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THE GOVERNMENT PRINTING WORKS

PUBLICATIONS DIVISION

NB: The Publications Division of the Government Printing Works will be relocating to its new premises within the:

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

For enquiries and information:

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GENERAL NOTICE ALGEMENE KENNISGEWING

NOTICE 1692 OF 2005

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 1692 VAN 2005**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 Goeie 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 Goeie 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 goedgevind deur die Raad.
6. Die eerste twee produksielotte moet ten volle gevalideer 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. Bemaking 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 kopieë van die protokolle vir die toets van die massalot en die vullot sowel as ses kopieë van die vrystellingstifikaat 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: 01/2.6/9

Name of medicine: BANAMINE

Dosage form: INJECTION

Active ingredients: EACH 1,0 ml SOLUTION CONTAINS:
FLUNIXIN MEGLUMINE EQUIVALENT TO
FLUNIXIN 50,0 mg

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

Applicant: SCHERING-PLOUGH (PTY) LTD

Manufacturer: SCHERING-PLOUGH SANTE ANIMALE, SEGRE,
FRANCE

Packer: SCHERING-PLOUGH SANTE ANIMALE, SEGRE,
FRANCE
SCHERING-PLOUGH, ISANDO, GAUTENG, RSA

Laboratory: SCHERING-PLOUGH SANTE ANIMALE, SEGRE,
FRANCE
SCHERING-PLOUGH, ISANDO, GAUTENG, RSA

Shelf-life: 24 months

Date of registration: 29 JULY 2005

MRF 15 (MBR 15)

Registration number: 31/10.2.2/0470

Name of medicine: VENTA

Dosage form: INJECTION

Active ingredients: EACH 1,0 ml AMPOULE CONTAINS:
SALBUTAMOL SULPHATE EQUIVALENT TO
SALBUTAMOL 0,5 mg

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

Applicant: COMPUPHARM (PTY) LTD

Manufacturer: PHARMA-Q, INDUSTRIA, JOHANNESBURG, RSA

Packer: PHARMA-Q, INDUSTRIA, JOHANNESBURG, RSA

Laboratory: PHARMA-Q, INDUSTRIA, JOHANNESBURG, RSA
COMPUPHARM, LYNNWOOD, PRETORIA, RSA

Shelf-life: 24 months

Date of registration: 29 JULY 2005

MRF 15 (MBR 15)

Registration number: 36/1.2/0046

Name of medicine: FLUVOHEXAL 50

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
FLUVOXAMINE MALEATE 50,0 mg

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

Applicant: HEXAL PHARMA (SA) (PTY) LTD

Manufacturer: SALUTAS PHARMA GmbH, BARLEBEN, GERMANY

Packer: SALUTAS PHARMA GmbH, BARLEBEN, GERMANY
DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, RSA

Laboratory: SALUTAS PHARMA GmbH, BARLEBEN, GERMANY
CONSULTING CHEMICAL LABORATORIES, STAR
STREET, BOKSBURG, RSA
ANALYTICON, KEMPTON PARK, RSA
HEXAL PHARMA, WESTMEAD, RSA

Shelf-life: 36 months

Date of registration: 29 JULY 2005

MRF 15 (MBR 15)

Registration number: 36/1.2/0047

Name of medicine: FLUVOHEXAL 100

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
FLUVOXAMINE MALEATE 100,0 mg

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

Applicant: HEXAL PHARMA (SA) (PTY) LTD

Manufacturer: SALUTAS PHARMA GmbH, BARLEBEN, GERMANY

Packer: SALUTAS PHARMA GmbH, BARLEBEN, GERMANY
DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, RSA

Laboratory: SALUTAS PHARMA GmbH, BARLEBEN, GERMANY
CONSULTING CHEMICAL LABORATORIES, STAR
STREET, BOKSBURG, RSA
ANALYTICON, KEMPTON PARK, RSA
HEXAL PHARMA, WESTMEAD, RSA

Shelf-life: 36 months

Date of registration: 29 JULY 2005

MRF 15 (MBR 15)

Registration number: 36/7.5/0213

Name of medicine: LIPIDEX 10

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
SIMVASTATIN 10,0 mg

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

Applicant: HEXAL PHARMA (SA) (PTY) LTD

Manufacturer: GEA FARMACEUTISK FABRIK, FREDERIKSBERG,
DENMARK

Packer: GEA FARMACEUTISK FABRIK, FREDERIKSBERG,
DENMARK
DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, RSA
PHARMA-Q, INDUSTRIA WEST, GAUTENG, RSA

Laboratory: GEA FARMACEUTISK FABRIK, FREDERIKSBERG,
DENMARK
CONSULTING CHEMICAL LABORATORIES, STAR
STREET, BOKSBURG, RSA
ANALYTICON, KEMPTON PARK, RSA
PHARMA-Q, INDUSTRIA WEST, GAUTENG, RSA
HEXAL PHARMA, WESTMEAD, RSA

Shelf-life: 24 months

Date of registration: 29 JULY 2005

MRF 15 (MBR 15)

Registration number: 36/7.5/0214

Name of medicine: LIPIDEX 20

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
SIMVASTATIN 20,0 mg

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

Applicant: HEXAL PHARMA (SA) (PTY) LTD

Manufacturer: GEA FARMACEUTISK FABRIK, FREDERIKSBERG,
DENMARK

Packer: GEA FARMACEUTISK FABRIK, FREDERIKSBERG,
DENMARK
DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, RSA
PHARMA-Q, INDUSTRIA WEST, GAUTENG, RSA

Laboratory: GEA FARMACEUTISK FABRIK, FREDERIKSBERG,
DENMARK
CONSULTING CHEMICAL LABORATORIES, STAR
STREET, BOKSBURG, RSA
ANALYTICON, KEMPTON PARK, RSA
PHARMA-Q, INDUSTRIA WEST, GAUTENG, RSA
HEXAL PHARMA, WESTMEAD, RSA

Shelf-life: 24 months

Date of registration: 29 JULY 2005

MRF 15 (MBR 15)

Registration number: 36/7.5/0215

Name of medicine: HEXAL-SIMVASTATIN 10

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
SIMVASTATIN 10,0 mg

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

Applicant: HEXAL PHARMA (SA) (PTY) LTD

Manufacturer: GEA FARMACEUTISK FABRIK, FREDERIKSBERG,
DENMARK

Packer: GEA FARMACEUTISK FABRIK, FREDERIKSBERG,
DENMARK
DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, RSA
PHARMA-Q, INDUSTRIA WEST, GAUTENG, RSA

Laboratory: GEA FARMACEUTISK FABRIK, FREDERIKSBERG,
DENMARK
CONSULTING CHEMICAL LABORATORIES, STAR
STREET, BOKSBURG, RSA
ANALYTICON, KEMPTON PARK, RSA
PHARMA-Q, INDUSTRIA WEST, GAUTENG, RSA
HEXAL PHARMA, WESTMEAD, RSA

Shelf-life: 24 months

Date of registration: 29 JULY 2005

MRF 15 (MBR 15)

Registration number: 36/7.5/0216

Name of medicine: HEXAL-SIMVASTATIN 20

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
SIMVASTATIN 20,0 mg

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

Applicant: HEXAL PHARMA (SA) (PTY) LTD

Manufacturer: GEA FARMACEUTISK FABRIK, FREDERIKSBERG,
DENMARK

Packer: GEA FARMACEUTISK FABRIK, FREDERIKSBERG,
DENMARK
DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, RSA
PHARMA-Q, INDUSTRIA WEST, GAUTENG, RSA

Laboratory: GEA FARMACEUTISK FABRIK, FREDERIKSBERG,
DENMARK
CONSULTING CHEMICAL LABORATORIES, STAR
STREET, BOKSBURG, RSA
ANALYTICON, KEMPTON PARK, RSA
PHARMA-Q, INDUSTRIA WEST, GAUTENG, RSA
HEXAL PHARMA, WESTMEAD, RSA

Shelf-life: 24 months

Date of registration: 29 JULY 2005

MRF 15 (MBR 15)

Registration number: 36/7.5/0280

Name of medicine: VALPHARMA BEZAFIBRATE SR

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
BEZAFIBRATE 400,0 mg

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

Applicant: COMPUPHARM (PTY) LTD

Manufacturer: EUDERMA S.p.A., RIMINI, ITALY

Packer: WRAPSA MANUFACTURING & PACKAGING,
CENTURION, RSA

Laboratory: EUDERMA S.p.A., RIMINI, ITALY
SEDEK AGRIKEM, KAMEELDRIFT, PRETORIA, RSA
INSTITUTE FOR PHARMACEUTICAL SERVICES,
SILVERTONDALE, RSA
COMPUPHARM, LYNNWOOD, PRETORIA, RSA

Shelf-life: 24 months

Date of registration: 29 JULY 2005

MRF 15 (MBR 15)

Registration number: 36/21.8.2/0454

Name of medicine: CYPRENE-35 ED

Dosage form: TABLET

Active ingredients: EACH PACK CONTAINS:
21 HORMONAL TABLETS CONTAINING:
CYPROTERONE ACETATE 2,0 mg
ETHINYLESTRADIOL 0,035 mg
7 PLACEBO TABLETS

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

Applicant: PHARMAPLAN (PTY) LTD

Manufacturer: DOUGLAS PHARMACEUTICALS LTD, LINCOLN,
AUCKLAND, NEW ZEALAND

Packer: DOUGLAS PHARMACEUTICALS LTD, LINCOLN,
AUCKLAND, NEW ZEALAND
DOUGLAS PHARMACEUTICALS, NADI, FIJI

Laboratory: DOUGLAS PHARMACEUTICALS LTD, LINCOLN,
AUCKLAND, NEW ZEALAND
CONSULTING CHEMICAL LABORATORIES, STAR
STREET, BOKSBURG, RSA
PHARMAPLAN, MIDRAND, RSA

Shelf-life: 24 months

Date of registration: 29 JULY 2005

MRF 15 (MBR 15)

Registration number: 36/7.1/0480

Name of medicine: CPL ALLIANCE AMLODIPINE 5 MG

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
AMLODIPINE BESYLATE EQUIVALENT TO
AMLODIPINE 5,0 mg

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

Applicant: ALLIANCE PHARMA (PTY) LTD

Manufacturer: CADILA PHARMACEUTICALS, AHMEDABAD,
GUJARAT, INDIA

Packer: CADILA PHARMACEUTICALS, AHMEDABAD,
GUJARAT, INDIA

Laboratory: CADILA PHARMACEUTICALS, AHMEDABAD,
GUJARAT, INDIA
ANALYTICON, KEMPTON PARK, GAUTENG, RSA
ALLIANCE PHARMA, VILLAGE MAIN,
JOHANNESBURG, RSA

Shelf-life: 24 months

Date of registration: 29 JULY 2005

MRF 15 (MBR 15)

Registration number: 36/7.1/0481

Name of medicine: CPL ALLIANCE AMLODIPINE 10 MG

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
AMLODIPINE BESYLATE EQUIVALENT TO
AMLODIPINE 10,0 mg

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

Applicant: ALLIANCE PHARMA (PTY) LTD

Manufacturer: CADILA PHARMACEUTICALS, AHMEDABAD,
GUJARAT, INDIA

Packer: CADILA PHARMACEUTICALS, AHMEDABAD,
GUJARAT, INDIA

Laboratory: CADILA PHARMACEUTICALS, AHMEDABAD,
GUJARAT, INDIA
ANALYTICON, KEMPTON PARK, GAUTENG, RSA
ALLIANCE PHARMA, VILLAGE MAIN,
JOHANNESBURG, RSA

Shelf-life: 24 months

Date of registration: 29 JULY 2005

MRF 15 (MBR 15)

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| Registration number: | 36/20.2.3/0494 |
| Name of medicine: | KOXIRIP TABLETS |
| Dosage form: | TABLET |
| Active ingredients: | EACH TABLET CONTAINS: RIFAMPICIN 120,0 mg ISONIAZID 60,0 mg PYRAZINAMIDE 300,0 mg ETHAMBUTOL 200,0 mg |
| Conditions of registration: | 1, 2, 3, 4, 5, 6, 7 |
| Applicant: | INNOVATA PHARMACEUTICALS CC |
| Manufacturer: | PLETHICO PHARMACEUTICALS LTD, MADHYA PRADESH, INDIA |
| Packer: | PLETHICO PHARMACEUTICALS LTD, MADHYA PRADESH, INDIA |
| Laboratory: | PLETHICO PHARMACEUTICALS LTD, MADHYA PRADESH, INDIA WRAPSA, CENTURION, RSA INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY, POTCHEFSTROOM SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA, RSA INSPECTORATE M&L, ORMONDE, JOHANNESBURG, RSA KHULULEKANI LABORATORY SERVICES, MIDRAND, RSA INNOVATA PHARMACEUTICALS, ROSHNEE, VEREENIGING |
| Shelf-life: | 36 months |
| Date of registration: | 29 JULY 2005 |

MRF 15 (MBR 15)

Registration number: 36/20.2.3/0496

Name of medicine: MONTONEX - 150 TABLETS

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
RIFAMPICIN 150,0 mg
ISONIAZID 100,0 mg

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

Applicant: INNOVATA PHARMACEUTICALS CC

Manufacturer: PLETHICO PHARMACEUTICALS LTD,
MADHYA PRADESH, INDIA

Packer: PLETHICO PHARMACEUTICALS LTD,
MADHYA PRADESH, INDIA

Laboratory: PLETHICO PHARMACEUTICALS LTD,
MADHYA PRADESH, INDIA
WRAPSA, CENTURION, RSA
INSTITUTE FOR INDUSTRIAL PHARMACY,
UNIVERSITY, POTCHEFSTROOM
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
INSPECTORATE M&L, ORMONDE,
JOHANNESBURG, RSA
KHULULEKANI LABORATORY SERVICES,
MIDRAND, RSA
INNOVATA PHARMACEUTICALS, ROSHNEE,
VEREENIGING, RSA

Shelf-life: 36 months

Date of registration: 29 JULY 2005

MRF 15 (MBR 15)

Registration number: 36/20.2.3/0497

Name of medicine: MONTONEX - 300 TABLETS

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
RIFAMPICIN 300,0 mg
ISONIAZID 150,0 mg

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

Applicant: INNOVATA PHARMACEUTICALS CC

Manufacturer: PLETHICO PHARMACEUTICALS LTD,
MADHYA PRADESH, INDIA

Packer: PLETHICO PHARMACEUTICALS LTD,
MADHYA PRADESH, INDIA

Laboratory: PLETHICO PHARMACEUTICALS LTD,
MADHYA PRADESH, INDIA
WRAPSA, CENTURION, RSA
INSTITUTE FOR INDUSTRIAL PHARMACY,
UNIVERSITY, POTCHEFSTROOM
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
INSPECTORATE M&L, ORMONDE,
JOHANNESBURG, RSA
KHULULEKANI LABORATORY SERVICES,
MIDRAND, RSA
INNOVATA PHARMACEUTICALS, ROSHNEE,
VEREENIGING, RSA

Shelf-life: 36 months

Date of registration: 29 JULY 2005

MRF 15

| | |
|-----------------------------|---|
| Registration number: | 36/22.1/0508 |
| Name of medicine: | CERNEVIT |
| Dosage form: | INJECTION |
| Active ingredients: | EACH VIAL CONTAINS: RETINOL PALMITATE 3 500 iu CHOLECALCIFEROL 220 iu DL-ALPHA-TOCOPHEROL 10,20 mg ASCORBIC ACID 125,00 mg COCARBOXYLASE TETRAHYDRATE 5,80 mg RIBOFLAVIN SODIUM PHOSPHATE 5,67 mg PYRIDOXINE HYDROCHLORIDE 5,50 mg CYANOCOBALAMIN 0,006 mg FOLIC ACID 0,414 mg DEXPANTHENOL 16,150 mg D-BIOTIN 0,069 mg NICOTINAMIDE 46,00 mg |
| Conditions of registration: | 1, 2, 3, 4, 5, 6, 7 |
| Applicant: | ADCOCK INGRAM CRITICAL CARE (PTY) LTD |
| Manufacturer: | CLINTEC PARENTERAL S.A., MONTARGIS CEDEX, FRANCE AQUITAINE PHARM INTERNATIONAL, IDRON, FRANCE |
| Packer: | LABORATOIRE LIPHA, SEMOY, FRANCE AQUITAINE PHARM INTERNATIONAL, IDRON, FRANCE LABORATOIRE LIPHA, SEMOY, FRANCE ADCOCK INGRAM CRITICAL CARE, AEROTON, JOHANNESBURG |
| Laboratory: | CLINTEC PARENTERAL S.A., MONTARGIS CEDEX, FRANCE AQUITAINE PHARM INTERNATIONAL, IDRON, FRANCE LABORATOIRE LIPHA, SEMOY, FRANCE ADCOCK INGRAM CRITICAL CARE, AEROTON, JOHANNESBURG |
| Shelf-life: | 36 months |
| Date of registration: | 29 JULY 2005 |

MRF 15 (MBR 15)

Registration number: 37/15.1/0082

Name of medicine: TOBRABACT

Dosage form: DROPS

Active ingredients: EACH 1,0 ml SOLUTION CONTAINS:
TOBRAMYCIN 3,0 mg

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

Applicant: ADCOCK INGRAM LIMITED

Manufacturer: LABORATOIRES CIBA VISION FAURE, ANNONAY,
FRANCE

Packer: LABORATOIRES CIBA VISION FAURE, ANNONAY,
FRANCE

Laboratory: LABORATOIRES CIBA VISION FAURE, ANNONAY,
FRANCE
ADCOCK INGRAM HEALTHCARE, WADEVILLE,
GERMISTON, RSA
ADCOCK INGRAM HEALTHCARE,
OLIFANTSFONTEIN, CLAYVILLE, RSA
ADCOCK INGRAM LTD, BRYANSTON, RSA

Shelf-life: 24 months

Date of registration: 29 JULY 2005

MRF 15 (MBR 15)

Registration number: 37/2.8/0097

Name of medicine: AUSTELL - CO - CODAMOL

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
PARACETAMOL 500,0 mg
CODEINE PHOSPHATE 8,0 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
AUSTELL LABORATORIES, SAXONWOLD, RSA

Shelf-life: 24 months

Date of registration: 29 JULY 2005

MRF 15 (MBR 15)

Registration number: 37/1.2/0101

Name of medicine: FLUVOXAMINE-HEXAL 50

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
FLUVOXAMINE MALEATE 50,0 mg

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

Applicant: HEXAL PHARMA (SA) (PTY) LTD

Manufacturer: SALUTAS PHARMA GmbH, BARLEBEN, GERMANY

Packer: SALUTAS PHARMA GmbH, BARLEBEN, GERMANY
DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, JOHANNESBURG

Laboratory: SALUTAS PHARMA GmbH, BARLEBEN, GERMANY
CONSULTING CHEMICAL LABORATORIES,
STAR STREET, BOKSBURG
ANALYTICON, KEMPTON PARK, RSA
HEXAL PHARMA, WESTMEAD, RSA

Shelf-life: 24 months

Date of registration: 29 JULY 2005

MRF 15 (MBR 15)

Registration number: 37/1.2/0102

Name of medicine: FLUVOXAMINE-HEXAL 100

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
FLUVOXAMINE MALEATE 100,0 mg

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

Applicant: HEXAL PHARMA (SA) (PTY) LTD

Manufacturer: SALUTAS PHARMA GmbH, BARLEBEN, GERMANY

Packer: SALUTAS PHARMA GmbH, BARLEBEN, GERMANY
DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, JOHANNESBURG

Laboratory: SALUTAS PHARMA GmbH, BARLEBEN, GERMANY
CONSULTING CHEMICAL LABORATORIES,
STAR STREET, BOKSBURG
ANALYTICON, KEMPTON PARK, RSA
HEXAL PHARMA, WESTMEAD, RSA

Shelf-life: 24 months

Date of registration: 29 JULY 2005

MRF 15 (MBR 15)

Registration number: 37/2.6.5/0142

Name of medicine: RISPERDAL CONSTA 25 MG

Dosage form: INJECTION

Active ingredients: EACH VIAL CONTAINS:
RISPERIDONE 25,0 mg

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

Applicant: JANSSEN PHARMACEUTICA (PTY) LTD

Manufacturer: ALKERMES CONTROLLED THERAPEUTICS,
WILMINGTON, OHIO, USA

Packer: ALKERMES CONTROLLED THERAPEUTICS,
WILMINGTON, OHIO, USA
CILAG AG, SCHAFFHAUSSEN, SWITZERLAND

Laboratory: ALKERMES CONTROLLED THERAPEUTICS,
WILMINGTON, OHIO, USA
JANSSEN PHARMACEUTICA, BEERSE, BELGIUM
JANSSEN PHARMACEUTICA, HALFWAY HOUSE,
RSA

Shelf-life: 36 months

Date of registration: 29 JULY 2005

MRF 15 (MBR 15)

Registration number: 37/2.6.5/0143

Name of medicine: RISPERDAL CONSTA 37,5 MG

Dosage form: INJECTION

Active ingredients: EACH VIAL CONTAINS:
RISPERIDONE 37,5 mg

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

Applicant: JANSSEN PHARMACEUTICA (PTY) LTD

Manufacturer: ALKERMES CONTROLLED THERAPEUTICS,
WILMINGTON, OHIO, USA

Packer: ALKERMES CONTROLLED THERAPEUTICS,
WILMINGTON, OHIO, USA
CILAG AG, SCHAFFHAUSSEN, SWITZERLAND

Laboratory: ALKERMES CONTROLLED THERAPEUTICS,
WILMINGTON, OHIO, USA
JANSSEN PHARMACEUTICA, BEERSE, BELGIUM
JANSSEN PHARMACEUTICA, HALFWAY HOUSE,
RSA

Shelf-life: 36 months

Date of registration: 29 JULY 2005

MRF 15 (MBR 15)

Registration number: 37/2.6.5/0144

Name of medicine: RISPERDAL CONSTA 50 MG

Dosage form: INJECTION

Active ingredients: EACH VIAL CONTAINS:
RISPERIDONE 50,0 mg

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

Applicant: JANSSEN PHARMACEUTICA (PTY) LTD

Manufacturer: ALKERMES CONTROLLED THERAPEUTICS,
WILMINGTON, OHIO, USA

Packer: ALKERMES CONTROLLED THERAPEUTICS,
WILMINGTON, OHIO, USA
CILAG AG, SCHAFFHAUSSEN, SWITZERLAND

Laboratory: ALKERMES CONTROLLED THERAPEUTICS,
WILMINGTON, OHIO, USA
JANSSEN PHARMACEUTICA, BEERSE, BELGIUM
JANSSEN PHARMACEUTICA, HALFWAY HOUSE,
RSA

Shelf-life: 36 months

Date of registration: 29 JULY 2005

MRF 15 (MBR 15)

Registration number: 37/21.5.1/0146

Name of medicine: CIPLA-FLUTICASONE 50 DP-CAPS

Dosage form: CAPSULE

Active ingredients: EACH CAPSULE CONTAINS:
FLUTICASONE PROPIONATE 50,0 ug

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: 29 JULY 2005

MRF 15 (MBR 15)

Registration number: 37/21.5.1/0147

Name of medicine: CIPLA-FLUTICASONE 100 DP-CAPS

Dosage form: CAPSULE

Active ingredients: EACH CAPSULE CONTAINS:
FLUTICASONE PROPIONATE 100,0 ug

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: 29 JULY 2005

MRF 15 (MBR 15)

Registration number: 37/21.5.1/0148

Name of medicine: CIPLA-FLUTICASONE 250 DP-CAPS

Dosage form: CAPSULE

Active ingredients: EACH CAPSULE CONTAINS:
FLUTICASONE PROPIONATE 250,0 ug

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: 29 JULY 2005

MRF 15 (MBR 15)

Registration number: 37/3.1/0234

Name of medicine: ADCO-MELOXICAM 7,5

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
MELOXICAM 7,5 mg

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

Applicant: ADCOCK INGRAM LIMITED

Manufacturer: ADCOCK INGRAM HEALTHCARE, WADEVILLE,
GERMISTON, RSA
NOVARTIS S.A., SPARTAN, KEMPTON PARK

Packer: ADCOCK INGRAM HEALTHCARE, WADEVILLE,
GERMISTON, RSA
NOVARTIS S.A., SPARTAN, KEMPTON PARK

Laboratory: ADCOCK INGRAM HEALTHCARE, WADEVILLE,
GERMISTON, RSA
NOVARTIS S.A., SPARTAN, KEMPTON PARK
ADCOCK INGRAM LTD, BRYANSTON, RSA

Shelf-life: 24 months

Date of registration: 29 JULY 2005

MRF 15 (MBR 15)

Registration number: 37/3.1/0235

Name of medicine: ADCO-MELOXICAM 15

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
MELOXICAM 15,0 mg

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

Applicant: ADCOCK INGRAM LIMITED

Manufacturer: ADCOCK INGRAM HEALTHCARE, WADEVILLE,
GERMISTON, RSA
NOVARTIS S.A., SPARTAN, KEMPTON PARK

Packer: ADCOCK INGRAM HEALTHCARE, WADEVILLE,
GERMISTON, RSA
NOVARTIS S.A., SPARTAN, KEMPTON PARK

Laboratory: ADCOCK INGRAM HEALTHCARE, WADEVILLE,
GERMISTON, RSA
NOVARTIS S.A., SPARTAN, KEMPTON PARK
ADCOCK INGRAM LTD, BRYANSTON, RSA

Shelf-life: 24 months

Date of registration: 29 JULY 2005

MRF 15 (MBR 15)

Registration number: 37/3.1/0255

Name of medicine: M-CAM 7,5 MG

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
MELOXICAM 7,5 mg

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

Applicant: UNICHEM SA (PTY) LTD

Manufacturer: UNICHEM LABORATORIES LTD, BARDEZ, GOA,
INDIA

Packer: UNICHEM LABORATORIES LTD, BARDEZ, GOA,
INDIA

Laboratory: UNICHEM LABORATORIES LTD, BARDEZ, GOA,
INDIA
INSTITUTE FOR INDUSTRIAL PHARMACY,
UNIVERSITY, POTCHEFSTROOM, RSA
UNICHEM, VAN DER HOFFPARK,
POTCHEFSTROOM

Shelf-life: 24 months

Date of registration: 29 JULY 2005

MRF 15 (MBR 15)

Registration number: 37/3.1/0267

Name of medicine: ZYDUS-MELOXICAM 7,5 MG

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
MELOXICAM 7,5 mg

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

Applicant: ZYDUS HEALTHCARE SA (PTY) LTD

Manufacturer: ZYDUS CADILA HEALTHCARE LTD, AHMEDABAD,
INDIA

Packer: ZYDUS CADILA HEALTHCARE LTD, AHMEDABAD,
INDIA

Laboratory: ZYDUS CADILA HEALTHCARE LTD, AHMEDABAD,
INDIA
INSTITUTE FOR PHARMACEUTICAL & CHEMICAL
SERVICES, BARDENE, BOKSBURG, RSA
INSTITUTE FOR INDUSTRIAL PHARMACY,
UNIVERSITY, POTCHEFSTROOM, RSA
ZYDUS HEALTHCARE, POTCHEFSTROOM, RSA

Shelf-life: 24 months

Date of registration: 29 JULY 2005

MRF 15 (MBR 15)

Registration number: 37/3.1/0268

Name of medicine: ZYDUS-MELOXICAM 15 MG

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
MELOXICAM 15,0 mg

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

Applicant: ZYDUS HEALTHCARE SA (PTY) LTD

Manufacturer: ZYDUS CADILA HEALTHCARE LTD, AHMEDABAD,
INDIA

Packer: ZYDUS CADILA HEALTHCARE LTD, AHMEDABAD,
INDIA

Laboratory: ZYDUS CADILA HEALTHCARE LTD, AHMEDABAD,
INDIA
INSTITUTE FOR PHARMACEUTICAL & CHEMICAL
SERVICES, BARDENE, BOKSBURG, RSA
INSTITUTE FOR INDUSTRIAL PHARMACY,
UNIVERSITY, POTCHEFSTROOM, RSA
ZYDUS HEALTHCARE, POTCHEFSTROOM, RSA

Shelf-life: 24 months

Date of registration: 29 JULY 2005

MRF 15 (MBR 15)

Registration number: 37/3.1/0269

Name of medicine: M-CAM 15 MG

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
MELOXICAM 15,0 mg

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

Applicant: UNICHEM SA (PTY) LTD

Manufacturer: UNICHEM LABORATORIES LTD, BARDEZ, GOA,
INDIA

Packer: UNICHEM LABORATORIES LTD, BARDEZ, GOA,
INDIA

Laboratory: UNICHEM LABORATORIES LTD, BARDEZ, GOA,
INDIA
INSTITUTE FOR INDUSTRIAL PHARMACY,
UNIVERSITY, POTCHEFSTROOM, RSA
UNICHEM, VAN DER HOFFPARK,
POTCHEFSTROOM

Shelf-life: 24 months

Date of registration: 29 JULY 2005

MRF 15 (MBR 15)

Registration number: 37/21.8.2/0297

Name of medicine: NOVOFEM

Dosage form: TABLET

Active ingredients: EACH WHITE TABLET CONTAINS:
ESTRADIOL HEMIHYDRATE EQUIVALENT TO
ESTRADIOL 1,0 mg
NORETHISTERONE ACETATE 1,0 mg
EACH RED TABLET CONTAINS:
ESTRADIOL HEMIHYDRATE EQUIVALENT TO
ESTRADIOL 1,0 mg

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

Applicant: NOVO NORDISK (PTY) LTD

Manufacturer: NOVO NORDISK A/S, MAALOEV, DENMARK
NOVO NORDISK A/S, BAGSVAERD, DENMARK

Packer: NOVO NORDISK A/S, MAALOEV, DENMARK

Laboratory: NOVO NORDISK A/S, MAALOEV, DENMARK
NOVO NORDISK A/S, BAGSVAERD, DENMARK
NOVO NORDISK, JOHANNESBURG, RSA

Shelf-life: 48 months

Date of registration: 29 JULY 2005

MRF 15 (MBR 15)

Registration number: 37/7.5/0335

Name of medicine: ASPEN SIMVASTATIN 10 MG

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
SIMVASTATIN 10,0 mg

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

Applicant: PHARMACARE LIMITED

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

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

Laboratory: GENPHARM PHARMACEUTICALS, TOBICOKE,
ONTARIO, CANADA
LENNON LTD, KORSTEN, PORT ELIZABETH
PHARMACARE LTD, KORSTEN, PORT ELIZABETH

Shelf-life: 24 months

Date of registration: 29 JULY 2005

MRF 15 (MBR 15)

Registration number: 37/7.5/0336

Name of medicine: ASPEN SIMVASTATIN 20 MG

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
SIMVASTATIN 20,0 mg

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

Applicant: PHARMACARE LIMITED

Manufacturer: GENPHARM PHARMACEUTICALS, TOBICOKE,
ONTARIO, CANADA

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

Laboratory: GENPHARM PHARMACEUTICALS, TOBICOKE,
ONTARIO, CANADA
LENNON LTD, KORSTEN, PORT ELIZABETH
PHARMACARE LTD, KORSTEN, PORT ELIZABETH

Shelf-life: 24 months

Date of registration: 29 JULY 2005

MRF 15 (MBR 15)

Registration number: 37/7.5/0337

Name of medicine: ASPEN SIMVASTATIN 40 MG

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
SIMVASTATIN 40,0 mg

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

Applicant: PHARMACARE LIMITED

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

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

Laboratory: GENPHARM PHARMACEUTICALS, TOBICOKE,
ONTARIO, CANADA
LENNON LTD, KORSTEN, PORT ELIZABETH
PHARMACARE LTD, KORSTEN, PORT ELIZABETH

Shelf-life: 24 months

Date of registration: 29 JULY 2005

MRF 15 (MBR 15)

Registration number: 37/26/0466

Name of medicine: EMTHEXATE 2,5 MG TABLETS

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
METHOTREXATE DISODIUM EQUIVALENT TO
METHOTREXATE 2,5 mg

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

Applicant: PHARMACHEMIE (PTY) LTD

Manufacturer: PHARMACHEMIE BV, HAARLEM,
THE NETHERLANDS

Packer: PHARMACHEMIE BV, HAARLEM,
THE NETHERLANDS
DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, JOHANNESBURG, RSA

Laboratory: PHARMACHEMIE BV, HAARLEM,
THE NETHERLANDS
CONSULTING CHEMICAL LABORATORIES, STAR
STREET, BOKSBURG, RSA
PHARMACHEMIE, MIDRAND, RSA

Shelf-life: 24 months

Date of registration: 29 JULY 2005

MRF 15 (MBR 15)

Registration number: 37/26/0487

Name of medicine: LARACIT 100 MG

Dosage form: INJECTION

Active ingredients: EACH VIAL CONTAINS:
CYTARABINE 100,0 mg

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

Applicant: KEY ONCOLOGICS (PTY) LTD

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

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

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

Shelf-life: 24 months

Date of registration: 29 JULY 2005

MRF 15 (MBR 15)

Registration number: 37/26/0488

Name of medicine: LARACIT 500 MG

Dosage form: INJECTION

Active ingredients: EACH VIAL CONTAINS:
CYTARABINE 500,0 mg

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

Applicant: KEY ONCOLOGICS (PTY) LTD

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

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

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

Shelf-life: 24 months

Date of registration: 29 JULY 2005

MRF 15 (MBR 15)

Registration number: 37/21.5.1/0529

Name of medicine: ALVESCO 40

Dosage form: INHALATION

Active ingredients: EACH 1,0 ml SOLUTION CONTAINS:
CICLESONIDE 1,0 mg

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

Applicant: ALTANA MADAUS (PTY) LTD

Manufacturer: 3M HEALTH CARE LIMITED, LOUGHBOROUGH,
LEICESTERSHIRE, UK

Packer: 3M HEALTH CARE LIMITED, LOUGHBOROUGH,
LEICESTERSHIRE, UK
ALTANA PHARMA AG, SINGEN, GERMANY

Laboratory: 3M HEALTH CARE LIMITED, LOUGHBOROUGH,
LEICESTERSHIRE, UK
ALTANA PHARMA AG, SINGEN, GERMANY
ALTANA MADAUS, MIDRAND, RSA

Shelf-life: 24 months

Date of registration: 29 JULY 2005

MRF 15 (MBR 15)

Registration number: 37/21.5.1/0530

Name of medicine: ALVESCO 80

Dosage form: INHALATION

Active ingredients: EACH 1,0 ml SOLUTION CONTAINS:
CICLESONIDE 2,0 mg

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

Applicant: ALTANA MADAUS (PTY) LTD

Manufacturer: 3M HEALTH CARE LIMITED, LOUGHBOROUGH,
LEICESTERSHIRE, UK

Packer: 3M HEALTH CARE LIMITED, LOUGHBOROUGH,
LEICESTERSHIRE, UK
ALTANA PHARMA AG, SINGEN, GERMANY

Laboratory: 3M HEALTH CARE LIMITED, LOUGHBOROUGH,
LEICESTERSHIRE, UK
ALTANA PHARMA AG, SINGEN, GERMANY
ALTANA MADAUS, MIDRAND, RSA

Shelf-life: 24 months

Date of registration: 29 JULY 2005

MRF 15 (MBR 15)

Registration number: 37/21.5.1/0531

Name of medicine: ALVESCO 160

Dosage form: INHALATION

Active ingredients: EACH 1,0 ml SOLUTION CONTAINS:
CICLESONIDE 4,0 mg

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

Applicant: ALTANA MADAUS (PTY) LTD

Manufacturer: 3M HEALTH CARE LIMITED, LOUGHBOROUGH,
LEICESTERSHIRE, UK

Packer: 3M HEALTH CARE LIMITED, LOUGHBOROUGH,
LEICESTERSHIRE, UK
ALTANA PHARMA AG, SINGEN, GERMANY

Laboratory: 3M HEALTH CARE LIMITED, LOUGHBOROUGH,
LEICESTERSHIRE, UK
ALTANA PHARMA AG, SINGEN, GERMANY
ALTANA MADAUS, MIDRAND, RSA

Shelf-life: 24 months

Date of registration: 29 JULY 2005

MRF 15 (MBR 15)

Registration number: 37/2.9/0596

Name of medicine: DOMADOL

Dosage form: CAPSULE

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

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

Applicant: UNICHEM SA (PTY) LTD

Manufacturer: UNICHEM LABORATORIES LTD, BARDEZ, GOA,
INDIA

Packer: UNICHEM LABORATORIES LTD, BARDEZ, GOA,
INDIA

Laboratory: UNICHEM LABORATORIES LTD, BARDEZ, GOA,
INDIA
INSTITUTE FOR INDUSTRIAL PHARMACY,
POTCHEFSTROOM, RSA
INSTITUTE FOR PHARMACEUTICAL & CHEMICAL
SERVICES, BARDENE, BOKSBURG, RSA
CONSULTING CHEMICAL LABORATORIES,
STAR STREET, BOKSBURG, RSA
UNICHEM, VAN DER HOFFPARK,
POTCHEFSTROOM

Shelf-life: 24 months

Date of registration: 29 JULY 2005

MRF 15 (MBR 15)

| | |
|-----------------------------|--|
| Registration number: | 37/1.2/0612 |
| Name of medicine: | TRIZAC 20 MG |
| Dosage form: | CAPSULE |
| Active ingredients: | EACH CAPSULE CONTAINS: FLUOXETINE HYDROCHLORIDE EQUIVALENT TO FLUOXETINE 20,0 mg |
| Conditions of registration: | 1, 2, 3, 4, 5, 6, 7 |
| Applicant: | UNICHEM SA (PTY) LTD |
| Manufacturer: | UNICHEM LABORATORIES LTD, BARDEZ, GOA, INDIA |
| Packer: | UNICHEM LABORATORIES LTD, BARDEZ, GOA, INDIA |
| Laboratory: | UNICHEM LABORATORIES LTD, BARDEZ, GOA, INDIA INSTITUTE FOR INDUSTRIAL CHEMISTRY, UNIVERSITY, POTCHEFSTROOM, RSA CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA INSTITUTE FOR PHARMACEUTICAL & CHEMICAL SERVICES, BARDENE, BOKSBURG, RSA UNICHEM, VAN DER HOFF PARK, POTCHEFSTROOM |
| Shelf-life: | 36 months |
| Date of registration: | 29 JULY 2005 |

MRF 15 (MBR 15)

Registration number: 38/1.2/0034

Name of medicine: RAN-CITALOPRAM 10 TABLETS

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
CITALOPRAM HYDROBROMIDE EQUIVALENT TO
CITALOPRAM 10,0 mg

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

Applicant: RANBAXY (SA) (PTY) LTD

Manufacturer: RANBAXY LABORATORIES LTD, DEWAS, INDIA

Packer: RANBAXY LABORATORIES LTD, DEWAS, INDIA

Laboratory: RANBAXY LABORATORIES LTD, DEWAS, INDIA
KHULULEKANI LABORATORY SERVICES,
MIDRAND, RSA
CENTRE FOR QUALITY ASSURANCE, UNIVERSITY,
POTCHEFSTROOM, RSA
RANBAXY, CENTURION, RSA

Shelf-life: 24 months

Date of registration: 29 JULY 2005

MRF 15 (MBR 15)

Registration number: 38/1.2/0035

Name of medicine: SERAN 40 TABLETS

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
CITALOPRAM HYDROBROMIDE EQUIVALENT TO
CITALOPRAM 40,0 mg

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

Applicant: RANBAXY (SA) (PTY) LTD

Manufacturer: RANBAXY LABORATORIES LTD, DEWAS, INDIA

Packer: RANBAXY LABORATORIES LTD, DEWAS, INDIA

Laboratory: RANBAXY LABORATORIES LTD, DEWAS, INDIA
KHULULEKANI LABORATORY SERVICES,
MIDRAND, RSA
CENTRE FOR QUALITY ASSURANCE, UNIVERSITY,
POTCHEFSTROOM, RSA
RANBAXY, CENTURION, RSA

Shelf-life: 24 months

Date of registration: 29 JULY 2005

MRF 15 (MBR 15)

Registration number: 38/1.2/0036

Name of medicine: RAN-CITALOPRAM 40 TABLETS

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
CITALOPRAM HYDROBROMIDE EQUIVALENT TO
CITALOPRAM 40,0 mg

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

Applicant: RANBAXY (SA) (PTY) LTD

Manufacturer: RANBAXY LABORATORIES LTD, DEWAS, INDIA

Packer: RANBAXY LABORATORIES LTD, DEWAS, INDIA

Laboratory: RANBAXY LABORATORIES LTD, DEWAS, INDIA
KHULULEKANI LABORATORY SERVICES,
MIDRAND, RSA
CENTRE FOR QUALITY ASSURANCE, UNIVERSITY,
POTCHEFSTROOM, RSA
RANBAXY, CENTURION, RSA

Shelf-life: 24 months

Date of registration: 29 JULY 2005

MRF 15 (MBR 15)

Registration number: 38/1.2/0037

Name of medicine: SERAN 20 TABLETS

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
CITALOPRAM HYDROBROMIDE EQUIVALENT TO
CITALOPRAM 20,0 mg

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

Applicant: RANBAXY (SA) (PTY) LTD

Manufacturer: RANBAXY LABORATORIES LTD, DEWAS, INDIA

Packer: RANBAXY LABORATORIES LTD, DEWAS, INDIA

Laboratory: RANBAXY LABORATORIES LTD, DEWAS, INDIA
KHULULEKANI LABORATORY SERVICES,
MIDRAND, RSA
CENTRE FOR QUALITY ASSURANCE, UNIVERSITY,
POTCHEFSTROOM, RSA
RANBAXY, CENTURION, RSA

Shelf-life: 24 months

Date of registration: 29 JULY 2005

MRF 15 (MBR 15)

Registration number: 38/1.2/0038

Name of medicine: SERAN 10 TABLETS

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
CITALOPRAM HYDROBROMIDE EQUIVALENT TO
CITALOPRAM 10,0 mg

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

Applicant: RANBAXY (SA) (PTY) LTD

Manufacturer: RANBAXY LABORATORIES LTD, DEWAS, INDIA

Packer: RANBAXY LABORATORIES LTD, DEWAS, INDIA

Laboratory: RANBAXY LABORATORIES LTD, DEWAS, INDIA
KHULULEKANI LABORATORY SERVICES,
MIDRAND, RSA
CENTRE FOR QUALITY ASSURANCE, UNIVERSITY,
POTCHEFSTROOM, RSA
RANBAXY, CENTURION, RSA

Shelf-life: 24 months

Date of registration: 29 JULY 2005

MRF 15 (MBR 15)

Registration number: 38/1.2/0039

Name of medicine: RAN-CITALOPRAM 20 TABLETS

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
CITALOPRAM HYDROBROMIDE EQUIVALENT TO
CITALOPRAM 20,0 mg

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

Applicant: RANBAXY (SA) (PTY) LTD

Manufacturer: RANBAXY LABORATORIES LTD, DEWAS, INDIA

Packer: RANBAXY LABORATORIES LTD, DEWAS, INDIA

Laboratory: RANBAXY LABORATORIES LTD, DEWAS, INDIA
KHULULEKANI LABORATORY SERVICES,
MIDRAND, RSA
CENTRE FOR QUALITY ASSURANCE, UNIVERSITY,
POTCHEFSTROOM, RSA
RANBAXY, CENTURION, RSA

Shelf-life: 24 months

Date of registration: 29 JULY 2005

MRF 15 (MBR 15)

Registration number: 38/11.4.3/0060

Name of medicine: ALTANA-PANTOPRAZOLE 40

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
PANTOPRAZOLE SODIUM SESQUIHYDRATE
EQUIVALENT TO PANTOPRAZOLE 40,0 mg

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

Applicant: ALTANA MADAUS (PTY) LTD

Manufacturer: ALTANA PHARMA AG, ORANIENBURG, GERMANY

Packer: ALTANA PHARMA AG, ORANIENBURG, GERMANY

Laboratory: ALTANA PHARMA AG, ORANIENBURG, GERMANY
ALTANA MADAUS, MIDRAND, RSA

Shelf-life: 36 months

Date of registration: 29 JULY 2005

MRF 15 (MBR 15)

Registration number: 38/11.4.3/0061

Name of medicine: ALTANA-PANTOPRAZOLE 20

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
PANTOPRAZOLE SODIUM SESQUIHYDRATE
EQUIVALENT TO PANTOPRAZOLE 20,0 mg

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

Applicant: ALTANA MADAUS (PTY) LTD

Manufacturer: ALTANA PHARMA AG, ORANIENBURG, GERMANY

Packer: ALTANA PHARMA AG, ORANIENBURG, GERMANY

Laboratory: ALTANA PHARMA AG, ORANIENBURG, GERMANY
ALTANA MADAUS, MIDRAND, RSA

Shelf-life: 36 months

Date of registration: 29 JULY 2005

MRF 15 (MBR 15)

Registration number: 38/5.7.1/0083

Name of medicine: AP LORATADINE SYRUP

Dosage form: SYRUP

Active ingredients: EACH 5,0 ml SYRUP CONTAINS:
LORATADINE 5,0 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: PHARMACARE LTD, KORSTEN, PORT ELIZABETH
ASPEN PHARMACARE, WILSONIA, EAST LONDON
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, UNIVERSITY, POTCHEFSTROOM, RSA

Shelf-life: 24 months

Date of registration: 29 JULY 2005

MRF 15 (MBR 15)

Registration number: 38/5.2/0105

Name of medicine: BISOPROLOL HEXAL 5

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
BISOPROLOL FUMARATE 5,0 mg

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

Applicant: HEXAL PHARMA (SA) (PTY) LTD

Manufacturer: SALUTAS PHARMA GmbH, BARLEBEN, GERMANY

Packer: SALUTAS PHARMA GmbH, BARLEBEN, GERMANY
DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, GAUTENG, RSA
PHARMA-Q, INDUSTRIA WEST, GAUTENG, RSA

Laboratory: SALUTAS PHARMA GmbH, BARLEBEN, GERMANY
PHARMA-Q, INDUSTRIA WEST, GAUTENG, RSA
CONSULTING CHEMICAL LABORATORIES, STAR
STREET, BOKSBURG, RSA
ANALYTICON, KEMPTON PARK, RSA
HEXAL PHARMA, WESTMEAD, RSA

Shelf-life: 24 months

Date of registration: 29 JULY 2005

MRF 15 (MBR 15)

Registration number: 38/5.2/0106

Name of medicine: BISOPROLOL HEXAL 10

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
BISOPROLOL FUMARATE 10,0 mg

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

Applicant: HEXAL PHARMA (SA) (PTY) LTD

Manufacturer: SALUTAS PHARMA GmbH, BARLEBEN, GERMANY

Packer: SALUTAS PHARMA GmbH, BARLEBEN, GERMANY
DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, GAUTENG, RSA
PHARMA-Q, INDUSTRIA WEST, GAUTENG, RSA

Laboratory: SALUTAS PHARMA GmbH, BARLEBEN, GERMANY
PHARMA-Q, INDUSTRIA WEST, GAUTENG, RSA
CONSULTING CHEMICAL LABORATORIES, STAR
STREET, BOKSBURG, RSA
ANALYTICON, KEMPTON PARK, RSA
HEXAL PHARMA, WESTMEAD, RSA

Shelf-life: 24 months

Date of registration: 29 JULY 2005

MRF 15 (MBR 15)

Registration number: 38/21.2/0206

Name of medicine: AUSTELL-GLICLAZIDE 40 MG TABLETS

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
GLICLAZIDE 40,0 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: 38/21.2/0207

Name of medicine: AUSTELL–GLICLAZIDE 80 MG TABLETS

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
GLICLAZIDE 80,0 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: 38/3.1/0242

Name of medicine: APEX-MELOXICAM 7,5 MG

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
MELOXICAM 7,5 mg

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

Applicant: CAMOX PHARMACEUTICALS (PTY) LTD

Manufacturer: FARMACEUTISCH ANALYTISCH LABORATORIUM
B.V., DUIVEN, THE NETHERLANDS

Packer: FARMACEUTISCH ANALYTISCH LABORATORIUM
B.V., DUIVEN, THE NETHERLANDS

Laboratory: FARMACEUTISCH ANALYTISCH LABORATORIUM
B.V., DUIVEN, THE NETHERLANDS
SOUTH AFRICAN BUREAU OF STANDARDS,
PRETORIA, RSA
INSTITUTE FOR PHARMACEUTICALS SERVICES,
BARDENE, BOKSBURG, RSA
INSPECTORATE M&L, ORMONDE, JOHANNESBURG
CAMOX PHARMACEUTICALS, CROWN MINES, RSA

Shelf-life: 24 months

Date of registration: 29 JULY 2005

MRF 15 (MBR 15)

Registration number: 38/3.1/0243

Name of medicine: APEX-MELOXICAM 15 MG

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
MELOXICAM 15,0 mg

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

Applicant: CAMOX PHARMACEUTICALS (PTY) LTD

Manufacturer: FARMACEUTISCH ANALYTISCH LABORATORIUM
B.V., DUIVEN, THE NETHERLANDS

Packer: FARMACEUTISCH ANALYTISCH LABORATORIUM
B.V., DUIVEN, THE NETHERLANDS

Laboratory: FARMACEUTISCH ANALYTISCH LABORATORIUM
B.V., DUIVEN, THE NETHERLANDS
SOUTH AFRICAN BUREAU OF STANDARDS,
PRETORIA, RSA
INSTITUTE FOR PHARMACEUTICALS SERVICES,
BARDENE, BOKSBURG, RSA
INSPECTORATE M&L, ORMONDE, JOHANNESBURG
CAMOX PHARMACEUTICALS, CROWN MINES, RSA

Shelf-life: 24 months

Date of registration: 29 JULY 2005

MRF 15 (MBR 15)

Registration number: 38/2.9/0274

Name of medicine: TRAMGESIC FLASHTABS

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
TRAMADOL HYDROCHLORIDE 50,0 mg

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

Applicant: ADCOCK INGRAM LIMITED

Manufacturer: ETHYPHARM INDUSTRIES, CHATEAUNEUF-EN-
THYMER AIS, FRANCE

Packer: ETHYPHARM INDUSTRIES, CHATEAUNEUF-EN-
THYMER AIS, FRANCE
ADCOCK INGRAM HEALTHCARE, WADEVILLE,
GERMISTON
ADCOCK INGRAM HEALTHCARE,
OLIFANTSFONTEIN, CLAYVILLE

Laboratory: ETHYPHARM INDUSTRIES, CHATEAUNEUF-EN-
THYMER AIS, FRANCE
ADCOCK INGRAM HEALTHCARE, WADEVILLE,
GERMISTON
ADCOCK INGRAM HEALTHCARE,
OLIFANTSFONTEIN, CLAYVILLE
ADCOCK INGRAM LTD, BRYANSTON, RSA

Shelf-life: 24 months

Date of registration: 29 JULY 2005

MRF 15 (MBR 15)

Registration number: A38/3.1/0383

Name of medicine: ASPEN DICLOFENAC

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

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

Laboratory: LENNON 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, KORSTEN, PORT ELIZABETH

Shelf-life: 24 months

Date of registration: 29 JULY 2005

MRF 15 (MBR 15)

Registration number: A38/26/0387

Name of medicine: KEMOSID 100

Dosage form: INJECTION

Active ingredients: EACH 5,0 ml SOLUTION CONTAINS:
ETOPOSIDE 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: CIPLA LTD, KURKUMBH, MAHARASHTRA, INDIA
CIPLA-MEDPRO (PTY) LTD

Shelf-life: 24 months

Date of registration: 29 JULY 2005

MRF 15 (MBR 15)

Registration number: A38/34/0440

Name of medicine: RAPAMUNE 2 MG

Dosage form: TABLET

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

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

Applicant: WYETH SOUTH AFRICA (PTY) LTD

Manufacturer: WYETH PHARMACEUTICALS Inc, ROUSES POINT,
NEW YORK, USA
WYETH PHARMACEUTICALS CO, GUAYAMA,
PUERTO RICO

Packer: WYETH PHARMACEUTICALS, NEW LANE,
HAVANT, U.K.

Laboratory: WYETH PHARMACEUTICALS Inc, ROUSES POINT,
NEW YORK, USA
WYETH PHARMACEUTICALS CO, GUAYAMA,
PUERTO RICO
WYETH PHARMACEUTICALS, NEW LANE,
HAVANT, U.K.
CONSULTING CHEMICAL LABORATORIES, STAR
STREET, BOKSBURG, RSA
WYETH, VORNA VALLEY, MIDRAND, RSA

Shelf-life: 24 months

Date of registration: 29 JULY 2005

MRF 15 (MBR 15)

Registration number: A38/7.1.3/0470

Name of medicine: RAMPREN 10 CAPSULES

Dosage form: CAPSULE

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

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

Applicant: RANBAXY (SA) (PTY) LTD

Manufacturer: RANBAXY LABORATORIES LTD, DEWAS, INDIA

Packer: RANBAXY LABORATORIES LTD, DEWAS, INDIA

Laboratory: RANBAXY LABORATORIES LTD, DEWAS, INDIA
KHULULEKANI LABORATORY SERVICES,
MIDRAND, RSA
CENTRE FOR QUALITY ASSURANCE OF
MEDICINES, UNIVERSITY, POTCHEFSTROOM, RSA
RANBAXY, CENTURION, RSA

Shelf-life: 24 months

Date of registration: 29 JULY 2005

MRF 15 (MBR 15)

Registration number: A38/7.1.3/0471

Name of medicine: RAN-RAMIPRIL 10 CAPSULES

Dosage form: CAPSULE

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

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

Applicant: RANBAXY (SA) (PTY) LTD

Manufacturer: RANBAXY LABORATORIES LTD, DEWAS, INDIA

Packer: RANBAXY LABORATORIES LTD, DEWAS, INDIA

Laboratory: RANBAXY LABORATORIES LTD, DEWAS, INDIA
KHULULEKANI LABORATORY SERVICES,
MIDRAND, RSA
CENTRE FOR QUALITY ASSURANCE OF
MEDICINES, UNIVERSITY, POTCHEFSTROOM, RSA
RANBAXY, CENTURION, RSA

Shelf-life: 24 months

Date of registration: 29 JULY 2005

MRF 15 (MBR 15)

Registration number: A38/7.5/0477

Name of medicine: AUSTELL – SIMVASTATIN 10 MG

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
SIMVASTATIN 10,0 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: A38/7.5/0478

Name of medicine: AUSTELL – SIMVASTATIN 20 MG

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
SIMVASTATIN 20,0 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: A38/7.5/0479

Name of medicine: AUSTELL – SIMVASTATIN 40 MG

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
SIMVASTATIN 40,0 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: A38/1.2/0487

Name of medicine: CIPLA-CITALOPRAM 40

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
CITALOPRAM HYDROBROMIDE EQUIVALENT TO
CITALOPRAM 40,0 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: CIPLA LTD, KURKUMBH, MAHARASHTRA, INDIA
CIPLA-MEDPRO, ROSENPARK, RSA

Shelf-life: 24 months

Date of registration: 29 JULY 2005

MRF 15 (MBR 15)

Registration number: A38/1.2/0490

Name of medicine: DEPRAMIL 40

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
CITALOPRAM HYDROBROMIDE EQUIVALENT TO
CITALOPRAM 40,0 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: CIPLA LTD, KURKUMBH, MAHARASHTRA, INDIA
CIPLA-MEDPRO, ROSENPARK, RSA

Shelf-life: 24 months

Date of registration: 29 JULY 2005

MRF 15 (MBR 15)

Registration number: A38/3.1/0495

Name of medicine: PHARMA DYNAMICS MELOXICAM 7,5

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
MELOXICAM 7,5 mg

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

Applicant: PHARMA DYNAMICS (PTY) LTD

Manufacturer: UNICHEM LABORATORIES, BATDEZ, GOA, INDIA

Packer: UNICHEM LABORATORIES, BATDEZ, GOA, INDIA
DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, RSA
TECHNIKON LABORATORIES, FLORIDA, RSA
PHARMACEUTICAL ENTERPRISES, N'DABENI, RSA

Laboratory: UNICHEM LABORATORIES, BATDEZ, GOA, INDIA
CONSULTING CHEMICAL LABORATORIES, STAR
STREET, BOKSBURG, RSA
PHARMA DYNAMICS, WESTLAKE, RSA

Shelf-life: 24 months

Date of registration: 29 JULY 2005

MRF 15 (MBR 15)

Registration number: A38/3.1/0496

Name of medicine: PHARMA DYNAMICS MELOXICAM 15

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
MELOXICAM 15,0 mg

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

Applicant: PHARMA DYNAMICS (PTY) LTD

Manufacturer: UNICHEM LABORATORIES, BATDEZ, GOA, INDIA

Packer: UNICHEM LABORATORIES, BATDEZ, GOA, INDIA
DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, RSA
TECHNIKON LABORATORIES, FLORIDA, RSA
PHARMACEUTICAL ENTERPRISES, N'DABENI, RSA

Laboratory: UNICHEM LABORATORIES, BATDEZ, GOA, INDIA
CONSULTING CHEMICAL LABORATORIES, STAR
STREET, BOKSBURG, RSA
PHARMA DYNAMICS, WESTLAKE, RSA

Shelf-life: 24 months

Date of registration: 29 JULY 2005

MRF 15 (MBR 15)

Registration number: A38/3.1/0497

Name of medicine: FLEXOCAM 7,5

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
MELOXICAM 7,5 mg

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

Applicant: PHARMA DYNAMICS (PTY) LTD

Manufacturer: UNICHEM LABORATORIES, BATDEZ, GOA, INDIA

Packer: UNICHEM LABORATORIES, BATDEZ, GOA, INDIA
DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, RSA
TECHNIKON LABORATORIES, FLORIDA, RSA
PHARMACEUTICAL ENTERPRISES, N'DABENI, RSA

Laboratory: UNICHEM LABORATORIES, BATDEZ, GOA, INDIA
CONSULTING CHEMICAL LABORATORIES, STAR
STREET, BOKSBURG, RSA
PHARMA DYNAMICS, WESTLAKE, RSA

Shelf-life: 24 months

Date of registration: 29 JULY 2005

MRF 15 (MBR 15)

Registration number: A38/3.1/0498

Name of medicine: FLEXOCAM 15

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
MELOXICAM 15 mg

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

Applicant: PHARMA DYNAMICS (PTY) LTD

Manufacturer: UNICHEM LABORATORIES, BATDEZ, GOA, INDIA

Packer: UNICHEM LABORATORIES, BATDEZ, GOA, INDIA
DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, RSA
TECHNIKON LABORATORIES, FLORIDA, RSA
PHARMACEUTICAL ENTERPRISES, N'DABENI, RSA

Laboratory: UNICHEM LABORATORIES, BATDEZ, GOA, INDIA
CONSULTING CHEMICAL LABORATORIES, STAR
STREET, BOKSBURG, RSA
PHARMA DYNAMICS, WESTLAKE, RSA

Shelf-life: 24 months

Date of registration: 29 JULY 2005

MRF 15 (MBR 15)

Registration number: A38/2.8/0527

Name of medicine: MYBULEN CAPSULES

Dosage form: CAPSULE

Active ingredients: EACH CAPSULE CONTAINS:
IBUPROFEN 200,0 mg
PARACETAMOL 250,0 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

Packer: LENNON LTD, KORSTEN, PORT ELIZABETH

Laboratory: LENNON LTD, KORSTEN, PORT ELIZABETH
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, UNIVERSITY, POTCHEFSTROOM, RSA
PHARMACARE LTD, KORSTEN, PORT ELIZABETH

Shelf-life: 24 months

Date of registration: 29 JULY 2005

MRF 15 (MBR 15)

Registration number: A38/1.2/0547

Name of medicine: MERCK-CITALOPRAM 10

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
CITALOPRAM HYDROCHLORIDE EQUIVALENT TO
CITALOPRAM 10,0 mg

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

Applicant: XIXIA PHARMACEUTICALS (PTY) LTD

Manufacturer: ALPHAPHARM, CAROLE PARK, QUEENSLAND,
AUSTRALIA

Packer: ALPHAPHARM, CAROLE PARK, QUEENSLAND,
AUSTRALIA
GENERIC UK LTD, POTTERS BAR,
HERTFORDSHIRE, UK
GERARD LABORATORIES, DUBLIN, IRELAND

Laboratory: ALPHAPHARM, CAROLE PARK, QUEENSLAND,
AUSTRALIA
GENERIC UK LTD, POTTERS BAR,
HERTFORDSHIRE, UK
GERARD LABORATORIES, DUBLIN, IRELAND
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, UNIVERSITY, POTCHEFSTROOM, RSA
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
MERCK PHARMACEUTICAL MANUFACTURING,
WADEVILLE, GERMISTON
XIXIA PHARMACEUTICALS, MODDERFONTEIN,
RSA

Shelf-life: 24 months

Date of registration: 29 JULY 2005

MRF 15 (MBR 15)

| | |
|-----------------------------|---|
| Registration number: | A38/1.2/0548 |
| Name of medicine: | MERCK-CITALOPRAM 20 |
| Dosage form: | TABLET |
| Active ingredients: | EACH TABLET CONTAINS: CITALOPRAM HYDROCHLORIDE EQUIVALENT TO CITALOPRAM 20,0 mg |
| Conditions of registration: | 1, 2, 3, 4, 5, 6, 7 |
| Applicant: | XIXIA PHARMACEUTICALS (PTY) LTD |
| Manufacturer: | ALPHAPHARM, CAROLE PARK, QUEENSLAND, AUSTRALIA |
| Packer: | ALPHAPHARM, CAROLE PARK, QUEENSLAND, AUSTRALIA GENERICUS UK LTD, POTTERS BAR, HERTFORDSHIRE, UK GERARD LABORATORIES, DUBLIN, IRELAND |
| Laboratory: | ALPHAPHARM, CAROLE PARK, QUEENSLAND, AUSTRALIA GENERICUS UK LTD, POTTERS BAR, HERTFORDSHIRE, UK GERARD LABORATORIES, DUBLIN, IRELAND RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY, POTCHEFSTROOM, RSA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA, RSA MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON XIXIA PHARMACEUTICALS, MODDERFONTEIN, RSA |
| Shelf-life: | 24 months |
| Date of registration: | 29 JULY 2005 |

MRF 15 (MBR 15)

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|-----------------------------|---|
| Registration number: | A38/1.2/0549 |
| Name of medicine: | MERCK-CITALOPRAM 40 |
| Dosage form: | TABLET |
| Active ingredients: | EACH TABLET CONTAINS: CITALOPRAM HYDROCHLORIDE EQUIVALENT TO CITALOPRAM 40,0 mg |
| Conditions of registration: | 1, 2, 3, 4, 5, 6, 7 |
| Applicant: | XIXIA PHARMACEUTICALS (PTY) LTD |
| Manufacturer: | ALPHAPHARM, CAROLE PARK, QUEENSLAND, AUSTRALIA |
| Packer: | ALPHAPHARM, CAROLE PARK, QUEENSLAND, AUSTRALIA GENERIC UK LTD, POTTERS BAR, HERTFORDSHIRE, UK GERARD LABORATORIES, DUBLIN, IRELAND |
| Laboratory: | ALPHAPHARM, CAROLE PARK, QUEENSLAND, AUSTRALIA GENERIC UK LTD, POTTERS BAR, HERTFORDSHIRE, UK GERARD LABORATORIES, DUBLIN, IRELAND RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY, POTCHEFSTROOM, RSA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA, RSA MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON XIXIA PHARMACEUTICALS, MODDERFONTEIN, RSA |
| Shelf-life: | 24 months |
| Date of registration: | 29 JULY 2005 |

MRF 15 (MBR 15)

Registration number: A38/7.1.3/0600

Name of medicine: RILACE 1,25 CAPSULES

Dosage form: CAPSULE

Active ingredients: EACH CAPSULE 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
ADCOCK INGRAM HEALTHCARE,
OLIFANTSFONTEIN, CLAYVILLE

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

Shelf-life: 24 months

Date of registration: 29 JULY 2005

MRF 15 (MBR 15)

Registration number: A38/7.1.3/0601

Name of medicine: RILACE 2,5 CAPSULES

Dosage form: CAPSULE

Active ingredients: EACH CAPSULE 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
ADCOCK INGRAM HEALTHCARE,
OLIFANTSFONTEIN, CLAYVILLE

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

Shelf-life: 24 months

Date of registration: 29 JULY 2005

MRF 15 (MBR 15)

Registration number: A38/7.1.3/0602

Name of medicine: RILACE 5 CAPSULES

Dosage form: CAPSULE

Active ingredients: EACH CAPSULE CONTAINS:
RAMIPRIL 5,0 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
ADCOCK INGRAM HEALTHCARE,
OLIFANTSFONTEIN, CLAYVILLE

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

Shelf-life: 24 months

Date of registration: 29 JULY 2005

MRF 15 (MBR 15)

Registration number: A38/7.1.3/0603

Name of medicine: RILACE 10 CAPSULES

Dosage form: CAPSULE

Active ingredients: EACH CAPSULE CONTAINS:
RAMIPRIL 10,0 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
ADCOCK INGRAM HEALTHCARE,
OLIFANTSFONTEIN, CLAYVILLE

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

Shelf-life: 24 months

Date of registration: 29 JULY 2005

MRF 15 (MBR 15)

Registration number: A38/21.8.2/0615

Name of medicine: CRINONE 8 %

Dosage form: GEL

Active ingredients: EACH 1,125 g GEL CONTAINS:
PROGESTERONE 90,0 mg

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

Applicant: SERONO SOUTH AFRICA (PTY) LTD

Manufacturer: FLEET LABORATORIES LTD, BEDFORDSHIRE,
ENGLAND

Packer: MAROPACK AG, ZELL/LU, SWITZERLAND
M.Y. HEALTHCARE, BEDFORD, ENGLAND

Laboratory: CARDINAL HEALTH, BREDBURY, STOCKPORT, UK
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
SERONO SA, SANDTON, RSA

Shelf-life: 36 months

Date of registration: 29 JULY 2005

MRF 15 (MBR 15)

Registration number: A38/5.7.1/0621

Name of medicine: LORFAST

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
LORATADINE 10,0 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: CADILA PHARMACEUTICALS LTD, AHMEDABAD,
GUJARAT, INDIA
BE-TABS PHARMACEUTICALS, ROODEPOORT, RSA

Shelf-life: 24 months

Date of registration: 29 JULY 2005

MRF 15 (MBR 15)

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| Registration number: | A38/20.1.1/0630 |
| Name of medicine: | XIXIA-CLARITHROMYCIN 250 MG |
| Dosage form: | TABLET |
| Active ingredients: | EACH TABLET CONTAINS: CLARITHROMYCIN 250,0 mg |
| Conditions of registration: | 1, 2, 3, 4, 5, 6, 7 |
| Applicant: | XIXIA PHARMACEUTICALS (PTY) LTD |
| Manufacturer: | GENPHARM PHARMACEUTICALS, ETOBICOKE, ONTARIO, CANADA |
| Packer: | GENPHARM PHARMACEUTICALS, ETOBICOKE, ONTARIO, CANADA GENERICUS UK LTD, POTTERS BAR, HERTFORDSHIRE, U.K. GERARD LABORATORIES, DUBLIN, IRELAND MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON, RSA |
| Laboratory: | GENPHARM PHARMACEUTICALS, ETOBICOKE, ONTARIO, CANADA GENERICUS UK LTD, POTTERS BAR, HERTFORDSHIRE, U.K. GERARD LABORATORIES, DUBLIN, IRELAND MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY, POTCHEFSTROOM, RSA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA, RSA XIXIA PHARMACEUTICALS, MODDERFONTEIN, RSA |
| Shelf-life: | 24 months |
| Date of registration: | 29 JULY 2005 |

MRF 15 (MBR 15)

| | |
|-----------------------------|--|
| Registration number: | A38/20.1.1/0631 |
| Name of medicine: | XIXIA-CLARITHROMYCIN 500 MG |
| Dosage form: | TABLET |
| Active ingredients: | EACH TABLET CONTAINS: CLARITHROMYCIN 500,0 mg |
| Conditions of registration: | 1, 2, 3, 4, 5, 6, 7 |
| Applicant: | XIXIA PHARMACEUTICALS (PTY) LTD |
| Manufacturer: | GENPHARM PHARMACEUTICALS, ETOBICOKE, ONTARIO, CANADA |
| Packer: | GENPHARM PHARMACEUTICALS, ETOBICOKE, ONTARIO, CANADA GENERIC UK LTD, POTTERS BAR, HERTFORDSHIRE, U.K. GERARD LABORATORIES, DUBLIN, IRELAND MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON, RSA |
| Laboratory: | GENPHARM PHARMACEUTICALS, ETOBICOKE, ONTARIO, CANADA GENERIC UK LTD, POTTERS BAR, HERTFORDSHIRE, U.K. GERARD LABORATORIES, DUBLIN, IRELAND MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY, POTCHEFSTROOM, RSA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA, RSA XIXIA PHARMACEUTICALS, MODDERFONTEIN, RSA |
| Shelf-life: | 24 months |
| Date of registration: | 29 JULY 2005 |

MRF 15 (MBR 15)

Registration number: A38/20.1.1/0676

Name of medicine: BETAROXIME - 250

Dosage form: INJECTION

Active ingredients: EACH VIAL CONTAINS:
CEFUROXIME SODIUM EQUIVALENT TO
CEFUROXIME 250,0 mg

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

Applicant: BE-TABS PHARMACEUTICALS (PTY) LTD

Manufacturer: AUROBINDO PHARMA LTD, PATANCHERU
MANDAL, MEDAK DT, INDIA

Packer: AUROBINDO PHARMA LTD, PATANCHERU
MANDAL, MEDAK DT, INDIA

Laboratory: AUROBINDO PHARMA LTD, PATANCHERU
MANDAL, MEDAK DT, INDIA
BE-TABS PHARMACEUTICALS, ROODEPOORT, RSA

Shelf-life: 24 months

Date of registration: 29 JULY 2005

MRF 15 (MBR 15)

Registration number: A38/20.1.1/0677

Name of medicine: **BETAROXIME - 750**

Dosage form: INJECTION

Active ingredients: EACH VIAL CONTAINS:
CEFUROXIME SODIUM EQUIVALENT TO
CEFUROXIME 750,0 mg

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

Applicant: BE-TABS PHARMACEUTICALS (PTY) LTD

Manufacturer: AUROBINDO PHARMA LTD, PATANCHERU
MANDAL, MEDAK DT, INDIA

Packer: AUROBINDO PHARMA LTD, PATANCHERU
MANDAL, MEDAK DT, INDIA

Laboratory: AUROBINDO PHARMA LTD, PATANCHERU
MANDAL, MEDAK DT, INDIA
BE-TABS PHARMACEUTICALS, ROODEPOORT, RSA

Shelf-life: 24 months

Date of registration: 29 JULY 2005

MRF 15 (MBR 15)

Registration number: A38/34/0685

Name of medicine: CERTICAN 0,5

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
EVEROLIMUS 0,5 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 SA, SPARTAN, GAUTENG, RSA

Laboratory: NOVARTIS PHARMA STEIN AG, STEIN,
SWITZERLAND
INSPECTORATE M&L, ORMONDE,
JOHANNESBURG, RSA
NOVARTIS SA, SPARTAN, GAUTENG, RSA

Shelf-life: 30 months

Date of registration: 29 JULY 2005

MRF 15 (MBR 15)

Registration number: A38/34/0686

Name of medicine: CERTICAN 0,25

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
EVEROLIMUS 0,25 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 SA, SPARTAN, GAUTENG, RSA

Laboratory: NOVARTIS PHARMA STEIN AG, STEIN,
SWITZERLAND
INSPECTORATE M&L, ORMONDE,
JOHANNESBURG, RSA
NOVARTIS SA, SPARTAN, GAUTENG, RSA

Shelf-life: 30 months

Date of registration: 29 JULY 2005

MRF 15 (MBR 15)

Registration number: A38/34/0687

Name of medicine: CERTICAN 0,75

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
EVEROLIMUS 0,75 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 SA, SPARTAN, GAUTENG, RSA

Laboratory: NOVARTIS PHARMA STEIN AG, STEIN,
SWITZERLAND
INSPECTORATE M&L, ORMONDE,
JOHANNESBURG, RSA
NOVARTIS SA, SPARTAN, GAUTENG, RSA

Shelf-life: 30 months

Date of registration: 29 JULY 2005

MRF 15 (MBR 15)

Registration number: A38/34/0688

Name of medicine: CERTICAN 1,0

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
EVEROLIMUS 1,0 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 SA, SPARTAN, GAUTENG, RSA

Laboratory: NOVARTIS PHARMA STEIN AG, STEIN,
SWITZERLAND
INSPECTORATE M&L, ORMONDE,
JOHANNESBURG, RSA
NOVARTIS SA, SPARTAN, GAUTENG, RSA

Shelf-life: 30 months

Date of registration: 29 JULY 2005

MRF 15 (MBR 15)

Registration number: A38/34/0689

Name of medicine: CERTICAN 0,1 DISPERSIBLE TABLET

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
EVEROLIMUS 0,1 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 SA, SPARTAN, GAUTENG, RSA

Laboratory: NOVARTIS PHARMA STEIN AG, STEIN,
SWITZERLAND
INSPECTORATE M&L, ORMONDE,
JOHANNESBURG, RSA
NOVARTIS SA, SPARTAN, GAUTENG, RSA

Shelf-life: 30 months

Date of registration: 29 JULY 2005

MRF 15 (MBR 15)

Registration number: A38/34/0690

Name of medicine: CERTICAN 0,25 DISPERSIBLE TABLET

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
EVEROLIMUS 0,25 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 SA, SPARTAN, GAUTENG, RSA

Laboratory: NOVARTIS PHARMA STEIN AG, STEIN,
SWITZERLAND
INSPECTORATE M&L, ORMONDE,
JOHANNESBURG, RSA
NOVARTIS SA, SPARTAN, GAUTENG, RSA

Shelf-life: 30 months

Date of registration: 29 JULY 2005

MRF 15 (MBR 15)

Registration number: A38/20.1.1/0694

Name of medicine: CEFU – HEXAL 250

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
CEFUROXIME AXETIL EQUIVALENT TO
CEFUROXIME 250,0 mg

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

Applicant: HEXAL PHARMA (SA) (PTY) LTD

Manufacturer: PENCEF PHARMA GmbH, GOTTINGEN, GERMANY

Packer: PENCEF PHARMA GmbH, GOTTINGEN, GERMANY
DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, RSA

Laboratory: PENCEF PHARMA GmbH, GOTTINGEN, GERMANY
CONSULTING CHEMICAL LABORATORIES, STAR
STREET, BOKSBURG, RSA
ANALYTICON, KEMPTON PARK, RSA
HEXAL PHARMA, WESTMEAD, RSA

Shelf-life: 24 months

Date of registration: 29 JULY 2005

MRF 15 (MBR 15)

Registration number: A38/20.1.1/0695

Name of medicine: CEFU – HEXAL 500

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
CEFUROXIME AXETIL EQUIVALENT TO
CEFUROXIME 500,0 mg

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

Applicant: HEXAL PHARMA (SA) (PTY) LTD

Manufacturer: PENCEF PHARMA GmbH, GOTTINGEN, GERMANY

Packer: PENCEF PHARMA GmbH, GOTTINGEN, GERMANY
DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, RSA

Laboratory: PENCEF PHARMA GmbH, GOTTINGEN, GERMANY
CONSULTING CHEMICAL LABORATORIES, STAR
STREET, BOKSBURG, RSA
ANALYTICON, KEMPTON PARK, RSA
HEXAL PHARMA, WESTMEAD, RSA

Shelf-life: 24 months

Date of registration: 29 JULY 2005

MRF 15 (MBR 15)

Registration number: A39/7.1.3/0047

Name of medicine: RAN-QUINAPRIL 5

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: RANBAXY (S.A.) (PTY) LTD

Manufacturer: RANBAXY LABORATORIES LTD, DEWAS, INDIA

Packer: RANBAXY LABORATORIES LTD, DEWAS, INDIA

Laboratory: RANBAXY LABORATORIES LTD, DEWAS, INDIA
KHULULEKANI LABORATORY SERVICES,
MIDRAND, RSA
CENTRE FOR QUALITY ASSURANCE OF
MEDICINES, UNIVERSITY, POTCHEFSTROOM, RSA
RANBAXY, CENTURION, RSA

Shelf-life: 24 months

Date of registration: 29 JULY 2005

MRF 15 (MBR 15)

Registration number: A39/7.1.3/0048

Name of medicine: RAN-QUINAPRIL 10

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: RANBAXY (S.A.) (PTY) LTD

Manufacturer: RANBAXY LABORATORIES LTD, DEWAS, INDIA

Packer: RANBAXY LABORATORIES LTD, DEWAS, INDIA

Laboratory: RANBAXY LABORATORIES LTD, DEWAS, INDIA
KHULULEKANI LABORATORY SERVICES,
MIDRAND, RSA
CENTRE FOR QUALITY ASSURANCE OF
MEDICINES, UNIVERSITY, POTCHEFSTROOM, RSA
RANBAXY, CENTURION, RSA

Shelf-life: 24 months

Date of registration: 29 JULY 2005

MRF 15 (MBR 15)

Registration number: A39/7.1.3/0049

Name of medicine: RAN-QUINAPRIL 20

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: RANBAXY (S.A.) (PTY) LTD

Manufacturer: RANBAXY LABORATORIES LTD, DEWAS, INDIA

Packer: RANBAXY LABORATORIES LTD, DEWAS, INDIA

Laboratory: RANBAXY LABORATORIES LTD, DEWAS, INDIA
KHULULEKANI LABORATORY SERVICES,
MIDRAND, RSA
CENTRE FOR QUALITY ASSURANCE OF
MEDICINES, UNIVERSITY, POTCHEFSTROOM, RSA
RANBAXY, CENTURION, RSA

Shelf-life: 24 months

Date of registration: 29 JULY 2005

MRF 15 (MBR 15)

Registration number: A39/7.1.3/0050

Name of medicine: RAN-QUINAPRIL 40

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: RANBAXY (S.A.) (PTY) LTD

Manufacturer: RANBAXY LABORATORIES LTD, DEWAS, INDIA

Packer: RANBAXY LABORATORIES LTD, DEWAS, INDIA

Laboratory: RANBAXY LABORATORIES LTD, DEWAS, INDIA
KHULULEKANI LABORATORY SERVICES,
MIDRAND, RSA
CENTRE FOR QUALITY ASSURANCE OF
MEDICINES, UNIVERSITY, POTCHEFSTROOM, RSA
RANBAXY, CENTURION, RSA

Shelf-life: 24 months

Date of registration: 29 JULY 2005

MRF 15 (MBR 15)

Registration number: A39/7.1.3/0051

Name of medicine: QUINPREN 5

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: RANBAXY (S.A.) (PTY) LTD

Manufacturer: RANBAXY LABORATORIES LTD, DEWAS, INDIA

Packer: RANBAXY LABORATORIES LTD, DEWAS, INDIA

Laboratory: RANBAXY LABORATORIES LTD, DEWAS, INDIA
KHULULEKANI LABORATORY SERVICES,
MIDRAND, RSA
CENTRE FOR QUALITY ASSURANCE OF
MEDICINES, UNIVERSITY, POTCHEFSTROOM, RSA
RANBAXY, CENTURION, RSA

Shelf-life: 24 months

Date of registration: 29 JULY 2005

MRF 15 (MBR 15)

Registration number: A39/7.1.3/0052

Name of medicine: QUINPREN 10

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: RANBAXY (S.A.) (PTY) LTD

Manufacturer: RANBAXY LABORATORIES LTD, DEWAS, INDIA

Packer: RANBAXY LABORATORIES LTD, DEWAS, INDIA

Laboratory: RANBAXY LABORATORIES LTD, DEWAS, INDIA
KHULULEKANI LABORATORY SERVICES,
MIDRAND, RSA
CENTRE FOR QUALITY ASSURANCE OF
MEDICINES, UNIVERSITY, POTCHEFSTROOM, RSA
RANBAXY, CENTURION, RSA

Shelf-life: 24 months

Date of registration: 29 JULY 2005

MRF 15 (MBR 15)

Registration number: A39/7.1.3/0053

Name of medicine: QUINPREN 20

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: RANBAXY (S.A.) (PTY) LTD

Manufacturer: RANBAXY LABORATORIES LTD, DEWAS, INDIA

Packer: RANBAXY LABORATORIES LTD, DEWAS, INDIA

Laboratory: RANBAXY LABORATORIES LTD, DEWAS, INDIA
KHULULEKANI LABORATORY SERVICES,
MIDRAND, RSA
CENTRE FOR QUALITY ASSURANCE OF
MEDICINES, UNIVERSITY, POTCHEFSTROOM, RSA
RANBAXY, CENTURION, RSA

Shelf-life: 24 months

Date of registration: 29 JULY 2005

MRF 15 (MBR 15)

Registration number: A39/7.1.3/0054

Name of medicine: QUINPREN 40

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: RANBAXY (S.A.) (PTY) LTD

Manufacturer: RANBAXY LABORATORIES LTD, DEWAS, INDIA

Packer: RANBAXY LABORATORIES LTD, DEWAS, INDIA

Laboratory: RANBAXY LABORATORIES LTD, DEWAS, INDIA
KHULULEKANI LABORATORY SERVICES,
MIDRAND, RSA
CENTRE FOR QUALITY ASSURANCE OF
MEDICINES, UNIVERSITY, POTCHEFSTROOM, RSA
RANBAXY, CENTURION, RSA

Shelf-life: 24 months

Date of registration: 29 JULY 2005

MRF 15 (MBR 15)

Registration number: A39/20.1.1/0055

Name of medicine: CEFTRIAZONE – SAFELINE 1 G

Dosage form: INJECTION

Active ingredients: EACH VIAL CONTAINS:
CEFTRIAZONE SODIUM EQUIVALENT TO
CEFTRIAZONE 1,0 g

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

Applicant: SAFELINE PHARMACEUTICALS (PTY) LTD

Manufacturer: DEMO S.A. PHARMACEUTICAL, ATHENS, GREECE

Packer: DEMO S.A. PHARMACEUTICAL, ATHENS, GREECE

Laboratory: DEMO S.A. PHARMACEUTICAL, ATHENS, GREECE
INSTITUTE FOR PHARMACEUTICAL SERVICES,
BARDENE, BOKSBURG, RSA
SAFELINE PHARMACEUTICALS, FLORIDA, RSA

Shelf-life: 24 months

Date of registration: 29 JULY 2005

MRF 15 (MBR 15)

Registration number: A39/20.1.1/0056

Name of medicine: CEFTRIAXONE – SAFELINE 250 MG

Dosage form: INJECTION

Active ingredients: EACH VIAL CONTAINS:
CEFTRIAXONE SODIUM EQUIVALENT TO
CEFTRIAXONE 250,0 mg

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

Applicant: SAFELINE PHARMACEUTICALS (PTY) LTD

Manufacturer: DEMO S.A. PHARMACEUTICAL, ATHENS, GREECE

Packer: DEMO S.A. PHARMACEUTICAL, ATHENS, GREECE

Laboratory: DEMO S.A. PHARMACEUTICAL, ATHENS, GREECE
INSTITUTE FOR PHARMACEUTICAL SERVICES,
BARDENE, BOKSBURG, RSA
SAFELINE PHARMACEUTICALS, FLORIDA, RSA

Shelf-life: 24 months

Date of registration: 29 JULY 2005

MRF 15 (MBR 15)

Registration number: A39/20.1.1/0057

Name of medicine: CEFTRIAXONE – SAFELINE 500 MG

Dosage form: INJECTION

Active ingredients: EACH VIAL CONTAINS:
CEFTRIAXONE SODIUM EQUIVALENT TO
CEFTRIAXONE 500,0 mg

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

Applicant: SAFELINE PHARMACEUTICALS (PTY) LTD

Manufacturer: DEMO S.A. PHARMACEUTICAL, ATHENS, GREECE

Packer: DEMO S.A. PHARMACEUTICAL, ATHENS, GREECE

Laboratory: DEMO S.A. PHARMACEUTICAL, ATHENS, GREECE
INSTITUTE FOR PHARMACEUTICAL SERVICES,
BARDENE, BOKSBURG, RSA
SAFELINE PHARMACEUTICALS, FLORIDA, RSA

Shelf-life: 24 months

Date of registration: 29 JULY 2005

MRF 15 (MBR 15)

Registration number: A39/1.2/0078

Name of medicine: PAXIL 20

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: GLAXOSMITHKLINE SOUTH AFRICA (PTY) LTD

Manufacturer: SMITHKLINE BEECHAM PHARMACEUTICALS,
CRAWLEY, SUSSEX, UK

Packer: SMITHKLINE BEECHAM PHARMACEUTICALS,
CRAWLEY, SUSSEX, UK
GLAXOSMITHKLINE, EPPING, CAPE TOWN, RSA

Laboratory: SMITHKLINE BEECHAM PHARMACEUTICALS,
CRAWLEY, SUSSEX, UK
GLAXOSMITHKLINE, EPPING, CAPE TOWN, RSA

Shelf-life: 36 months

Date of registration: 29 JULY 2005

MRF 15 (MBR 15)

Registration number: A39/1.2/0238

Name of medicine: PAXIL 30

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
PAROXETINE HYDROCHLORIDE EQUIVALENT TO
PAROXETINE 30,0 mg

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

Applicant: GLAXOSMITHKLINE SOUTH AFRICA (PTY) LTD

Manufacturer: SMITHKLINE BEECHAM PHARMACEUTICALS,
CRAWLEY, SUSSEX, UK

Packer: SMITHKLINE BEECHAM PHARMACEUTICALS,
CRAWLEY, SUSSEX, UK
GLAXOSMITHKLINE, EPPING, CAPE TOWN, RSA

Laboratory: SMITHKLINE BEECHAM PHARMACEUTICALS,
CRAWLEY, SUSSEX, UK
GLAXOSMITHKLINE, EPPING, CAPE TOWN, RSA

Shelf-life: 36 months

Date of registration: 29 JULY 2005

MRF 15 (MBR 15)

Registration number: A39/7.1.3/0239

Name of medicine: AUSTELL – 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: 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,
SILVERTONDALE, RSA
AUSTELL LABORATORIES, SAXONWOLD, RSA

Shelf-life: 24 months

Date of registration: 29 JULY 2005

MRF 15 (MBR 15)

Registration number: A39/7.1.3/0240

Name of medicine: AUSTELL – 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: 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,
SILVERTONDALE, RSA
AUSTELL LABORATORIES, SAXONWOLD, RSA

Shelf-life: 24 months

Date of registration: 29 JULY 2005

MRF 15 (MBR 15)

Registration number: A39/7.1.3/0241

Name of medicine: AUSTELL – 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: 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,
SILVERTONDALE, RSA
AUSTELL LABORATORIES, SAXONWOLD, RSA

Shelf-life: 24 months

Date of registration: 29 JULY 2005

MRF 15 (MBR 15)

Registration number: A39/7.1.3/0242

Name of medicine: AUSTELL – 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: 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,
SILVERTONDALE, RSA
AUSTELL LABORATORIES, SAXONWOLD, RSA

Shelf-life: 24 months

Date of registration: 29 JULY 2005

MRF 15 (MBR 15)

Registration number: A39/11.4.3/0322

Name of medicine: RANIT 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: BE-TABS PHARMACEUTICALS (PTY) LTD

Manufacturer: CADILA PHARMACEUTICALS LTD, AHMEDABAD,
GUJARAT, INDIA

Packer: CADILA PHARMACEUTICALS LTD, AHMEDABAD,
GUJARAT, INDIA

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

Shelf-life: 24 months

Date of registration: 29 JULY 2005

MRF 15 (MBR 15)

Registration number: A39/11.4.3/0323

Name of medicine: RANIT 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: BE-TABS PHARMACEUTICALS (PTY) LTD

Manufacturer: CADILA PHARMACEUTICALS LTD, AHMEDABAD,
GUJARAT, INDIA

Packer: CADILA PHARMACEUTICALS LTD, AHMEDABAD,
GUJARAT, INDIA

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

Shelf-life: 24 months

Date of registration: 29 JULY 2005

MRF 15 (MBR 15)

Registration number: A39/3.2/0396

Name of medicine: OSTEOBON-70

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
ALENDRONATE SODIUM EQUIVALENT TO
ALENDRONIC ACID 70,0 mg

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

Applicant: CIPLA MEDPRO (PTY) LTD

Manufacturer: CIPLA LTD (UNIT III), SALCETTE, GOA, INDIA
CIPLA LTD (UNIT IV), SALCETTE, GOA, INDIA

Packer: CIPLA LTD (UNIT III), SALCETTE, GOA, INDIA
CIPLA LTD (UNIT IV), SALCETTE, GOA, INDIA

Laboratory: CIPLA LTD (UNIT III), SALCETTE, GOA, INDIA
CIPLA LTD (UNIT IV), SALCETTE, GOA, INDIA
CIPLA MEDPRO, ROSENPARK, BELLVILLE, RSA

Shelf-life: 24 months

Date of registration: 29 JULY 2005

MRF 15 (MBR 15)

Registration number: A39/20.2.8/0446

Name of medicine: ASPEN LAMZID AND NEVIRAPINE COMBIPACK

Dosage form: TABLET

Active ingredients: EACH PACK CONTAINS:
EACH OVAL, WHITE TABLET CONTAINS:
LAMIVUDINE 150,0 mg
ZIDOVUDINE 300,0 mg
EACH ROUND, WHITE TABLET CONTAINS:
NEVIRAPINE 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: PHARMACARE LTD, KORSTEN, PORT ELIZABETH,
ASPEN PHARMACARE, WILSONIA, EAST LONDON
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, UNIVERSITY, POTCHEFSTROOM, RSA

Shelf-life: 24 months

Date of registration: 29 JULY 2005

MRF 15 (MBR 15)

Registration number: A39/5.10/0462

Name of medicine: NAUSETRON 4 MG INJECTION

Dosage form: INJECTION

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

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

Applicant: GENERIX INTERNATIONAL SA (PTY) LTD

Manufacturer: QILU PHARMACEUTICAL CO, SHANDONG, CHINA

Packer: QILU PHARMACEUTICAL CO, SHANDONG, CHINA

Laboratory: QILU PHARMACEUTICAL CO, SHANDONG, CHINA
CONSULTING CHEMICAL LABORATORIES, STAR
STREET, BOKSBURG, RSA
GENERIX INTERNATIONAL, INDUSTRIA,
CAPE TOWN, RSA

Shelf-life: 24 months

Date of registration: 20 JUNE 2005

MRF 15 (MBR 15)

Registration number: A39/5.10/0463

Name of medicine: NAUSETRON 8 MG INJECTION

Dosage form: INJECTION

Active ingredients: EACH AMPOULE CONTAINS:
ONDANSETRON HYDROCHLORIDE EQUIVALENT
TO ONDANSETRON 8,0 mg

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

Applicant: GENERIX INTERNATIONAL SA (PTY) LTD

Manufacturer: QILU PHARMACEUTICAL CO, SHANDONG, CHINA

Packer: QILU PHARMACEUTICAL CO, SHANDONG, CHINA

Laboratory: QILU PHARMACEUTICAL CO, SHANDONG, CHINA
CONSULTING CHEMICAL LABORATORIES, STAR
STREET, BOKSBURG, RSA
GENERIX INTERNATIONAL, INDUSTRIA,
CAPE TOWN, RSA

Shelf-life: 24 months

Date of registration: 20 JUNE 2005
