,
CANADA
LENNON LTD, KORSTEN, PORT ELIZABETH

Packer: GENPHARM PHARMACEUTICALS INC, ONTARIO,
CANADA
LENNON LTD, KORSTEN, PORT ELIZABETH

Laboratory: FPRC: GENPHARM PHARMACEUTICALS INC, ONTARIO,
CANADA
LENNON LTD, KORSTEN, PORT ELIZABETH
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
RESEARCH INSTITUTE FOR PHARMACEUTICAL
SERVICES, UNIVERSITY, POTCHEFSTROOM
FPRR: PHARMACARE LTD, KORSTEN, PORT ELIZABETH

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A38/2.5/0586

Name of medicine: ASPEN LAMOTRIGINE 50 MG

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
LAMOTRIGINE 50,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: PHARMACARE LIMITED

Manufacturer: GENPHARM PHARMACEUTICALS INC, ONTARIO,
CANADA
LENNON LTD, KORSTEN, PORT ELIZABETH

Packer: GENPHARM PHARMACEUTICALS INC, ONTARIO,
CANADA
LENNON LTD, KORSTEN, PORT ELIZABETH

Laboratory: FPRC: GENPHARM PHARMACEUTICALS INC, ONTARIO,
CANADA
LENNON LTD, KORSTEN, PORT ELIZABETH
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
RESEARCH INSTITUTE FOR PHARMACEUTICAL
SERVICES, UNIVERSITY, POTCHEFSTROOM
FPRR: PHARMACARE LTD, KORSTEN, PORT ELIZABETH

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A38/2.5/0587

Name of medicine: ASPEN LAMOTRIGINE 100 MG

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
LAMOTRIGINE 100,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: PHARMACARE LIMITED

Manufacturer: GENPHARM PHARMACEUTICALS INC, ONTARIO,
CANADA
LENNON LTD, KORSTEN, PORT ELIZABETH

Packer: GENPHARM PHARMACEUTICALS INC, ONTARIO,
CANADA
LENNON LTD, KORSTEN, PORT ELIZABETH

Laboratory: FPRC: GENPHARM PHARMACEUTICALS INC, ONTARIO,
CANADA
LENNON LTD, KORSTEN, PORT ELIZABETH
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
RESEARCH INSTITUTE FOR PHARMACEUTICAL
SERVICES, UNIVERSITY, POTCHEFSTROOM
FPRR: PHARMACARE LTD, KORSTEN, PORT ELIZABETH

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number:	A38/2.5/0588
Name of medicine:	ASPEN LAMOTRIGINE 200 MG
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LAMOTRIGINE 200,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMACARE LIMITED
Manufacturer:	GENPHARM PHARMACEUTICALS INC, ONTARIO, CANADA LENNON LTD, KORSTEN, PORT ELIZABETH
Packer:	GENPHARM PHARMACEUTICALS INC, ONTARIO, CANADA LENNON LTD, KORSTEN, PORT ELIZABETH
Laboratory: FPRC:	GENPHARM PHARMACEUTICALS INC, ONTARIO, CANADA LENNON LTD, KORSTEN, PORT ELIZABETH SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA, RSA RESEARCH INSTITUTE FOR PHARMACEUTICAL SERVICES, UNIVERSITY, POTCHEFSTROOM
FPRR:	PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Shelf-life:	24 months
Date of registration:	25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A38/15.4/0592

Name of medicine: REFRESH LIQUIGEL

Dosage form: EYE DROPS

Active ingredients: EACH 1,0 ml SOLUTION CONTAINS:
CARBOXYMETHYLCELLULOSE SODIUM 10,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: ALLERGAN PHARMACEUTICALS (PTY) LTD

Manufacturer: ALLERGAN INC., WACO, TEXAS

Packer: ALLERGAN INC., WACO, TEXAS

Laboratory: FPRC: ALLERGAN INC., WACO, TEXAS
INSTITUTE FOR PHARMACEUTICAL SERVICES,
BARDENE, BOKSBURG, RSA
FPRR: ALLERGAN PHARMACEUTICALS,
HALFWAY HOUSE, RSA

Shelf-life: 18 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number:	A38/2.6.5/0595
Name of medicine:	ABILIFY 10 MG
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ARIPRAZOLE 10,0 MG
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	BRISTOL-MYERS SQUIBB (PTY) LTD
Manufacturer:	BRISTOL-MYERS SQUIBB MANUFACTURING CO, MAYAGUEZ, PUERTO RICO
Packer:	BRISTOL-MYERS SQUIBB AUSTRALIA PTY LTD, NOBLE PARK, VICTORIA, AUSTRALIA
Laboratory: FPRC:	BRISTOL-MYERS SQUIBB MANUFACTURING CO, MAYAGUEZ, PUERTO RICO BRISTOL-MYERS SQUIBB AUSTRALIA PTY LTD, NOBLE PARK, VICTORIA, AUSTRALIA CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA MERCK PHARMACEUTICAL MANUFACTURER, WADEVILLE, GERMISTON, RSA
FPRR:	BRISTOL-MYERS SQUIBB, BEDFORDVIEW, RSA
Shelf-life:	24 months
Date of registration:	25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A38/2.6.5/0596

Name of medicine: ABILIFY 15 MG

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
ARIPRAZOLE 15,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: BRISTOL-MYERS SQUIBB (PTY) LTD

Manufacturer: BRISTOL-MYERS SQUIBB MANUFACTURING CO,
MAYAGUEZ, PUERTO RICO

Packer: BRISTOL-MYERS SQUIBB AUSTRALIA PTY LTD,
NOBLE PARK, VICTORIA, AUSTRALIA

Laboratory: FPRC: BRISTOL-MYERS SQUIBB MANUFACTURING CO,
MAYAGUEZ, PUERTO RICO
BRISTOL-MYERS SQUIBB AUSTRALIA PTY LTD,
NOBLE PARK, VICTORIA, AUSTRALIA
CONSULTING CHEMICAL LABORATORIES,
STAR STREET, BOKSBURG, RSA
MERCK PHARMACEUTICAL MANUFACTURER,
WADEVILLE, GERMISTON, RSA
FPRR: BRISTOL-MYERS SQUIBB, BEDFORDVIEW, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A38/2.6.5/0598

Name of medicine: ABILIFY 30 MG

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
ARIPRAZOLE 30,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: BRISTOL-MYERS SQUIBB (PTY) LTD

Manufacturer: BRISTOL-MYERS SQUIBB MANUFACTURING CO,
MAYAGUEZ, PUERTO RICO

Packer: BRISTOL-MYERS SQUIBB AUSTRALIA PTY LTD,
NOBLE PARK, VICTORIA, AUSTRALIA

Laboratory: FPRC: BRISTOL-MYERS SQUIBB MANUFACTURING CO,
MAYAGUEZ, PUERTO RICO
BRISTOL-MYERS SQUIBB AUSTRALIA PTY LTD,
NOBLE PARK, VICTORIA, AUSTRALIA
CONSULTING CHEMICAL LABORATORIES,
STAR STREET, BOKSBURG, RSA
MERCK PHARMACEUTICAL MANUFACTURER,
WADEVILLE, GERMISTON, RSA
FPRR: BRISTOL-MYERS SQUIBB, BEDFORDVIEW, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number:	A38/20.1.1/0632
Name of medicine:	REZIDIME 1000 INJECTION
Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: CEFTAZIDIME PENTAHYDRATE EQUIVALENT TO CEFTAZIDIME 1,0 G
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	RESMED HEALTHCARE
Manufacturer:	ASTRAL PHARMACEUTICAL INDUSTRIES, GUJARAT, INDIA
Packer:	ASTRAL PHARMACEUTICAL INDUSTRIES, GUJARAT, INDIA
Laboratory:	FPRC: ASTRAL PHARMACEUTICAL INDUSTRIES, GUJARAT, INDIA FPRR: RESMED HEALTHCARE, SPRINGFIELD PARK, DURBAN, RSA
Shelf-life:	36 months
Date of registration:	25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A38/20.1.1/0634

Name of medicine: REZIDIME 2000 INJECTION

Dosage form: INJECTION

Active ingredients: EACH VIAL CONTAINS:
CEFTAZIDIME PENTAHYDRATE EQUIVALENT TO
CEFTAZIDIME 2,0 G

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: RESMED HEALTHCARE

Manufacturer: ASTRAL PHARMACEUTICAL INDUSTRIES,
GUJARAT, INDIA

Packer: ASTRAL PHARMACEUTICAL INDUSTRIES,
GUJARAT, INDIA

Laboratory: FPRC: ASTRAL PHARMACEUTICAL INDUSTRIES,
GUJARAT, INDIA
FPRR: RESMED HEALTHCARE, SPRINGFIELD PARK,
DURBAN, RSA

Shelf-life: 36 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A38/13.4.1/0668

Name of medicine: ASPEN MOMETASONE CREAM

Dosage form: CREAM

Active ingredients: EACH 1,0 g CREAM CONTAINS:
MOMETASONE FUROATE 1,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: PHARMACARE LIMITED

Manufacturer: PHARMACARE LTD, KORSTEN, PORT ELIZABETH

Packer: PHARMACARE LTD, KORSTEN, PORT ELIZABETH

Laboratory: FPRC: SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
RESEARCH INSTITUTE FOR PHARMACEUTICAL
SERVICES, UNIVERSITY, POTCHEFSTROOM
FPRC/FPRR: PHARMACARE LTD, KORSTEN, PORT ELIZABETH

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A38/20.1.1/0692

Name of medicine: ZITHROGEN 250

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
AZITHROMYCIN MONOHYDRATE
HEMIETHANOLATE EQUIVALENT TO
AZITHROMYCIN 250,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: XIXIA PHARMACEUTICALS (PTY) LTD

Manufacturer: GERARD LABORATORIES, DUBLIN, IRELAND

Packer: GERARD LABORATORIES, DUBLIN, IRELAND
MERCK PHARMACEUTICAL MANUFACTURING,
WADEVILLE, GERMISTON, RSA

Laboratory: FPRC: GERARD LABORATORIES, DUBLIN, IRELAND
MERCK PHARMACEUTICAL MANUFACTURING,
WADEVILLE, GERMISTON, RSA
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, UNIVERSITY, POTCHEFSTROOM, RSA
FPRR: XIXIA PHARMACEUTICALS, MODDERFONTEIN,
RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A38/20.1.1/0693

Name of medicine: ZITHROGEN 500

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
AZITHROMYCIN MONOHYDRATE
HEMIETHANOLATE EQUIVALENT TO
AZITHROMYCIN 500,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: XIXIA PHARMACEUTICALS (PTY) LTD

Manufacturer: GERARD LABORATORIES, DUBLIN, IRELAND

Packer: GERARD LABORATORIES, DUBLIN, IRELAND
MERCK PHARMACEUTICAL MANUFACTURING,
WADEVILLE, GERMISTON, RSA

Laboratory: FPRC: GERARD LABORATORIES, DUBLIN, IRELAND
MERCK PHARMACEUTICAL MANUFACTURING,
WADEVILLE, GERMISTON, RSA
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, UNIVERSITY, POTCHEFSTROOM, RSA
FPRR: XIXIA PHARMACEUTICALS, MODDERFONTEIN,
RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A38/20.1.1/0715

Name of medicine: CIPRODAC 500

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
CIPROFLOXACIN HYDROCHLORIDE EQUIVALENT
TO CIPROFLOXACIN 500,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: BE-TABS PHARMACEUTICALS (PTY) LTD

Manufacturer: CADILA PHARMACEUTICALS LTD, AHMEDABAD,
GUJARAT, INDIA

Packer: CADILA PHARMACEUTICALS LTD, AHMEDABAD,
GUJARAT, INDIA

Laboratory: FPRC: CADILA PHARMACEUTICALS LTD, AHMEDABAD,
GUJARAT, INDIA
FPRR: BE-TABS PHARMACEUTICALS, ROODEPOORT, RSA

Shelf-life: 36 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A39/2.5/0002

Name of medicine: ASPEN LAMOTRIGINE 25 MG DISPERSIBLE

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
LAMOTRIGINE 25,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: PHARMACARE LIMITED

Manufacturer: GENPHARM PHARMACEUTICALS Inc, ONTARIO,
CANADA
ASPEN PHARMACARE LTD, KORSTEN, PORT
ELIZABETH

Packer: GENPHARM PHARMACEUTICALS Inc, ONTARIO,
CANADA
ASPEN PHARMACARE LTD, KORSTEN, PORT
ELIZABETH

Laboratory: FPRC: GENPHARM PHARMACEUTICALS Inc, ONTARIO,
CANADA
ASPEN PHARMACARE LTD, KORSTEN, PORT
ELIZABETH
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
RESEARCH INSTITUTE FOR PHARMACEUTICAL
SERVICES, UNIVERSITY, POTCHEFSTROOM, RSA
FPRR: PHARMACARE LTD, KORSTEN, PORT ELIZABETH

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number:	A39/2.5/0003
Name of medicine:	ASPEN LAMOTRIGINE 50 MG DISPERSIBLE
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LAMOTRIGINE 50,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMACARE LIMITED
Manufacturer:	GENPHARM PHARMACEUTICALS Inc, ONTARIO, CANADA ASPEN PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Packer:	GENPHARM PHARMACEUTICALS Inc, ONTARIO, CANADA ASPEN PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Laboratory: FPRC:	GENPHARM PHARMACEUTICALS Inc, ONTARIO, CANADA ASPEN PHARMACARE LTD, KORSTEN, PORT ELIZABETH SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA, RSA RESEARCH INSTITUTE FOR PHARMACEUTICAL SERVICES, UNIVERSITY, POTCHEFSTROOM, RSA
FPRR:	PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Shelf-life:	24 months
Date of registration:	25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A39/2.5/0004

Name of medicine: ASPEN LAMOTRIGINE 100 MG DISPERSIBLE

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
LAMOTRIGINE 100,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: PHARMACARE LIMITED

Manufacturer: GENPHARM PHARMACEUTICALS Inc, ONTARIO,
CANADA
ASPEN PHARMACARE LTD, KORSTEN, PORT
ELIZABETH

Packer: GENPHARM PHARMACEUTICALS Inc, ONTARIO,
CANADA
ASPEN PHARMACARE LTD, KORSTEN, PORT
ELIZABETH

Laboratory: FPRC: GENPHARM PHARMACEUTICALS Inc, ONTARIO,
CANADA
ASPEN PHARMACARE LTD, KORSTEN, PORT
ELIZABETH
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
RESEARCH INSTITUTE FOR PHARMACEUTICAL
SERVICES, UNIVERSITY, POTCHEFSTROOM, RSA
FPRR: PHARMACARE LTD, KORSTEN, PORT ELIZABETH

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A39/2.5/0006

Name of medicine: ASPEN LAMOTRIGINE 5 MG DISPERSIBLE

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
LAMOTRIGINE 5,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: PHARMACARE LIMITED

Manufacturer: GENPHARM PHARMACEUTICALS Inc, ONTARIO,
CANADA
ASPEN PHARMACARE LTD, KORSTEN, PORT
ELIZABETH

Packer: GENPHARM PHARMACEUTICALS Inc, ONTARIO,
CANADA
ASPEN PHARMACARE LTD, KORSTEN, PORT
ELIZABETH

Laboratory: FPRC: GENPHARM PHARMACEUTICALS Inc, ONTARIO,
CANADA
ASPEN PHARMACARE LTD, KORSTEN, PORT
ELIZABETH
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
RESEARCH INSTITUTE FOR PHARMACEUTICAL
SERVICES, UNIVERSITY, POTCHEFSTROOM, RSA
FPRR: PHARMACARE LTD, KORSTEN, PORT ELIZABETH

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A39/2.5/0007

Name of medicine: ASPEN LAMOTRIGINE 200 MG DISPERSIBLE

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
LAMOTRIGINE 200,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: PHARMACARE LIMITED

Manufacturer: GENPHARM PHARMACEUTICALS Inc, ONTARIO,
CANADA
ASPEN PHARMACARE LTD, KORSTEN, PORT
ELIZABETH

Packer: GENPHARM PHARMACEUTICALS Inc, ONTARIO,
CANADA
ASPEN PHARMACARE LTD, KORSTEN, PORT
ELIZABETH

Laboratory: FPRC: GENPHARM PHARMACEUTICALS Inc, ONTARIO,
CANADA
ASPEN PHARMACARE LTD, KORSTEN, PORT
ELIZABETH
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
RESEARCH INSTITUTE FOR PHARMACEUTICAL
SERVICES, UNIVERSITY, POTCHEFSTROOM, RSA
FPRR: PHARMACARE LTD, KORSTEN, PORT ELIZABETH

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A39/35/0016

Name of medicine: ZEVALIN

Dosage form: INFUSION

Active ingredients: EACH 1,0 ml SOLUTION CONTAINS:
IBRITUMOMAB TIUXETAN 1,6 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: SCHERING (PTY) LTD

Manufacturer: IDEC PHARMACEUTICALS, SAN DIEGO, CA, USA
BAXTER PHARMACEUTICAL SOLUTIONS,
BLOOMINGTON, INDIANA, USA

Packer: BAXTER PHARMACEUTICAL SOLUTIONS,
BLOOMINGTON, INDIANA, USA
SCHERING AG, BERLIN, GERMANY

Laboratory: FPRC: SCHERING AG, BERLIN, GERMANY
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA
FPRR: SCHERING, MIDRAND, RSA

Shelf-life: 12 months for BULK SOLUTIONS
24 months for KIT SOLUTIONS

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A39/20.1.1/0020

Name of medicine: MACROZIT 500 MG

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
AZITHROMYCIN 500,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: CAMOX PHARMACEUTICALS (PTY) LTD

Manufacturer: INTAS PHARMACEUTICALS LTD, MATODA,
GUJARAT, INDIA

Packer: INTAS PHARMACEUTICALS LTD, MATODA,
GUJARAT, INDIA

Laboratory: INTAS PHARMACEUTICALS LTD, MATODA,
GUJARAT, INDIA
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
INSTITUTE FOR PHARMACEUTICAL SERVICES,
BARDENE, BOKSBURG, RSA
INSPECTORATE M&L, ORMONDE,
JOHANNESBURG, RSA
CAMOX PHARMACEUTICALS, ROSEBANK, RSA

Shelf-life: 24 months

Date of registration: 23 SEPTEMBER 2005

MRF 15 (MBR 15)

Registration number: A39/5.10/0062

Name of medicine: ASPEN ONDANSETRON 4 MG/2 ML

Dosage form: INJECTION

Active ingredients: EACH 1,0 ml LIQUID CONTAINS:
ONDANSETRON HYDROCHLORIDE EQUIVALENT
TO ONDANSETRON 2,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: PHARMACARE LIMITED

Manufacturer: STRIDES ARCOLAB LTD, BANGALORE, INDIA

Packer: STRIDES ARCOLAB LTD, BANGALORE, INDIA

Laboratory: FPRC: STRIDES ARCOLAB LTD, BANGALORE, INDIA
LENNON LTD, KORSTEN, PORT ELIZABETH
FPRR: PHARMACARE LTD, KORSTEN, PORT ELIZABETH

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A39/5.10/0063

Name of medicine: ASPEN ONDANSETRON 8 MG/4 ML

Dosage form: INJECTION

Active ingredients: EACH 1,0 ml LIQUID CONTAINS:
ONDANSETRON HYDROCHLORIDE EQUIVALENT
TO ONDANSETRON 2,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: PHARMACARE LIMITED

Manufacturer: STRIDES ARCOLAB LTD, BANGALORE, INDIA

Packer: STRIDES ARCOLAB LTD, BANGALORE, INDIA

Laboratory: FPRC: STRIDES ARCOLAB LTD, BANGALORE, INDIA
LENNON LTD, KORSTEN, PORT ELIZABETH
FPRR: PHARMACARE LTD, KORSTEN, PORT ELIZABETH

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15

Registration number: A39/20.2.8/0088

Name of medicine: REYATAZ 150 MG

Dosage form: CAPSULE

Active ingredients: EACH CAPSULE CONTAINS:
ATAZANAVIR SULPHATE EQUIVALENT TO
ATAZANAVIR 150,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: BRISTOL-MYERS SQUIBB (PTY) LTD

Manufacturer: BRISTOL-MYERS SQUIBB CO, EVANSVILLE,
INDIANA, USA

Packer: BRISTOL-MYERS SQUIBB CO, EVANSVILLE,
INDIANA, USA
BRISTOL LABORATORIES INTERNATIONAL,
EDIFICIO, PANAMA
BRISTOL-MYERS SQUIBB, MEYMAC, FRANCE

Laboratory: FPRC: BRISTOL-MYERS SQUIBB CO, EVANSVILLE,
INDIANA, USA
CONSULTING CHEMICAL LABORATORIES,
STAR STREET, BOKSBURG, RSA
MERCK PHARMACEUTICAL MANUFACTURER,
WADEVILLE, GERMISTON, RSA
FPRR: BRISTOL-MYERS SQUIBB, BEDFORDVIEW, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15

Registration number: A39/20.2.8/0089

Name of medicine: REYATAZ 200 MG

Dosage form: CAPSULE

Active ingredients: EACH CAPSULE CONTAINS:
ATAZANAVIR SULPHATE EQUIVALENT TO
ATAZANAVIR 200,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: BRISTOL-MYERS SQUIBB (PTY) LTD

Manufacturer: BRISTOL-MYERS SQUIBB CO, EVANSVILLE,
INDIANA, USA

Packer: BRISTOL-MYERS SQUIBB CO, EVANSVILLE,
INDIANA, USA
BRISTOL LABORATORIES INTERNATIONAL,
EDIFICIO, PANAMA
BRISTOL-MYERS SQUIBB, MEYMAC, FRANCE

Laboratory: FPRC: BRISTOL-MYERS SQUIBB CO, EVANSVILLE,
INDIANA, USA
CONSULTING CHEMICAL LABORATORIES,
STAR STREET, BOKSBURG, RSA
MERCK PHARMACEUTICAL MANUFACTURER,
WADEVILLE, GERMISTON, RSA
FPRR: BRISTOL-MYERS SQUIBB, BEDFORDVIEW, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number:	A39/7.1.3/0108
Name of medicine:	LISOZIDE 10 (TABLETS)
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LISINOPRIL DIHYDRATE EQUIVALENT TO LISINOPRIL 10,0 mg HYDROCHLOROTHIAZIDE 12,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	AUSTELL LABORATORIES (PTY) LTD
Manufacturer:	IPCA LABORATORIES LTD, DADRA & NAGAR HAVELI, INDIA
Packer:	IPCA LABORATORIES LTD, DADRA & NAGAR HAVELI, INDIA
Laboratory:	IPCA LABORATORIES LTD, DADRA & NAGAR HAVELI, INDIA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA, RSA INSPECTORATE M&L, ORMONDE, JOHANNESBURG INSTITUTE FOR PHARMACEUTICAL SERVICES, BARDENE, BOKSBURG, RSA AUSTELL LABORATORIES, SAXONWOLD, RSA
Shelf-life:	24 months
Date of registration:	29 JULY 2005

MRF 15 (MBR 15)

Registration number:	A39/7.1.3/0109
Name of medicine:	LISOZIDE 20 (TABLETS)
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LISINOPRIL DIHYDRATE EQUIVALENT TO LISINOPRIL 20,0 mg HYDROCHLOROTHIAZIDE 12,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	AUSTELL LABORATORIES (PTY) LTD
Manufacturer:	IPCA LABORATORIES LTD, DADRA & NAGAR HAVELI, INDIA
Packer:	IPCA LABORATORIES LTD, DADRA & NAGAR HAVELI, INDIA
Laboratory:	IPCA LABORATORIES LTD, DADRA & NAGAR HAVELI, INDIA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA, RSA INSPECTORATE M&L, ORMONDE, JOHANNESBURG INSTITUTE FOR PHARMACEUTICAL SERVICES, BARDENE, BOKSBURG, RSA AUSTELL LABORATORIES, SAXONWOLD, RSA
Shelf-life:	24 months
Date of registration:	29 JULY 2005

MRF 15 (MBR 15)

Registration number: A39/7.1.3/0141

Name of medicine: RAMPIL 1,25 MG

Dosage form: CAPSULE

Active ingredients: EACH CAPSULE CONTAINS:
RAMIPRIL 1,25 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: PHARMACARE LIMITED

Manufacturer: GENPHARM INC, ETOBICOKE, ONTARIO, CANADA
MERCK FARMA y QUIMICA, BARCELONA, SPAIN
PHARMACARE LTD, KORSTEN, PORT ELIZABETH

Packer: GENPHARM INC, ETOBICOKE, ONTARIO, CANADA
MERCK FARMA y QUIMICA, BARCELONA, SPAIN
PHARMACARE LTD, KORSTEN, PORT ELIZABETH

Laboratory: FPRC: GENPHARM INC, ETOBICOKE, ONTARIO, CANADA
MERCK FARMA y QUIMICA, BARCELONA, SPAIN
SOUTH AFRICAN BUREAU OF
STANDARDS, GROENKLOOF, PRETORIA
RESEARCH INSTITUTE FOR PHARMACEUTICAL
SERVICES, UNIVERSITY, PRETORIA, RSA
FPRC/FPRR: PHARMACARE LTD, KORSTEN, PORT ELIZABETH

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A39/7.1.3/0142

Name of medicine: RAMPIL 2,5 MG

Dosage form: CAPSULE

Active ingredients: EACH CAPSULE CONTAINS:
RAMIPRIL 2,5 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: PHARMACARE LIMITED

Manufacturer: GENPHARM INC, ETOBICOKE, ONTARIO, CANADA
MERCK FARMA y QUIMICA, BARCELONA, SPAIN
PHARMACARE LTD, KORSTEN, PORT ELIZABETH

Packer: GENPHARM INC, ETOBICOKE, ONTARIO, CANADA
MERCK FARMA y QUIMICA, BARCELONA, SPAIN
PHARMACARE LTD, KORSTEN, PORT ELIZABETH

Laboratory: FPRC GENPHARM INC, ETOBICOKE, ONTARIO, CANADA
MERCK FARMA y QUIMICA, BARCELONA, SPAIN
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA
RESEARCH INSTITUTE FOR PHARMACEUTICAL
SERVICES, UNIVERSITY, PRETORIA, RSA
FPRC/FPRR: PHARMACARE LTD, KORSTEN, PORT ELIZABETH

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A39/7.1.3/0143

Name of medicine: RAMPIL 5 MG

Dosage form: CAPSULE

Active ingredients: EACH CAPSULE CONTAINS:
RAMIPRIL 5,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: PHARMACARE LIMITED

Manufacturer: GENPHARM INC, ETOBICOKE, ONTARIO, CANADA
MERCK FARMA y QUIMICA, BARCELONA, SPAIN
PHARMACARE LTD, KORSTEN, PORT ELIZABETH

Packer: GENPHARM INC, ETOBICOKE, ONTARIO, CANADA
MERCK FARMA y QUIMICA, BARCELONA, SPAIN
PHARMACARE LTD, KORSTEN, PORT ELIZABETH

Laboratory: FPRC: GENPHARM INC, ETOBICOKE, ONTARIO, CANADA
MERCK FARMA y QUIMICA, BARCELONA, SPAIN
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA
RESEARCH INSTITUTE FOR PHARMACEUTICAL
SERVICES, UNIVERSITY, PRETORIA, RSA
FPRC/FPRR: PHARMACARE LTD, KORSTEN, PORT ELIZABETH

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A39/7.1.3/0144

Name of medicine: RAMPIL 10 MG

Dosage form: CAPSULE

Active ingredients: EACH CAPSULE CONTAINS:
RAMIPRIL 10,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: PHARMACARE LIMITED

Manufacturer: GENPHARM INC, ETOBICOKE, ONTARIO, CANADA
MERCK FARMA y QUIMICA, BARCELONA, SPAIN
PHARMACARE LTD, KORSTEN, PORT ELIZABETH

Packer: GENPHARM INC, ETOBICOKE, ONTARIO, CANADA
MERCK FARMA y QUIMICA, BARCELONA, SPAIN
PHARMACARE LTD, KORSTEN, PORT ELIZABETH

Laboratory: FPRC: GENPHARM INC, ETOBICOKE, ONTARIO, CANADA
MERCK FARMA y QUIMICA, BARCELONA, SPAIN
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA
RESEARCH INSTITUTE FOR PHARMACEUTICAL
SERVICES, UNIVERSITY, PRETORIA, RSA
FPRC/FPRR: PHARMACARE LTD, KORSTEN, PORT ELIZABETH

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number:	A39/7.1.3/0145
Name of medicine:	MERCK-CARVEDILOL 3,125
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CARVEDILOL 3,125 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	XIXIA PHARMACEUTICALS (PTY) LTD
Manufacturer:	SPECIFAR S.A., ATHENS, GREECE CHANELLE MEDICAL LTD, GALWAY, IRELAND
Packer:	SPECIFAR S.A., ATHENS, GREECE CHANELLE MEDICAL LTD, GALWAY, IRELAND Mc DERMOTT LABORATORIES, DUBLIN, IRELAND GENERICS UK LTD, POTTERS BAR, HERTFORDSHIRE, UK MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON, RSA
Laboratory:	FPRC: SPECIFAR S.A., ATHENS, GREECE CHANELLE MEDICAL LTD, GALWAY, IRELAND Mc DERMOTT LABORATORIES, DUBLIN, IRELAND GENERICS UK LTD, POTTERS BAR, HERTFORDSHIRE, UK MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY, POTCHEFSTROOM, RSA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA, RSA FPRR: XIXIA PHARMACEUTICALS, MODDERFONTEIN, RSA
Shelf-life:	24 months
Date of registration:	25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A39/7.1.3/0146

Name of medicine: MERCK-CARVEDILOL 6,25

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
CARVEDILOL 6,25 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: XIXIA PHARMACEUTICALS (PTY) LTD

Manufacturer: SPECIFAR S.A., ATHENS, GREECE
CHANELLE MEDICAL LTD, GALWAY, IRELAND

Packer: SPECIFAR S.A., ATHENS, GREECE
CHANELLE MEDICAL LTD, GALWAY, IRELAND
Mc DERMOTT LABORATORIES, DUBLIN, IRELAND
GENERICS UK LTD, POTTERS BAR,
HERTFORDSHIRE, UK
MERCK PHARMACEUTICAL MANUFACTURING,
WADEVILLE, GERMISTON, RSA

Laboratory: FPRC: SPECIFAR S.A., ATHENS, GREECE
CHANELLE MEDICAL LTD, GALWAY, IRELAND
Mc DERMOTT LABORATORIES, DUBLIN, IRELAND
GENERICS UK LTD, POTTERS BAR,
HERTFORDSHIRE, UK
MERCK PHARMACEUTICAL MANUFACTURING,
WADEVILLE, GERMISTON, RSA
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, UNIVERSITY, POTCHEFSTROOM, RSA
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
FPRR: XIXIA PHARMACEUTICALS, MODDERFONTEIN,
RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number:	A39/7.1.3/0147
Name of medicine:	MERCK-CARVEDILOL 12,5
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CARVEDILOL 12,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	XIXIA PHARMACEUTICALS (PTY) LTD
Manufacturer:	SPECIFAR S.A., ATHENS, GREECE CHANELLE MEDICAL LTD, GALWAY, IRELAND
Packer:	SPECIFAR S.A., ATHENS, GREECE CHANELLE MEDICAL LTD, GALWAY, IRELAND Mc DERMOTT LABORATORIES, DUBLIN, IRELAND GENERICS UK LTD, POTTERS BAR, HERTFORDSHIRE, UK MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON, RSA
Laboratory:	FPRC: SPECIFAR S.A., ATHENS, GREECE CHANELLE MEDICAL LTD, GALWAY, IRELAND Mc DERMOTT LABORATORIES, DUBLIN, IRELAND GENERICS UK LTD, POTTERS BAR, HERTFORDSHIRE, UK MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY, POTCHEFSTROOM, RSA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA, RSA FPRR: XIXIA PHARMACEUTICALS, MODDERFONTEIN, RSA
Shelf-life:	24 months
Date of registration:	25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number:	A39/7.1.3/0148
Name of medicine:	MERCK-CARVEDILOL 25
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CARVEDILOL 25 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	XIXIA PHARMACEUTICALS (PTY) LTD
Manufacturer:	SPECIFAR S.A., ATHENS, GREECE CHANELLE MEDICAL LTD, GALWAY, IRELAND
Packer:	SPECIFAR S.A., ATHENS, GREECE CHANELLE MEDICAL LTD, GALWAY, IRELAND Mc DERMOTT LABORATORIES, DUBLIN, IRELAND GENERICUS UK LTD, POTTERS BAR, HERTFORDSHIRE, UK MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON, RSA
Laboratory:	FPRC: SPECIFAR S.A., ATHENS, GREECE CHANELLE MEDICAL LTD, GALWAY, IRELAND Mc DERMOTT LABORATORIES, DUBLIN, IRELAND GENERICUS UK LTD, POTTERS BAR, HERTFORDSHIRE, UK MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY, POTCHEFSTROOM, RSA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA, RSA FPRR: XIXIA PHARMACEUTICALS, MODDERFONTEIN, RSA
Shelf-life:	24 months
Date of registration:	25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A39/34/0162

Name of medicine: SABAX LOW GLUCOSE ACID DIASOL

Dosage form: SOLUTION

Active ingredients: EACH 1000,0 ml SOLUTION CONTAINS:

SODIUM CHLORIDE	214,8 G
GLACIAL ACETIC ACID	6,310 G
POTASSIUM CHLORIDE	3,920 G
CALCIUM CHLORIDE DIHYDRATE	7,720 G
MAGNESIUM CHLORIDE HEXAHYDRATE	2,135 G
GLUCOSE MONOHYDRATE	38,50 G

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: ADCOCK INGRAM CRITICAL CARE (PTY) LTD

Manufacturer: ADCOCK INGRAM CRITICAL CARE, AEROTON,
JOHANNESBURG, RSA

Packer: ADCOCK INGRAM CRITICAL CARE, AEROTON,
JOHANNESBURG, RSA

Laboratory: FPRC: WICKHAM LABORATORIES, WICKHAM,
HAMPSHIRE, U.K.
FPRC/FPRR: ADCOCK INGRAM CRITICAL CARE, AEROTON,
JOHANNESBURG, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A39/34/0163

Name of medicine: SABAX LOW MAGNESIUM ACID DIASOL

Dosage form: SOLUTION

Active ingredients: EACH 1000,0 ml SOLUTION CONTAINS:
SODIUM CHLORIDE 214,8 G
GLACIAL ACETIC ACID 6,310 G
POTASSIUM CHLORIDE 3,920 G
CALCIUM CHLORIDE DIHYDRATE 7,720 G
MAGNESIUM CHLORIDE HEXAHYDRATE 2,135 G

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: ADCOCK INGRAM CRITICAL CARE (PTY) LTD

Manufacturer: ADCOCK INGRAM CRITICAL CARE, AEROTON,
JOHANNESBURG, RSA

Packer: ADCOCK INGRAM CRITICAL CARE, AEROTON,
JOHANNESBURG, RSA

Laboratory: FPRC: WICKHAM LABORATORIES, WICKHAM,
HAMPSHIRE, U.K.
FPRC/FPRR: ADCOCK INGRAM CRITICAL CARE, AEROTON,
JOHANNESBURG, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A39/34/0164

Name of medicine: SABAX LIQUID BICARBONATE
CONCENTRATE 8,4 %

Dosage form: SOLUTION

Active ingredients: EACH 1000,0 ml SOLUTION CONTAINS:
SODIUM BICARBONATE 84,0 G

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: ADCOCK INGRAM CRITICAL CARE (PTY) LTD

Manufacturer: ADCOCK INGRAM CRITICAL CARE, AEROTON,
JOHANNESBURG, RSA

Packer: ADCOCK INGRAM CRITICAL CARE , AEROTON,
JOHANNESBURG, RSA

Laboratory: FPRC: WICKHAM LABORATORIES, WICKHAM,
HAMPSHIRE, U.K.
FPRR; ADCOCK INGRAM CRITICAL CARE, AEROTON,
JOHANNESBURG, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number:	A39/34/0165
Name of medicine:	SABAX STANDARD CHRONIC ACID DIASOL
Dosage form:	SOLUTION
Active ingredients:	EACH 1000,0 ml SOLUTION CONTAINS: SODIUM CHLORIDE 214,8 G GLACIAL ACETIC ACID 6,310 G POTASSIUM CHLORIDE 3,920 G CALCIUM CHLORIDE DIHYDRATE 7,720 G MAGNESIUM CHLORIDE HEXAHYDRATE 5,340 G
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM CRITICAL CARE (PTY) LTD
Manufacturer:	ADCOCK INGRAM CRITICAL CARE, AEROTON, JOHANNESBURG, RSA
Packer:	ADCOCK INGRAM CRITICAL CARE , AEROTON, JOHANNESBURG, RSA
Laboratory:	FPRC: WICKHAM LABORATORIES, WICKHAM, HAMPSHIRE, U.K. FPRC/FPRR: ADCOCK INGRAM CRITICAL CARE, AEROTON, JOHANNESBURG, RSA
Shelf-life:	24 months
Date of registration:	25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A39/34/0168

Name of medicine: SABAX STANDARD ACUTE ACID DIASOL

Dosage form: SOLUTION

Active ingredients: EACH 1000,0 ml SOLUTION CONTAINS:
SODIUM CHLORIDE 198,40 G
GLACIAL ACETIC ACID 6,310 G
POTASSIUM CHLORIDE 3,920 G
CALCIUM CHLORIDE DIHYDRATE 7,720 G
MAGNESIUM CHLORIDE HEXAHYDRATE 5,340 G
GLUCOSE MONOHYDRATE 154,00 G

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: ADCOCK INGRAM CRITICAL CARE (PTY) LTD

Manufacturer: ADCOCK INGRAM CRITICAL CARE, AEROTON,
JOHANNESBURG, RSA

Packer: ADCOCK INGRAM CRITICAL CARE , AEROTON,
JOHANNESBURG, RSA

Laboratory: FPRC: WICKHAM LABORATORIES, WICKHAM,
HAMPSHIRE, U.K.
FPRC/FPRR: ADCOCK INGRAM CRITICAL CARE, AEROTON,
JOHANNESBURG, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A39/34/0169

Name of medicine: SABAX HIGH POTASSIUM ACID DIASOL

Dosage form: SOLUTION

Active ingredients: EACH 1000,0 ml SOLUTION CONTAINS:

SODIUM CHLORIDE	198,40 G
GLACIAL ACETIC ACID	6,310 G
POTASSIUM CHLORIDE	9,130 G
CALCIUM CHLORIDE DIHYDRATE	7,720 G
MAGNESIUM CHLORIDE HEXAHYDRATE	5,340 G
GLUCOSE MONOHYDRATE	154,00 G

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: ADCOCK INGRAM CRITICAL CARE (PTY) LTD

Manufacturer: ADCOCK INGRAM CRITICAL CARE, AEROTON,
JOHANNESBURG, RSA

Packer: ADCOCK INGRAM CRITICAL CARE, AEROTON,
JOHANNESBURG, RSA

Laboratory: FPRC: WICKHAM LABORATORIES, WICKHAM,
HAMPSHIRE, U.K.
FPRR: ADCOCK INGRAM CRITICAL CARE, AEROTON,
JOHANNESBURG, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A39/2.2/0184

Name of medicine: MIDAZOLAM-CP 5 MG/5 ML

Dosage form: INJECTION

Active ingredients: EACH 5,0 ml AMPOULE CONTAINS:
MIDAZOLAM 5,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: PHARMAPLAN (PTY) LTD

Manufacturer: LABORATORIOS REIG JOFRE, BARCELONA, SPAIN

Packer: LABORATORIOS REIG JOFRE, BARCELONA, SPAIN

Laboratory: FPRC: LABORATORIOS REIG JOFRE, BARCELONA, SPAIN
COMBINO PHARM S.L., BARCELONA, SPAIN
CONSULTING CHEMICAL LABORATORIES,
STAR STREET, BOKSBURG, RSA
FPRR: PHARMAPLAN, MIDRAND, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A39/2.2/0185

Name of medicine: MIDAZOLAM-CP 15 MG/3 ML

Dosage form: INJECTION

Active ingredients: EACH 3,0 ml AMPOULE CONTAINS:
MIDAZOLAM 15,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: PHARMAPLAN (PTY) LTD

Manufacturer: LABORATORIOS REIG JOFRE, BARCELONA, SPAIN

Packer: LABORATORIOS REIG JOFRE, BARCELONA, SPAIN

Laboratory: FPRC: LABORATORIOS REIG JOFRE, BARCELONA, SPAIN
COMBINO PHARM S.L., BARCELONA, SPAIN
CONSULTING CHEMICAL LABORATORIES,
STAR STREET, BOKSBURG, RSA
FPRR: PHARMAPLAN, MIDRAND, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A39/2.2/0186

Name of medicine: MIDAZOLAM-CP 50 MG/10 ML

Dosage form: INJECTION

Active ingredients: EACH 10,0 ml AMPOULE CONTAINS:
MIDAZOLAM 50,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: PHARMAPLAN (PTY) LTD

Manufacturer: LABORATORIOS REIG JOFRE, BARCELONA, SPAIN

Packer: LABORATORIOS REIG JOFRE, BARCELONA, SPAIN

Laboratory: FPRC: LABORATORIOS REIG JOFRE, BARCELONA, SPAIN
COMBINO PHARM S.L., BARCELONA, SPAIN
CONSULTING CHEMICAL LABORATORIES,
STAR STREET, BOKSBURG, RSA
FPRR: PHARMAPLAN, MIDRAND, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number:	A39/1.2/0216
Name of medicine:	XET 20 TABLETS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PAROXETINE HYDROCHLORIDE EQUIVALENT TO PAROXETINE 20,0 MG
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ZYDUS HEALTHCARE S.A. (PTY) LTD
Manufacturer:	CADILA HEALTHCARE, SANAND, AHMEDABAD, INDIA
Packer:	CADILA HEALTHCARE, SANAND, AHMEDABAD, INDIA
Laboratory: FPRC:	CADILA HEALTHCARE, SANAND, AHMEDABAD, INDIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY, POTCHEFSTROOM INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA
FPRR:	ZYDUS HEALTHCARE, POTCHEFSTROOM, RSA
Shelf-life:	24 months
Date of registration:	25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A39/2.8/0228

Name of medicine: IBUMOL BANANA

Dosage form: SUSPENSION

Active ingredients: EACH 10,0 ml SUSPENSION CONTAINS:
PARACETAMOL 250,0 mg
IBUPROFEN 200,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: PHARMACARE LIMITED

Manufacturer: PHARMACARE LTD, KORSTEN, PORT ELIZABETH
ASPEN PHARMACARE, WILSONIA, EAST LONDON

Packer: PHARMACARE LTD, KORSTEN, PORT ELIZABETH
ASPEN PHARMACARE, WILSONIA, EAST LONDON

Laboratory: FPRC/FPRR: PHARMACARE LTD, KORSTEN, PORT ELIZABETH
ASPEN PHARMACARE, WILSONIA, EAST LONDON
FPRC: SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
RESEARCH I NSTITUTE FOR PHARMACEUTICAL
SERVICES, UNIVERSITY, POTCHEFSTROOM, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A39/2.8/0229

Name of medicine: IBUMOL GRAPE

Dosage form: SUSPENSION

Active ingredients: EACH 10,0 ml SUSPENSION CONTAINS:
PARACETAMOL 250,0 mg
IBUPROFEN 200,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: PHARMACARE LIMITED

Manufacturer: PHARMACARE LTD, KORSTEN, PORT ELIZABETH
ASPEN PHARMACARE, WILSONIA, EAST LONDON

Packer: PHARMACARE LTD, KORSTEN, PORT ELIZABETH
ASPEN PHARMACARE, WILSONIA, EAST LONDON

Laboratory: FPRC: ASPEN PHARMACARE, WILSONIA, EAST LONDON
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
RESEARCH INSTITUTE FOR PHARMACEUTICAL
SERVICES, UNIVERSITY, POTCHEFSTROOM, RSA
FPRR: PHARMACARE LTD, KORSTEN, PORT ELIZABETH

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A39/7.1.3/0231

Name of medicine: PREXUM 2,5 MG

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
PERINDOPRIL ARGININE 2,5 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: BIOGARAN SOUTH AFRICA (PTY) LTD

Manufacturer: LES LABORATOIRES SERVIER INDUSTRIE, GIDY,
FRANCE
SERVIER INDUSTRIES LTD, ARKLOW, IRELAND

Packer: LES LABORATOIRES SERVIER INDUSTRIE, GIDY,
FRANCE
SERVIER INDUSTRIES LTD, ARKLOW, IRELAND
TECHNIKON LABORATORIES, ROBERTVILLE, RSA

Laboratory: FPRC: LES LABORATOIRES SERVIER INDUSTRIE, GIDY,
FRANCE
SERVIER INDUSTRIES LTD, ARKLOW, IRELAND
INSPECTORATE M&L, ORMONDE, JOHANNESBURG
FPRR: BIOGARAN S.A., RIVONIA, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A39/7.1.3/0232

Name of medicine: PREXUM 5 MG

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
PERINDOPRIL ARGININE 5,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: BIOGARAN SOUTH AFRICA (PTY) LTD

Manufacturer: LES LABORATOIRES SERVIER INDUSTRIE, GIDY,
FRANCE
SERVIER INDUSTRIES LTD, ARKLOW, IRELAND

Packer: LES LABORATOIRES SERVIER INDUSTRIE, GIDY,
FRANCE
SERVIER INDUSTRIES LTD, ARKLOW, IRELAND
TECHNIKON LABORATORIES, ROBERTVILLE, RSA

Laboratory: FPRC: LES LABORATOIRES SERVIER INDUSTRIE, GIDY,
FRANCE
SERVIER INDUSTRIES LTD, ARKLOW, IRELAND
INSPECTORATE M&L, ORMONDE, JOHANNESBURG
FPRR: BIOGARAN S.A., RIVONIA, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number:	A39/7.1.3/0233	
Name of medicine:	PREXUM 10 MG	
Dosage form:	TABLET	
Active ingredients:	EACH TABLET CONTAINS: PERINDOPRIL ARGININE	10,0 MG
Conditions of registration:	1, 2, 3, 4, 5, 6, 7	
Applicant:	BIOGARAN SOUTH AFRICA (PTY) LTD	
Manufacturer:	LES LABORATOIRES SERVIER INDUSTRIE, GIDY, FRANCE SERVIER INDUSTRIES LTD, ARKLOW, IRELAND	
Packer:	LES LABORATOIRES SERVIER INDUSTRIE, GIDY, FRANCE SERVIER INDUSTRIES LTD, ARKLOW, IRELAND TECHNIKON LABORATORIES, ROBERTVILLE, RSA	
Laboratory:	FPRC:	LES LABORATOIRES SERVIER INDUSTRIE, GIDY, FRANCE SERVIER INDUSTRIES LTD, ARKLOW, IRELAND INSPECTORATE M&L, ORMONDE, JOHANNESBURG
	FPRR:	BIOGARAN S.A., RIVONIA, RSA
Shelf-life:	24 months	
Date of registration:	25 NOVEMBER 2005	

MRF 15 (MBR 15)

Registration number: A39/7.1.3/0234

Name of medicine: COVERSYL 2,5 MG

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
PERINDOPRIL ARGININE 2,5 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: SERVIER LABORATORIES SOUTH AFRICA (PTY) LTD

Manufacturer: LES LABORATOIRES SERVIER INDUSTRIE, GIDY,
FRANCE
SERVIER INDUSTRIES LTD, ARKLOW, IRELAND

Packer: LES LABORATOIRES SERVIER INDUSTRIE, GIDY,
FRANCE
SERVIER INDUSTRIES LTD, ARKLOW, IRELAND
TECHNIKON LABORATORIES, ROBERTVILLE, RSA

Laboratory: FPRC: LES LABORATOIRES SERVIER INDUSTRIE, GIDY,
FRANCE
SERVIER INDUSTRIES LTD, ARKLOW, IRELAND
INSPECTORATE M&L, ORMONDE, JOHANNESBURG
FPRR: SERVIER LABORATORIES, RIVONIA, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A39/7.1.3/0235

Name of medicine: COVERSYL 5 MG

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
PERINDOPRIL ARGININE 5,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: SERVIER LABORATORIES SOUTH AFRICA (PTY) LTD

Manufacturer: LES LABORATOIRES SERVIER INDUSTRIE, GIDY,
FRANCE
SERVIER INDUSTRIES LTD, ARKLOW, IRELAND

Packer: LES LABORATOIRES SERVIER INDUSTRIE, GIDY,
FRANCE
SERVIER INDUSTRIES LTD, ARKLOW, IRELAND
TECHNIKON LABORATORIES, ROBERTVILLE, RSA

Laboratory: FPRC: LES LABORATOIRES SERVIER INDUSTRIE, GIDY,
FRANCE
SERVIER INDUSTRIES LTD, ARKLOW, IRELAND
INSPECTORATE M&L, ORMONDE, JOHANNESBURG
FPRR: SERVIER LABORATORIES, RIVONIA, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A39/7.1.3/0236

Name of medicine: COVERSYL 10 MG

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
PERINDOPRIL ARGININE 10,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: SERVIER LABORATORIES SOUTH AFRICA (PTY) LTD

Manufacturer: LES LABORATOIRES SERVIER INDUSTRIE, GIDY,
FRANCE
SERVIER INDUSTRIES LTD, ARKLOW, IRELAND

Packer: LES LABORATOIRES SERVIER INDUSTRIE, GIDY,
FRANCE
SERVIER INDUSTRIES LTD, ARKLOW, IRELAND
TECHNIKON LABORATORIES, ROBERTVILLE, RSA

Laboratory: FPRC: LES LABORATOIRES SERVIER INDUSTRIE, GIDY,
FRANCE
SERVIER INDUSTRIES LTD, ARKLOW, IRELAND
INSPECTORATE M&L, ORMONDE, JOHANNESBURG
FPRR: SERVIER LABORATORIES, RIVONIA, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A39/20.2.8/0249

Name of medicine: ASPEN ZIDOVUDINE 100 MG

Dosage form: CAPSULE

Active ingredients: EACH CAPSULE CONTAINS:
ZIDOVUDINE 100,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: PHARMACARE LIMITED

Manufacturer: PHARMACARE LTD, KORSTEN, PORT ELIZABETH
ASPEN PHARMACARE, WILSONIA, EAST LONDON

Packer: PHARMACARE LTD, KORSTEN, PORT ELIZABETH
ASPEN PHARMACARE, WILSONIA, EAST LONDON

Laboratory: FPRC: ASPEN PHARMACARE, WILSONIA, EAST LONDON
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
RESEARCH INSTITUTE FOR PHARMACEUTICAL
SERVICES, UNIVERSITY, POTCHEFSTROOM
FPRC/FPRR: PHARMACARE LTD, KORSTEN, PORT ELIZABETH

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A39/20.2.8/0250

Name of medicine: ASPEN ZIDOVUDINE 250 MG

Dosage form: CAPSULE

Active ingredients: EACH CAPSULE CONTAINS:
ZIDOVUDINE 250,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: PHARMACARE LIMITED

Manufacturer: PHARMACARE LTD, KORSTEN, PORT ELIZABETH
ASPEN PHARMACARE, WILSONIA, EAST LONDON

Packer: PHARMACARE LTD, KORSTEN, PORT ELIZABETH
ASPEN PHARMACARE, WILSONIA, EAST LONDO

Laboratory: FPRC: ASPEN PHARMACARE, WILSONIA, EAST LONDO
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA
RESEARCH INSTITUTE FOR PHARMACEUTICAL
SERVICES, UNIVERSITY, POTCHEFSTROOM
FPRC/FPRR: PHARMACARE LTD, KORSTEN, PORT ELIZABETH

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A39/11.4.3/0255

Name of medicine: APEX-RANTIDINE 150 MG

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
RANTIDINE HYDROCHLORIDE EQUIVALENT TO
RANTIDINE 150,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: CAMOX PHARMACEUTICALS (PTY) LTD

Manufacturer: MEDREICH STERILAB LTD, VIRGONAGAR,
BANGALORE, INDIA

Packer: MEDREICH STERILAB LTD, VIRGONAGAR,
BANGALORE, INDIA

Laboratory: FPRC: MEDREICH STERILAB LTD, VIRGONAGAR,
BANGALORE, INDIA
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
INSTITUTE FOR PHARMACEUTICAL SERVICES,
BARDENE, BOKSBURG, RSA
INSPECTORATE M&L, ORMONDE, JOHANNESBURG
FPRR: CAMOX PHARMACEUTICALS, ROSEBANK, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number:	A39/11.4.3/0256
Name of medicine:	APEX-RANITIDINE 300 MG
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RANITIDINE HYDROCHLORIDE EQUIVALENT TO RANITIDINE 300,0 MG
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CAMOX PHARMACEUTICALS (PTY) LTD
Manufacturer:	MEDREICH STERILAB LTD, VIRGONAGAR, BANGALORE, INDIA
Packer:	MEDREICH STERILAB LTD, VIRGONAGAR, BANGALORE, INDIA
Laboratory: FPRC:	MEDREICH STERILAB LTD, VIRGONAGAR, BANGALORE, INDIA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES, BARDENE, BOKSBURG, RSA INSPECTORATE M&L, ORMONDE, JOHANNESBURG
FPRR:	CAMOX PHARMACEUTICALS, ROSEBANK, RSA
Shelf-life:	24 months
Date of registration:	25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number:	A39/11.4.3/0276
Name of medicine:	CAMOX-RANITIDINE 150 MG
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RANITIDINE HYDROCHLORIDE EQUIVALENT TO RANITIDINE 150,0 MG
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CAMOX PHARMACEUTICALS (PTY) LTD
Manufacturer:	MEDREICH STERILAB LTD, VIRGONAGAR, BANGALORE, INDIA
Packer:	MEDREICH STERILAB LTD, VIRGONAGAR, BANGALORE, INDIA
Laboratory:	FPRC: MEDREICH STERILAB LTD, VIRGONAGAR, BANGALORE, INDIA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES, BARDENE, BOKSBURG, RSA INSPECTORATE M&L, ORMONDE, JOHANNESBURG FPRR: CAMOX PHARMACEUTICALS, ROSEBANK, RSA
Shelf-life:	24 months
Date of registration:	25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number:	A39/11.4.3/0277
Name of medicine:	CAMOX-RANITIDINE 300 MG
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RANITIDINE HYDROCHLORIDE EQUIVALENT TO RANITIDINE 300,0 MG
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CAMOX PHARMACEUTICALS (PTY) LTD
Manufacturer:	MEDREICH STERILAB LTD, VIRGONAGAR, BANGALORE, INDIA
Packer:	MEDREICH STERILAB LTD, VIRGONAGAR, BANGALORE, INDIA
Laboratory:	FPRC: MEDREICH STERILAB LTD, VIRGONAGAR, BANGALORE, INDIA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES, BARDENE, BOKSBURG, RSA INSPECTORATE M&L, ORMONDE, JOHANNESBURG FPRR: CAMOX PHARMACEUTICALS, ROSEBANK, RSA
Shelf-life:	24 months
Date of registration:	25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A39/20.1.1/0292

Name of medicine: SANDOZ CLARITHROMYCIN 125 P

Dosage form: SUSPENSION

Active ingredients: EACH 5,0 ml SUSPENSION CONTAINS:
CLARITHROMYCIN 125,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: SANDOZ (PTY) LTD

Manufacturer: LEK d.d., LJUBLJANA, SLOVENIA
KERN PHARMA S.A., VENUS, TERRASSA, SPAIN

Packer: KERN PHARMA S.A., VENUS, TERRASSA, SPAIN
NOVARTIS, SPARTAN, KEMPTON PARK, RSA

Laboratory: FPRC: KERN PHARMA S.A., VENUS, TERRASSA, SPAIN
FPRC/FPRR: NOVARTIS, SPARTAN, KEMPTON PARK, RSA
FPRR: SANDOZ, SPARTAN, KEMPTON PARK, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A39/20.1.1/0293

Name of medicine: SANDOZ CLARITHROMYCIN 250 P

Dosage form: SUSPENSION

Active ingredients: EACH 5,0 ml SUSPENSION CONTAINS:
CLARITHROMYCIN 250,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: SANDOZ (PTY) LTD

Manufacturer: LEK d.d., LJUBLJANA, SLOVENIA
KERN PHARMA S.A., VENUS, TERRASSA, SPAIN

Packer: KERN PHARMA S.A., VENUS, TERRASSA, SPAIN
NOVARTIS, SPARTAN, KEMPTON PARK, RSA

Laboratory: FPRC: KERN PHARMA S.A., VENUS, TERRASSA, SPAIN
FPRC/FPRR: NOVARTIS, SPARTAN, KEMPTON PARK, RSA
FPRR: SANDOZ, SPARTAN, KEMPTON PARK, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number:	A39/7.1.3/0304
Name of medicine:	APEX – RAMIPRIL 1,25 MG
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: RAMIPRIL 1,25 MG
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CAMOX PHARMACEUTICALS (PTY) LTD
Manufacturer:	IPCA LABORATORIES LTD, DADRA & NAGAR HAVELI, INDIA
Packer:	IPCA LABORATORIES LTD, DADRA & NAGAR HAVELI, INDIA
Laboratory:	FPRC: IPCA LABORATORIES LTD, DADRA & NAGAR HAVELI, INDIA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA, RSA INSPECTORATE M&L, ORMONDE, JOHANNESBURG INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, RSA FPRR: CAMOX PHARMACEUTICALS, ROSEBANK, RSA
Shelf-life:	24 months
Date of registration:	25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A39/7.1.3/0305

Name of medicine: APEX – RAMIPRIL 2,5 MG

Dosage form: CAPSULE

Active ingredients: EACH CAPSULE CONTAINS:
RAMIPRIL 2,5 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: CAMOX PHARMACEUTICALS (PTY) LTD

Manufacturer: IPCA LABORATORIES LTD, DADRA &
NAGAR HAVELI, INDIA

Packer: IPCA LABORATORIES LTD, DADRA &
NAGAR HAVELI, INDIA

Laboratory: FPRC: IPCA LABORATORIES LTD, DADRA &
NAGAR HAVELI, INDIA
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
INSPECTORATE M&L, ORMONDE, JOHANNESBURG
INSTITUTE FOR PHARMACEUTICAL SERVICES,
SILVERTONDALE, RSA
FPRR: CAMOX PHARMACEUTICALS, ROSEBANK, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number:	A39/7.1.3/0306
Name of medicine:	APEX – RAMIPRIL 5 MG
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: RAMIPRIL 5,0 MG
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CAMOX PHARMACEUTICALS (PTY) LTD
Manufacturer:	IPCA LABORATORIES LTD, DADRA & NAGAR HAVELI, INDIA
Packer:	IPCA LABORATORIES LTD, DADRA & NAGAR HAVELI, INDIA
Laboratory:	FPRC: IPCA LABORATORIES LTD, DADRA & NAGAR HAVELI, INDIA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA, RSA INSPECTORATE M&L, ORMONDE, JOHANNESBURG INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, RSA FPRR: CAMOX PHARMACEUTICALS, ROSEBANK, RSA
Shelf-life:	24 months
Date of registration:	25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A39/7.1.3/0307

Name of medicine: APEX – RAMIPRIL 10 MG

Dosage form: CAPSULE

Active ingredients: EACH CAPSULE CONTAINS:
RAMIPRIL 10,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: CAMOX PHARMACEUTICALS (PTY) LTD

Manufacturer: IPCA LABORATORIES LTD, DADRA &
NAGAR HAVELI, INDIA

Packer: IPCA LABORATORIES LTD, DADRA &
NAGAR HAVELI, INDIA

Laboratory: FPRC: IPCA LABORATORIES LTD, DADRA &
NAGAR HAVELI, INDIA
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
INSPECTORATE M&L, ORMONDE, JOHANNESBURG
INSTITUTE FOR PHARMACEUTICAL SERVICES,
SILVERTONDALE, RSA
FPRR: CAMOX PHARMACEUTICALS, ROSEBANK, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number:	A39/2.2/0348
Name of medicine:	MERCK-ZOLPIDEM
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ZOLPIDEM TARTRATE 10,0 MG
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	MERCK GENERICS RSA (PTY) LTD
Manufacturer:	MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON, RSA MERCK FARMA y QUIMICA SA, BARCELONA, SPAIN
Packer:	MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON, RSA MERCK FARMA y QUIMICA SA, BARCELONA, SPAIN GERARD LABORATORIES, DUBLIN, IRELAND GENERICS UK LTD, POTTERS BAR, HERTFORDSHIRE, UK
Laboratory:	FPRC: MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON, RSA MERCK FARMA y QUIMICA SA, BARCELONA, SPAIN GERARD LABORATORIES, DUBLIN, IRELAND GENERICS UK LTD, POTTERS BAR, HERTFORDSHIRE, UK RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY, POTCHEFSTROOM, RSA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA, RSA FPRR: MERCK GENERICS RSA, MODDERFONTEIN, RSA
Shelf-life:	24 months
Date of registration:	25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A39/5.10/0413

Name of medicine: ODARON 4 MG TABLETS

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
ONDANSETRON HYDROCHLORIDE EQUIVALENT
TO ONDANSETRON 4,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: PHARMAPLAN (PTY) LTD

Manufacturer: M J PHARMACEUTICALS LTD, GUJARAT, INDIA

Packer: M J PHARMACEUTICALS LTD, GUJARAT, INDIA

Laboratory: FPRC: M J PHARMACEUTICALS LTD, GUJARAT, INDIA
CONSULTING CHEMICAL LABORATORIES, STAR
STREET, BOKSBURG, RSA
FPRR: PHARMAPLAN, MIDRAND, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number:	A39/5.10/0414
Name of medicine:	ODARON 8 MG TABLETS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ONDANSETRON HYDROCHLORIDE EQUIVALENT TO ONDANSETRON 8,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMAPLAN (PTY) LTD
Manufacturer:	M J PHARMACEUTICALS LTD, GUJARAT, INDIA
Packer:	M J PHARMACEUTICALS LTD, GUJARAT, INDIA
Laboratory: FPRC:	M J PHARMACEUTICALS LTD, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA
FPRR:	PHARMAPLAN, MIDRAND, RSA
Shelf-life:	24 months
Date of registration:	25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A39/7.1.3/0441

Name of medicine: MERCK-FOSINOPRIL 10

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
FOSINOPRIL SODIUM 10,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: MERCK GENERICS RSA (PTY) LTD

Manufacturer: GENPHARM PHARMACEUTICALS INC, ONTARIO,
CANADA

Packer: GENPHARM PHARMACEUTICALS INC, ONTARIO,
CANADA
GENERICS [UK] LTD, POTTERS BAR,
HERTFORDSHIRE, U.K.
GERARD LABORATORIES, DUBLIN, IRELAND

Laboratory: FPRC: GENPHARM PHARMACEUTICALS INC, ONTARIO,
CANADA
GENERICS [UK] LTD, POTTERS BAR,
HERTFORDSHIRE, U.K.
GERARD LABORATORIES, DUBLIN, IRELAND
MERCK PHARMACEUTICALS MANUFACTURING,
WADEVILLE, GERMISTON, RSA
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, UNIVERSITY, POTCHEFSTROOM
FPRR: MERCK GENERICS, MODDERFONTEIN, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number:	A39/5.10/0448
Name of medicine:	ODARON 4 MG INJECTION
Dosage form:	INJECTION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: ONDASETRON HYDROCHLORIDE EQUIVALENT TO ONDANSETRON 2,0 MG
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMAPLAN (PTY) LTD
Manufacturer:	M J PHARMACEUTICALS LTD, PANCHMAHAL, GUJARAT, INDIA
Packer:	M J PHARMACEUTICALS LTD, PANCHMAHAL, GUJARAT, INDIA
Laboratory:	FPRC: M J PHARMACEUTICALS LTD, PANCHMAHAL, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA FPRR: PHARMAPLAN, MIDRAND, RSA
Shelf-life:	24 months
Date of registration:	25 NOVEMBER 2005

MRF 15

Registration number: A39/5.10/0509

Name of medicine: MERCK-ONDANSETRON 4 MG/2 ML

Dosage form: INJECTION

Active ingredients: EACH 2,0 ml AMPOULE CONTAINS:
ONDANSETRON HYDROCHLORIDE
EQUIVALENT TO ONDANSETRON 4,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: MERCK GENERICS RSA (PTY) LTD

Manufacturer: PHARMATHEN PHARMACEUTICAL INDUSTRY,
ATHENS, GREECE

Packer: PHARMATHEN PHARMACEUTICAL INDUSTRY,
ATHENS, GREECE
GERARD LABORATORIES, DUBLIN, IRELAND
GENERICS, POTTERS BAR, HERTFORDSHIRE,
UK
MERCK PHARMACEUTICAL MANUFACTURING,
WADEVILLE, GERMISTON, RSA

Laboratory: PHARMATHEN PHARMACEUTICAL INDUSTRY,
ATHENS, GREECE
GERARD LABORATORIES, DUBLIN, IRELAND
GENERICS, POTTERS BAR, HERTFORDSHIRE,
UK
MERCK PHARMACEUTICAL MANUFACTURING,
WADEVILLE, GERMISTON, RSA
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, UNIVERSITY, POTCHEFSTROOM
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
MERCK GENERICS, MODDERFONTEIN, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15

Registration number: A39/5.10/0510

Name of medicine: MERCK-ONDANSETRON 8 MG/4 ML

Dosage form: INJECTION

Active ingredients: EACH 4,0 ml AMPOULE CONTAINS:
ONDANSETRON HYDROCHLORIDE
EQUIVALENT TO ONDANSETRON 8,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: MERCK GENERICS RSA (PTY) LTD

Manufacturer: PHARMATHEN PHARMACEUTICAL INDUSTRY,
ATHENS, GREECE

Packer: PHARMATHEN PHARMACEUTICAL INDUSTRY,
ATHENS, GREECE
GERARD LABORATORIES, DUBLIN, IRELAND
GENERICS, POTTERS BAR, HERTFORDSHIRE,
UK
MERCK PHARMACEUTICAL MANUFACTURING,
WADEVILLE, GERMISTON, RSA

Laboratory: FPRC: PHARMATHEN PHARMACEUTICAL INDUSTRY,
ATHENS, GREECE
GERARD LABORATORIES, DUBLIN, IRELAND
GENERICS, POTTERS BAR, HERTFORDSHIRE,
UK
MERCK PHARMACEUTICAL MANUFACTURING,
WADEVILLE, GERMISTON, RSA
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, UNIVERSITY, POTCHEFSTROOM
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
FPRR: MERCK GENERICS, MODDERFONTEIN, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A40/21.2/0006

Name of medicine: DIAGLIM 1

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
GLIMEPIRIDE 1,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: SANDOZ (PTY) LTD

Manufacturer: NOVARTIS S.A., SPARTAN, KEMPTON PARK, RSA

Packer: NOVARTIS S.A., SPARTAN, KEMPTON PARK, RSA

Laboratory: FPRC: SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
ANALYTICON, KEMPTON PARK, RSA
FPRC/FPRR: NOVARTIS S.A., SPARTAN, KEMPTON PARK, RSA
FPRR: SANDOZ, SPARTAN, KEMPTON PARK, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A40/21.2/0007

Name of medicine: DIAGLIM 2

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
GLIMEPIRIDE 2,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: SANDOZ (PTY) LTD

Manufacturer: NOVARTIS S.A., SPARTAN, KEMPTON PARK, RSA

Packer: NOVARTIS S.A., SPARTAN, KEMPTON PARK, RSA

Laboratory: FPRC: SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
ANALYTICON, KEMPTON PARK, RSA
FPRC/FPRR: NOVARTIS S.A., SPARTAN, KEMPTON PARK, RSA
FPRR: SANDOZ, SPARTAN, KEMPTON PARK

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A40/21.2/0008

Name of medicine: DIAGLIM 4

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
GLIMEPIRIDE 4,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: SANDOZ (PTY) LTD

Manufacturer: NOVARTIS S.A., SPARTAN, KEMPTON PARK, RSA

Packer: NOVARTIS S.A., SPARTAN, KEMPTON PARK, RSA

Laboratory: FPRC: SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
ANALYTICON, KEMPTON PARK, RSA
FPRC/FPRR: NOVARTIS S.A., SPARTAN, KEMPTON PARK, RSA
FPRR: SANDOZ, SPARTAN, KEMPTON PARK

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A40/2.7/0255

Name of medicine: BARRS PARACETAMOL SYRUP

Dosage form: SYRUP

Active ingredients: EACH 5,0 ml SYRUP CONTAINS:
PARACETAMOL 120,0 ml

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: BARRS PHARMACEUTICAL INDUSTRIES CC

Manufacturer: BARRS PHARMACEUTICAL INDUSTRIES,
OBSERVATORY, CAPE TOWN

Packer: BARRS PHARMACEUTICAL INDUSTRIES,
OBSERVATORY, CAPE TOWN

Laboratory: FPRC/FPRR: BARRS PHARMACEUTICAL INDUSTRIES,
OBSERVATORY, CAPE TOWN
FPRC: SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

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