# Government Gazette
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## CONTENTS


| No. | | Page No. | Gazette No. |
|---|---|---|---|
| | **GENERAL NOTICE** | | |
| **Health, Department of** | | | |
| *General Notice* | | | |
| 1680 | Medicines and Related Substances Act (101/1965): Medicines Control Council: Conditions of registration of a medicine in terms of the provisions of section 15 (7) | 3 | 29393 |


## INHOUD


| No. | | Bladsy No. | Koerant No. |
|---|---|---|---|
| | **ALGEMENE KENNISGEWING** | | |
| **Gesondheid, Departement van** | | | |
| *Algemene Kennisgewing* | | | |
| 1680 | Wet op Beheer van Medisyne en Verwante Stowwe (101/1965): Medisyne-beheerraad: Voorwaardes vir die registrasie van 'n medisyne in terme van die bepalings van artikel 15 (7) | 4 | 29393 |

# GENERAL NOTICE
# ALGEMENE KENNISGEWING

## NOTICE 1680 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 1680 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 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 goedgedink 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. Bemarking 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 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

| | |
|---|---|
| Registration number: | A04/2.1/9 |
| Name of medicine: | RAPINOVET INJECTION |
| Dosage form: | INJECTION |
| Active ingredients: | EACH 1,0 ml EMULSION CONTAINS:<br>Propofol ..... 10,0 mg |
| Conditions of registration: | 1, 2, 3, 4, 5, 6 |
| Applicant: | SCHERING-PLOUGH (PTY) LTD |
| Manufacturer: | SICOR PHARMACEUTICALS INC, IRVINE, CALIFORNIA, USA |
| Packer: | SICOR PHARMACEUTICALS INC, IRVINE, CALIFORNIA, USA<br>SCHERING-PLOUGH, BRAY, WICKLOW, IRELAND<br>SCHERING-PLOUGH, ISANDO, RSA |
| Laboratory:FPRC: | SICOR PHARMACEUTICALS INC, IRVINE, CALIFORNIA, USA<br>SCHERING-PLOUGH, BRAY, WICKLOW, IRELAND<br>CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA<br>ANALYTICON, TERENURE, KEMPTON PARK, RSA |
| FPRR: | SCHERING-PLOUGH, ISANDO, RSA |
| Shelf-life: | 36 months |
| Date of registration: | 6 OCTOBER 2006 |

MRF 15

| | |
|---|---|
| Registration number: | 34/7.1.3/0137 |
| Name of medicine: | CONCOR 5 PLUS |
| Dosage form: | TABLET |
| Active ingredients: | EACH TABLET CONTAINS:<br>BISOPROLOL FUMARATE 5,0 mg<br>HYDROCHLOROTHIAZIDE 12,5 mg |
| Conditions of registration: | 1, 2, 3, 4, 5, 6 |
| Applicant: | MERCK (PTY) LTD |
| Manufacturer: | MERCK KGaA, DARMSTADT, GERMANY |
| Packer: | MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON |
| Laboratory:FPRC: | MERCK KGaA, DARMSTADT, GERMANY<br>MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON |
| FPRR: | MERCK, MODDERFONTEIN, RSA |
| Shelf-life: | 24 months |
| Date of registration: | 6 OCTOBER 2006 |

MRF 15

| | |
|---|---|
| Registration number: | 34/7.1.3/0138 |
| Name of medicine: | CONCOR 10 PLUS |
| Dosage form: | TABLET |
| Active ingredients: | EACH TABLET CONTAINS:<br>BISOPROLOL FUMARATE 10,0 mg<br>HYDROCHLOROTHIAZIDE 25,0 mg |
| Conditions of registration: | 1, 2, 3, 4, 5, 6 |
| Applicant: | MERCK (PTY) LTD |
| Manufacturer: | MERCK KGaA, DARMSTADT, GERMANY |
| Packer: | MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON |
| Laboratory:FPRC: | MERCK KGaA, DARMSTADT, GERMANY<br>MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON |
| FPRR: | MERCK, MODDERFONTEIN, RSA |
| Shelf-life: | 24 months |
| Date of registration: | 6 OCTOBER 2006 |

MRF 15

| | |
|---|---|
| Registration number: | 36/7.1.3/0383 |
| Name of medicine: | TAREG 40 |
| Dosage form: | TABLET |
| Active ingredients: | EACH TABLET CONTAINS:<br>VALSARTAN 40,0 mg |
| Conditions of registration: | 1, 2, 3, 4, 5, 6 |
| Applicant: | NOVARTIS SOUTH AFRICA (PTY) LTD |
| Manufacturer: | NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND |
| Packer: | NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND<br>KONPHARMA AG, PRATTELN, SWITZERLAND<br>ALLPACK AG, MUTTENZ, SWITZERLAND<br>NOVARTIS PHARMA GmbH, WEHR/BADEN, GERMANY<br>NOVARTIS, SPARTAN, KEMPTON PARK |
| Laboratory:FPRC: | NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND<br>INSPECTORATE M&L, ORMONDE, JOHANNESBURG |
| FPRC/FPRR: | NOVARTIS, SPARTAN, KEMPTON PARK |
| Shelf-life: | 24 months |
| Date of registration: | 6 OCTOBER 2006 |

MRF 15

| | |
|---|---|
| Registration number: | 37/7.1.3/0327 |
| Name of medicine: | BIO-ENALAPRIL MALEATE 5 mg |
| Dosage form: | TABLET |
| Active ingredients: | EACH TABLET CONTAINS:<br>ENALAPRIL MALEATE 5,0 mg |
| Conditions of registration: | 1, 2, 3, 4, 5, 6 |
| Applicant: | BIOTECH LABORATORIES (PTY) LTD |
| Manufacturer: | LEK PHARMACEUTICAL & CHEMICAL COMPANY, VEROVSKOVA, SLOVENIA |
| Packer: | LEK PHARMACEUTICAL & CHEMICAL COMPANY, VEROVSKOVA, SLOVENIA<br>DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG |
| Laboratory:FPRC: | LEK PHARMACEUTICAL & CHEMICAL COMPANY, VEROVSKOVA, SLOVENIA<br>CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA<br>INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, RSA |
| FPRR: | BIOTECH LABORATORIES, MIDRAND, RSA |
| Shelf-life: | 24 months |
| Date of registration: | 6 OCTOBER 2006 |

MRF 15

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|---|---|
| Registration number: | 37/7.1.3/0328 |
| Name of medicine: | BIO-ENALAPRIL MALEATE 10 mg |
| Dosage form: | TABLET |
| Active ingredients: | EACH TABLET CONTAINS:<br>ENALAPRIL MALEATE 10,0 mg |
| Conditions of registration: | 1, 2, 3, 4, 5, 6 |
| Applicant: | BIOTECH LABORATORIES (PTY) LTD |
| Manufacturer: | LEK PHARMACEUTICAL & CHEMICAL COMPANY, VEROVSKOVA, SLOVENIA |
| Packer: | LEK PHARMACEUTICAL & CHEMICAL COMPANY, VEROVSKOVA, SLOVENIA<br>DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG |
| Laboratory:FPRC: | LEK PHARMACEUTICAL & CHEMICAL COMPANY, VEROVSKOVA, SLOVENIA<br>CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA<br>INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, RSA |
| FPRR: | BIOTECH LABORATORIES, MIDRAND, RSA |
| Shelf-life: | 24 months |
| Date of registration: | 6 OCTOBER 2006 |

MRF 15

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|---|---|
| Registration number: | 37/7.1.3/0329 |
| Name of medicine: | BIO-ENALAPRIL MALEATE 20 mg |
| Dosage form: | TABLET |
| Active ingredients: | EACH TABLET CONTAINS:<br>ENALAPRIL MALEATE 20,0 mg |
| Conditions of registration: | 1, 2, 3, 4, 5, 6 |
| Applicant: | BIOTECH LABORATORIES (PTY) LTD |
| Manufacturer: | LEK PHARMACEUTICAL & CHEMICAL COMPANY, VEROVSKOVA, SLOVENIA |
| Packer: | LEK PHARMACEUTICAL & CHEMICAL COMPANY, VEROVSKOVA, SLOVENIA<br>DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG |
| Laboratory:FPRC: | LEK PHARMACEUTICAL & CHEMICAL COMPANY, VEROVSKOVA, SLOVENIA<br>CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA<br>INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, RSA |
| FPRR: | BIOTECH LABORATORIES, MIDRAND, RSA |
| Shelf-life: | 24 months |
| Date of registration: | 6 OCTOBER 2006 |

MRF 15

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|---|---|
| Registration number: | 37/7.1.4/0339 |
| Name of medicine: | IMOTRATE 60 mg SR |
| Dosage form: | TABLET |
| Active ingredients: | EACH TABLET CONTAINS:<br>ISOSORBIDE-5-MONONITRATE 60,0 mg |
| Conditions of registration: | 1, 2, 3, 4, 5, 6 |
| Applicant: | COMPUPHARM (PTY) LTD |
| Manufacturer: | VALPHARMA INTERNATIONAL S.p.A, PENNABILLI, ITALY<br>EUDERMA S.p.A, RIMINI, ITALY |
| Packer: | VALPHARMA INTERNATIONAL S.p.A, PENNABILLI, ITALY<br>EUDERMA S.p.A, RIMINI, ITALY |
| Laboratory:FPRC: | VALPHARMA INTERNATIONAL S.p.A, PENNABILLI, ITALY<br>EUDERMA S.p.A, RIMINI, ITALY<br>SEDEK AGRIKEM, KAMEELDRIFT, PRETORIA<br>INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE |
| FPRR: | COMPUPHARM, LYNNWOOD, PRETORIA |
| Shelf-life: | 36 months |
| Date of registration: | 6 OCTOBER 2006 |

MRF 15

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|---|---|
| Registration number: | 37/7.1.4/0340 |
| Name of medicine: | VALPHARMA ISOSORBIDE-5-MONONITRATE 60 mg SR |
| Dosage form: | TABLET |
| Active ingredients: | EACH TABLET CONTAINS:<br>ISOSORBIDE-5-MONONITRATE 60,0 mg |
| Conditions of registration: | 1, 2, 3, 4, 5, 6 |
| Applicant: | COMPUPHARM (PTY) LTD |
| Manufacturer: | VALPHARMA INTERNATIONAL S.p.A, PENNABILLI, ITALY<br>EUDERMA S.p.A, RIMINI, ITALY |
| Packer: | VALPHARMA INTERNATIONAL S.p.A, PENNABILLI, ITALY<br>EUDERMA S.p.A, RIMINI, ITALY |
| Laboratory:FPRC: | VALPHARMA INTERNATIONAL S.p.A, PENNABILLI, ITALY<br>EUDERMA S.p.A, RIMINI, ITALY<br>SEDEK AGRIKEM, KAMEELDRIFT, PRETORIA<br>INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE |
| FPRR: | COMPUPHARM, LYNNWOOD, PRETORIA |
| Shelf-life: | 36 months |
| Date of registration: | 6 OCTOBER 2006 |

MRF 15

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|---|---|
| Registration number: | 37/7.1/0378 |
| Name of medicine: | OROVASC 5 |
| Dosage form: | TABLET |
| Active ingredients: | EACH TABLET CONTAINS:<br>AMLODIPINE MALEATE EQUIVALENT TO<br>AMLODIPINE 5,0 mg |
| Conditions of registration: | 1, 2, 3, 4, 5, 6 |
| Applicant: | SANDOZ (PTY) LTD |
| Manufacturer: | NOVARTIS LTD, TONGI, GAZIPUR, BANGLADESH<br>NOVARTIS SA, SPARTAN, KEMPTON PARK |
| Packer: | NOVARTIS LTD, TONGI, GAZIPUR, BANGLADESH<br>NOVARTIS SA, SPARTAN, KEMPTON PARK |
| Laboratory:FPRC: | NOVARTIS LTD, TONGI, GAZIPUR, BANGLADESH |
| FPRC/FPRR: | NOVARTIS SA, SPARTAN, KEMPTON PARK |
| Shelf-life: | 24 months |
| Date of registration: | 6 OCTOBER 2006 |

MRF 15

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|---|---|
| Registration number: | 37/7.1/0379 |
| Name of medicine: | OROVASC 10 |
| Dosage form: | TABLET |
| Active ingredients: | EACH TABLET CONTAINS:<br>AMLODIPINE MALEATE EQUIVALENT TO<br>AMLODIPINE 10,0 mg |
| Conditions of registration: | 1, 2, 3, 4, 5, 6 |
| Applicant: | SANDOZ (PTY) LTD |
| Manufacturer: | NOVARTIS LTD, TONGI, GAZIPUR, BANGLADESH<br>NOVARTIS SA, SPARTAN, KEMPTON PARK |
| Packer: | NOVARTIS LTD, TONGI, GAZIPUR, BANGLADESH<br>NOVARTIS SA, SPARTAN, KEMPTON PARK |
| Laboratory:FPRC: | NOVARTIS LTD, TONGI, GAZIPUR, BANGLADESH |
| FPRC/FPRR: | NOVARTIS SA, SPARTAN, KEMPTON PARK |
| Shelf-life: | 24 months |
| Date of registration: | 6 OCTOBER 2006 |

MRF 15

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|---|---|
| Registration number: | 38/7.5/0225 |
| Name of medicine: | BEZACHOLE |
| Dosage form: | TABLET |
| Active ingredients: | EACH TABLET CONTAINS:<br>BEZAFIBRATE 200,0 mg |
| Conditions of registration: | 1, 2, 3, 4, 5, 6 |
| Applicant: | PHARMACARE LIMITED |
| Manufacturer: | ALPHAPHARM, BRISBANE, QUEENSLAND, AUSTRALIA<br>PHARMACARE LTD, KORSTEN, PORT ELIZABETH |
| Packer: | ALPHAPHARM, BRISBANE, QUEENSLAND, AUSTRALIA<br>PHARMACARE LTD, KORSTEN, PORT ELIZABETH<br>GERARD LABORATORIES, DUBLIN, IRELAND<br>GENERICS (UK) LTD, STATION CLOSE, HERTFORDSHIRE, U.K. |
| Laboratory:FPRC: | ALPHAPHARM, BRISBANE, QUEENSLAND, AUSTRALIA<br>GERARD LABORATORIES, DUBLIN, IRELAND<br>GENERICS (UK) LTD, STATION CLOSE, HERTFORDSHIRE, U.K.<br>SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA<br>RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY, POTCHEFSTROOM |
| FPRC/FPRR: | PHARMACARE LTD, KORSTEN, PORT ELIZABETH |
| Shelf-life: | 24 months |
| Date of registration: | 6 OCTOBER 2006 |

MRF 15

| | |
|---|---|
| Registration number: | A38/7.1.3/0392 |
| Name of medicine: | QUINAZIDE 10/12,5 |
| Dosage form: | TABLET |
| Active ingredients: | EACH TABLET CONTAINS:<br>QUINAPRIL HYDROCHLORIDE EQUIVALENT TO<br>QUINAPRIL 10,0 mg<br>HYDROCHLOROTHIAZIDE 12,5 mg |
| Conditions of registration: | 1, 2, 3, 4, 5, 6 |
| Applicant: | HEXAL PHARMA (S.A.) (PTY) LTD |
| Manufacturer: | ACTAVIS hf, HAFNARFJORDUR, ICELAND |
| Packer: | ACTAVIS hf, HAFNARFJORDUR, ICELAND<br>DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG |
| Laboratory:FPRC: | ACTAVIS hf, HAFNARFJORDUR, ICELAND<br>SALUTAS PHARMA GmbH, BARLEBEN, GERMANY<br>CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA<br>ANALYTICON, TERENURE, KEMPTON PARK |
| FPRR: | HEXAL PHARMA, PINETOWN, KZN |
| Shelf-life: | 24 months |
| Date of registration: | 6 OCTOBER 2006 |

MRF 15

| | |
|---|---|
| Registration number: | A38/7.1.3/0393 |
| Name of medicine: | QUINAZIDE 20/12,5 |
| Dosage form: | TABLET |
| Active ingredients: | EACH TABLET CONTAINS:<br>QUINAPRIL HYDROCHLORIDE EQUIVALENT TO<br>QUINAPRIL 20,0 mg<br>HYDROCHLOROTHIAZIDE 12,5 mg |
| Conditions of registration: | 1, 2, 3, 4, 5, 6 |
| Applicant: | HEXAL PHARMA (S.A.) (PTY) LTD |
| Manufacturer: | ACTAVIS hf, HAFNARFJORDUR, ICELAND |
| Packer: | ACTAVIS hf, HAFNARFJORDUR, ICELAND<br>DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG |
| Laboratory:FPRC: | ACTAVIS hf, HAFNARFJORDUR, ICELAND<br>SALUTAS PHARMA GmbH, BARLEBEN, GERMANY<br>CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA<br>ANALYTICON, TERENURE, KEMPTON PARK |
| FPRR: | HEXAL PHARMA, PINETOWN, KZN |
| Shelf-life: | 24 months |
| Date of registration: | 6 OCTOBER 2006 |

MRF 15

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|---|---|
| Registration number: | A38/1.2/0482 |
| Name of medicine: | ASPEN SERTRALINE 50 mg |
| Dosage form: | TABLET |
| Active ingredients: | EACH TABLET CONTAINS:<br>SERTRALINE HYDROCHLORIDE EQUIVALENT TO<br>SERTRALINE 50,0 mg |
| Conditions of registration: | 1, 2, 3, 4, 5, 6 |
| Applicant: | PHARMACARE LIMITED |
| Manufacturer: | GENPHARM PHARMACEUTICALS INC, ONTARIO, CANADA<br>PHARMACARE LTD, KORSTEN, PORT ELIZABETH |
| Packer: | GENPHARM PHARMACEUTICALS INC, ONTARIO, CANADA<br>PHARMACARE LTD, KORSTEN, PORT ELIZABETH |
| Laboratory:FPRC: | GENPHARM PHARMACEUTICALS INC, ONTARIO, CANADA<br>PHARMACARE LTD, KORSTEN, PORT ELIZABETH<br>SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA<br>RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY, POTCHEFSTROOM |
| FPRR: | PHARMACARE LTD, KORSTEN, PORT ELIZABETH |
| Shelf-life: | 24 months |
| Date of registration: | 6 OCTOBER 2006 |

MRF 15

| | |
|---|---|
| Registration number: | A38/1.2/0483 |
| Name of medicine: | ASPEN SERTRALINE 100 mg |
| Dosage form: | TABLET |
| Active ingredients: | EACH TABLET CONTAINS:<br>SERTRALINE HYDROCHLORIDE EQUIVALENT TO<br>SERTRALINE 100,0 mg |
| Conditions of registration: | 1, 2, 3, 4, 5, 6 |
| Applicant: | PHARMACARE LIMITED |
| Manufacturer: | GENPHARM PHARMACEUTICALS INC, ONTARIO, CANADA<br>PHARMACARE LTD, KORSTEN, PORT ELIZABETH |
| Packer: | GENPHARM PHARMACEUTICALS INC, ONTARIO, CANADA<br>PHARMACARE LTD, KORSTEN, PORT ELIZABETH |
| Laboratory:FPRC: | GENPHARM PHARMACEUTICALS INC, ONTARIO, CANADA<br>PHARMACARE LTD, KORSTEN, PORT ELIZABETH<br>SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA<br>RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY, POTCHEFSTROOM |
| FPRR: | PHARMACARE LTD, KORSTEN, PORT ELIZABETH |
| Shelf-life: | 24 months |
| Date of registration: | 6 OCTOBER 2006 |

MRF 15

| | |
|---|---|
| Registration number: | A38/21.2/0560 |
| Name of medicine: | ALEMBIC GLICLAZIDE 80 |
| Dosage form: | TABLET |
| Active ingredients: | EACH TABLET CONTAINS:<br>GLICLAZIDE 80,0 mg |
| Conditions of registration: | 1, 2, 3, 4, 5, 6 |
| Applicant: | GULF DRUG COMPANY (PTY) LTD |
| Manufacturer: | ALEMBIC LTD, PANCHMAHALS, GUJARAT, INDIA |
| Packer: | ALEMBIC LTD, PANCHMAHALS, GUJARAT, INDIA |
| Laboratory:FPRC: | ALEMBIC LTD, PANCHMAHALS, GUJARAT, INDIA<br>SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA, RSA<br>INSPECTORATE M&L, ORMONDE, JOHANNESBURG, RSA<br>CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA<br>PHARMA-Q, INDUSTRIA, JOHANNESBURG<br>INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, RSA<br>CONSULTING MICROBIOLOGICAL LABORATORY, MOREWILL, BEYERSPARK, RSA |
| FPRR: | GULF DRUG CO, MOUNT EDGECOMBE, RSA |
| Shelf-life: | 24 months |
| Date of registration: | 6 OCTOBER 2006 |

MRF 15

| | |
|---|---|
| Registration number: | A38/7.1.3/0639 |
| Name of medicine: | PHARMAPRESS 2,5 mg |
| Dosage form: | TABLET |
| Active ingredients: | EACH TABLET CONTAINS:<br>ENALAPRIL MALEATE 2,5 mg |
| Conditions of registration: | 1, 2, 3, 4, 5, 6 |
| Applicant: | PHARMACARE LIMITED |
| Manufacturer: | GENPHARM INC, ETOBICOKE, ONTARIO, CANADA<br>MERCK FARMA y QUIMICA S.A, BARCELONA, SPAIN<br>PHARMACARE LTD, KORSTEN, PORT ELIZABETH |
| Packer: | GENPHARM INC, ETOBICOKE, ONTARIO, CANADA<br>MERCK FARMA y QUIMICA S.A, BARCELONA, SPAIN<br>PHARMACARE LTD, KORSTEN, PORT ELIZABETH<br>GERARD LABORATORIES LTD, DUBLIN, IRELAND<br>GENERICS (UK) LTD, STATION CLOSE, HERTFORDSHIRE, UK |
| Laboratory:FPRC: | GENPHARM INC, ETOBICOKE, ONTARIO, CANADA<br>MERCK FARMA y QUIMICA S.A, BARCELONA, SPAIN<br>SOUTH AFRICAN BUREAU OF STANDRADS, GROENKLOOF, PRETORIA<br>RESEARCH INSTITUTE FOR PHARMACEUTICAL SERVICES, UNIVERSITY, POTCHEFSTROOM |
| FPRC/FPRR: | PHARMACARE LTD, KORSTEN, PORT ELIZABETH |
| Shelf-life: | 24 months |
| Date of registration: | 6 OCTOBER 2006 |

MRF 15

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|---|---|
| Registration number: | A38/7.1.3/0640 |
| Name of medicine: | PHARMAPRESS 5 mg |
| Dosage form: | TABLET |
| Active ingredients: | EACH TABLET CONTAINS:<br>ENALAPRIL MALEATE 5,0 mg |
| Conditions of registration: | 1, 2, 3, 4, 5, 6 |
| Applicant: | PHARMACARE LIMITED |
| Manufacturer: | GENPHARM INC, ETOBICOKE, ONTARIO, CANADA<br>MERCK FARMA y QUIMICA S.A, BARCELONA, SPAIN<br>PHARMACARE LTD, KORSTEN, PORT ELIZABETH |
| Packer: | GENPHARM INC, ETOBICOKE, ONTARIO, CANADA<br>MERCK FARMA y QUIMICA S.A, BARCELONA, SPAIN<br>PHARMACARE LTD, KORSTEN, PORT ELIZABETH<br>GERARD LABORATORIES LTD, DUBLIN, IRELAND<br>GENERICS (UK) LTD, STATION CLOSE, HERTFORDSHIRE, UK |
| Laboratory:FPRC: | GENPHARM INC, ETOBICOKE, ONTARIO, CANADA<br>MERCK FARMA y QUIMICA S.A, BARCELONA, SPAIN<br>SOUTH AFRICAN BUREAU OF STANDRADS, GROENKLOOF, PRETORIA<br>RESEARCH INSTITUTE FOR PHARMACEUTICAL SERVICES, UNIVERSITY, POTCHEFSTROOM |
| FPRC/FPRR: | PHARMACARE LTD, KORSTEN, PORT ELIZABETH |
| Shelf-life: | 24 months |
| Date of registration: | 6 OCTOBER 2006 |

MRF 15

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|---|---|
| Registration number: | A38/30.1/0717 |
| Name of medicine: | IMOVAX POLIO |
| Dosage form: | INJECTION |
| Active ingredients: | EACH 0,5 ml DOSE CONTAINS:<br>POLIO VIRUS TYPE 1 (MAHONEY) 40,0 ANTIGEN D UNITS<br>POLIO VIRUS TYPE 2 (MEF-1) 8,0 ANTIGEN D UNITS<br>POLIO VIRUS TYPE 3 (SAUKETT) 32,0 ANTIGEN D UNITS |
| Conditions of registration: | 1, 2, 3, 4, 5, 6 |
| Applicant: | AVENTIS PHARMA (PTY) LTD |
| Manufacturer: | AVENTIS PASTEUR, MARCY L'ETOILE, FRANCE |
| Packer: | AVENTIS PASTEUR, MARCY L'ETOILE, FRANCE |
| Laboratory:FPRC: | AVENTIS PASTEUR, MARCY L'ETOILE, FRANCE |
| FPRR: | AVENTIS PHARMA, WALTLOO, PRETORIA |
| Shelf-life: | 36 months |
| Date of registration: | 6 OCTOBER 2006 |

MRF 15

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|---|---|
| Registration number: | A39/21.12/0258 |
| Name of medicine: | FINAHEXAL 5 |
| Dosage form: | TABLET |
| Active ingredients: | EACH TABLET CONTAINS:<br>FINASTERIDE 5,0 mg |
| Conditions of registration: | 1, 2, 3, 4, 5, 6 |
| Applicant: | HEXAL PHARMA (S.A.) (PTY) LTD |
| Manufacturer: | CIPLA LTD, PATALGANGA, MAHARASHTRA, INDIA |
| Packer: | CIPLA LTD, PATALGANGA, MAHARASHTRA, INDIA<br>TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA |
| Laboratory:FPRC: | CIPLA LTD, PATALGANGA, MAHARASHTRA, INDIA<br>SALUTAS PHARMA GmbH, BARLEBEN, GERMANY<br>CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA<br>ANALYTICON, TERENURE, KEMPTON PARK |
| FPRR: | HEXAL PHARMA, PINETOWN, KZN |
| Shelf-life: | 24 months |
| Date of registration: | 6 OCTOBER 2006 |

MRF 15

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|---|---|
| Registration number: | A39/21.12/0259 |
| Name of medicine: | FINASTERIDE HEXAL 5 |
| Dosage form: | TABLET |
| Active ingredients: | EACH TABLET CONTAINS:<br>FINASTERIDE 5,0 mg |
| Conditions of registration: | 1, 2, 3, 4, 5, 6 |
| Applicant: | HEXAL PHARMA (S.A.) (PTY) LTD |
| Manufacturer: | CIPLA LTD, PATALGANGA, MAHARASHTRA, INDIA |
| Packer: | CIPLA LTD, PATALGANGA, MAHARASHTRA, INDIA<br>TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA |
| Laboratory:FPRC: | CIPLA LTD, PATALGANGA, MAHARASHTRA, INDIA<br>SALUTAS PHARMA GmbH, BARLEBEN, GERMANY<br>CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA<br>ANALYTICON, TERENURE, KEMPTON PARK |
| FPRR: | HEXAL PHARMA, PINETOWN, KZN |
| Shelf-life: | 24 months |
| Date of registration: | 6 OCTOBER 2006 |

MRF 15

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|---|---|
| Registration number: | A39/24/0312 |
| Name of medicine: | 0,9 % w/v SODIUM CHLORIDE INJECTION B BRAUN |
| Dosage form: | INJECTION |
| Active ingredients: | EACH 100,0 ml SOLUTION CONTAINS:<br>SODIUM CHLORIDE 0,9 g |
| Conditions of registration: | 1, 2, 3, 4, 5, 6 |
| Applicant: | B BRAUN MEDICAL (PTY) LTD |
| Manufacturer: | B BRAUN MELSUNGEN AG, BERLIN, GERMANY |
| Packer: | B BRAUN MELSUNGEN AG, BERLIN, GERMANY |
| Laboratory:FPRC: | B BRAUN MELSUNGEN AG, BERLIN, GERMANY<br>CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA |
| FPRR: | B BRAUN MEDICAL, HONEYDEW, GAUTENG,RSA |
| Shelf-life: | 36 months |
| Date of registration: | 6 OCTOBER 2006 |

MRF 15

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|---|---|
| Registration number: | A39/34/0313 |
| Name of medicine: | WATER FOR INJECTIONS B BRAUN |
| Dosage form: | SOLUTION |
| Active ingredients: | EACH 1,0 ml SOLUTION CONTAINS:<br>WATER FOR INJECTIONS 1,0 ml |
| Conditions of registration: | 1, 2, 3, 4, 5, 6 |
| Applicant: | B BRAUN MEDICAL (PTY) LTD |
| Manufacturer: | B BRAUN MELSUNGEN AG, BERLIN, GERMANY |
| Packer: | B BRAUN MELSUNGEN AG, BERLIN, GERMANY |
| Laboratory:FPRC:<br>FPRR: | B BRAUN MELSUNGEN AG, BERLIN, GERMANY<br>B BRAUN MEDICAL, HONEYDEW, GAUTENG |
| Shelf-life: | 36 months |
| Date of registration: | 6 OCTOBER 2006 |

MRF 15

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|---|---|
| Registration number: | A39/20.1.1/0334 |
| Name of medicine: | CIPROFLOXACIN – SAFELINE 100 |
| Dosage form: | INFUSION |
| Active ingredients: | EACH 1,0 ml SOLUTION CONTAINS:<br>CIPROFLOXACIN LACTATE EQUIVALENT TO<br>CIPROFLOXACIN 2,0 mg |
| Conditions of registration: | 1, 2, 3, 4, 5, 6 |
| Applicant: | SAFELINE PHARMACEUTICALS (PTY) LTD |
| Manufacturer: | DEMO S.A. PHARMACEUTICAL INDUSTRY,<br>ATHENS, GREECE |
| Packer: | DEMO S.A. PHARMACEUTICAL INDUSTRY,<br>ATHENS, GREECE |
| Laboratory:FPRC: | DEMO S.A. PHARMACEUTICAL INDUSTRY,<br>ATHENS, GREECE<br>INSTITUTE FOR PHARMACEUTICAL SERVICES,<br>SILVERTONDALE, RSA |
| FPRR: | SAFELINE PHARMACEUTICALS, FLORIDA, RSA |
| Shelf-life: | 24 months |
| Date of registration: | 6 OCTOBER 2006 |

MRF 15

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|---|---|
| Registration number: | A39/20.1.1/0335 |
| Name of medicine: | CIPROFLOXACIN – SAFELINE 200 |
| Dosage form: | INFUSION |
| Active ingredients: | EACH 1,0 ml SOLUTION CONTAINS:<br>CIPROFLOXACIN LACTATE EQUIVALENT TO<br>CIPROFLOXACIN 2,0 mg |
| Conditions of registration: | 1, 2, 3, 4, 5, 6 |
| Applicant: | SAFELINE PHARMACEUTICALS (PTY) LTD |
| Manufacturer: | DEMO S.A. PHARMACEUTICAL INDUSTRY,<br>ATHENS, GREECE |
| Packer: | DEMO S.A. PHARMACEUTICAL INDUSTRY,<br>ATHENS, GREECE |
| Laboratory:FPRC: | DEMO S.A. PHARMACEUTICAL INDUSTRY,<br>ATHENS, GREECE<br>INSTITUTE FOR PHARMACEUTICAL SERVICES,<br>SILVERTONDALE, RSA |
| FPRR: | SAFELINE PHARMACEUTICALS, FLORIDA, RSA |
| Shelf-life: | 24 months |
| Date of registration: | 6 OCTOBER 2006 |

MRF 15

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|---|---|
| Registration number: | A39/20.1.1/0336 |
| Name of medicine: | CIPROFLOXACIN – SAFELINE 400 |
| Dosage form: | INFUSION |
| Active ingredients: | EACH 1,0 ml SOLUTION CONTAINS:<br>CIPROFLOXACIN LACTATE EQUIVALENT TO<br>CIPROFLOXACIN 2,0 mg |
| Conditions of registration: | 1, 2, 3, 4, 5, 6 |
| Applicant: | SAFELINE PHARMACEUTICALS (PTY) LTD |
| Manufacturer: | DEMO S.A. PHARMACEUTICAL INDUSTRY,<br>ATHENS, GREECE |
| Packer: | DEMO S.A. PHARMACEUTICAL INDUSTRY,<br>ATHENS, GREECE |
| Laboratory:FPRC: | DEMO S.A. PHARMACEUTICAL INDUSTRY,<br>ATHENS, GREECE<br>INSTITUTE FOR PHARMACEUTICAL SERVICES,<br>SILVERTONDALE, RSA |
| FPRR: | SAFELINE PHARMACEUTICALS, FLORIDA, RSA |
| Shelf-life: | 24 months |
| Date of registration: | 6 OCTOBER 2006 |

MRF 15

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|---|---|
| Registration number: | A39/21.10/0357 |
| Name of medicine: | MENOPUR POWDER FOR SOLUTION FOR INJECTION |
| Dosage form: | POWDER |
| Active ingredients: | EACH VIAL CONTAINS:<br>MENOTROPHIN EQUIVALENT TO<br>FOLLICLE STIMULATING HORMONE 75,0 iu<br>LUTEINISING HORMONE 75,0 iu |
| Conditions of registration: | 1, 2, 3, 4, 5, 6 |
| Applicant: | FERRING (PTY) LTD |
| Manufacturer: | DR RENTSCHLER BIOTECHNOLOGIE GmbH, LAUPHEIM, GERMANY<br>PATHEON ITALIA S.p.A, MONZA, ITALY<br>FERRING GmbH, KIEL, GERMANY |
| Packer: | DR RENTSCHLER BIOTECHNOLOGIE GmbH, LAUPHEIM, GERMANY<br>PATHEON ITALIA S.p.A, MONZA, ITALY<br>FERRING GmbH, KIEL, GERMANY |
| Laboratory:FPRC: | FERRING GmbH, KIEL, GERMANY<br>CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA |
| FPRR: | FERRING, IRENE, RSA |
| Shelf-life: | 24 months (provisional) |
| Date of registration: | 6 OCTOBER 2006 |

MRF 15

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|---|---|
| Registration number: | A39/8.2/0375 |
| Name of medicine: | ENOXAPARIN-HEXAL 40 PRE-FILLED SYRINGE |
| Dosage form: | INJECTION |
| Active ingredients: | EACH 0,4 ml SOLUTION CONTAINS:<br>ENOXAPARIN SODIUM 40,0 mg |
| Conditions of registration: | 1, 2, 3, 4, 5, 6 |
| Applicant: | HEXAL PHARMA (S.A.) (PTY) LTD |
| Manufacturer: | IMPFSTOFFWERK DESSAU-TORNAU GmbH, RODLEBEN/ORTSTEIL TORNAU, GERMANY |
| Packer: | IMPFSTOFFWERK DESSAU-TORNAU GmbH, RODLEBEN/ORTSTEIL TORNAU, GERMANY<br>DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG |
| Laboratory:FPRC: | SALUTAS PHARMA GmbH, BARLEBEN, GERMANY<br>CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA<br>ANALYTICON, TERENURE, KEMPTON PARK |
| FPRR: | HEXAL PHARMA , PINETOWN, RSA |
| Shelf-life: | 24 months |
| Date of registration: | 6 OCTOBER 2006 |

MRF 15

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|---|---|
| Registration number: | A39/8.2/0376 |
| Name of medicine: | ENOXAPARIN-HEXAL 60 PRE-FILLED SYRINGE |
| Dosage form: | INJECTION |
| Active ingredients: | EACH 0,6 ml SOLUTION CONTAINS:<br>ENOXAPARIN SODIUM 60,0 mg |
| Conditions of registration: | 1, 2, 3, 4, 5, 6 |
| Applicant: | HEXAL PHARMA (S.A.) (PTY) LTD |
| Manufacturer: | IMPFSTOFFWERK DESSAU-TORNAU GmbH, RODLEBEN/ORTSTEIL TORNAU, GERMANY |
| Packer: | IMPFSTOFFWERK DESSAU-TORNAU GmbH, RODLEBEN/ORTSTEIL TORNAU, GERMANY<br>DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG |
| Laboratory:FPRC: | SALUTAS PHARMA GmbH, BARLEBEN, GERMANY<br>CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA<br>ANALYTICON, TERENURE, KEMPTON PARK |
| FPRR: | HEXAL PHARMA , PINETOWN, RSA |
| Shelf-life: | 24 months |
| Date of registration: | 6 OCTOBER 2006 |

MRF 15

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|---|---|
| Registration number: | A39/8.2/0377 |
| Name of medicine: | ENOXAPARIN-HEXAL 80 PRE-FILLED SYRINGE |
| Dosage form: | INJECTION |
| Active ingredients: | EACH 0,8 ml SOLUTION CONTAINS:<br>ENOXAPARIN SODIUM 80,0 mg |
| Conditions of registration: | 1, 2, 3, 4, 5, 6 |
| Applicant: | HEXAL PHARMA (S.A.) (PTY) LTD |
| Manufacturer: | IMPFSTOFFWERK DESSAU-TORNAU GmbH, RODLEBEN/ORTSTEIL TORNAU, GERMANY |
| Packer: | IMPFSTOFFWERK DESSAU-TORNAU GmbH, RODLEBEN/ORTSTEIL TORNAU, GERMANY<br>DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG |
| Laboratory:FPRC: | SALUTAS PHARMA GmbH, BARLEBEN, GERMANY<br>CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA<br>ANALYTICON, TERENURE, KEMPTON PARK |
| FPRR: | HEXAL PHARMA , PINETOWN, RSA |
| Shelf-life: | 24 months |
| Date of registration: | 6 OCTOBER 2006 |

MRF 15

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|---|---|
| Registration number: | A39/8.2/0378 |
| Name of medicine: | ENOXAPARIN-HEXAL 100 PRE-FILLED SYRINGE |
| Dosage form: | INJECTION |
| Active ingredients: | EACH 1,0 ml SOLUTION CONTAINS:<br>ENOXAPARIN SODIUM 100,0 mg |
| Conditions of registration: | 1, 2, 3, 4, 5, 6 |
| Applicant: | HEXAL PHARMA (S.A.) (PTY) LTD |
| Manufacturer: | IMPFSTOFFWERK DESSAU-TORNAU GmbH, RODLEBEN/ORTSTEIL TORNAU, GERMANY |
| Packer: | IMPFSTOFFWERK DESSAU-TORNAU GmbH, RODLEBEN/ORTSTEIL TORNAU, GERMANY<br>DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG |
| Laboratory:FPRC: | SALUTAS PHARMA GmbH, BARLEBEN, GERMANY<br>CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA<br>ANALYTICON, TERENURE, KEMPTON PARK |
| FPRR: | HEXAL PHARMA , PINETOWN, RSA |
| Shelf-life: | 24 months |
| Date of registration: | 6 OCTOBER 2006 |

MRF 15

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|---|---|
| Registration number: | A39/8.2/0379 |
| Name of medicine: | ENOXAPARIN-HEXAL 40 AMPOULES |
| Dosage form: | INJECTION |
| Active ingredients: | EACH 0,4 ml SOLUTION CONTAINS:<br>ENOXAPARIN SODIUM 40,0 mg |
| Conditions of registration: | 1, 2, 3, 4, 5, 6 |
| Applicant: | HEXAL PHARMA (S.A.) (PTY) LTD |
| Manufacturer: | IMPFSTOFFWERK DESSAU-TORNAU GmbH, RODLEBEN/ORTSTEIL TORNAU, GERMANY |
| Packer: | IMPFSTOFFWERK DESSAU-TORNAU GmbH, RODLEBEN/ORTSTEIL TORNAU, GERMANY<br>DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG |
| Laboratory:FPRC: | SALUTAS PHARMA GmbH, BARLEBEN, GERMANY<br>CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA<br>ANALYTICON, TERENURE, KEMPTON PARK |
| FPRR: | HEXAL PHARMA , PINETOWN, RSA |
| Shelf-life: | 24 months |
| Date of registration: | 6 OCTOBER 2006 |

MRF 15

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|---|---|
| Registration number: | A39/8.2/0380 |
| Name of medicine: | ENOXAPARIN-HEXAL 300 MULTI-DOSE VIAL |
| Dosage form: | INJECTION |
| Active ingredients: | EACH 3,0 ml SOLUTION CONTAINS:<br>ENOXAPARIN SODIUM 300,0 mg |
| Conditions of registration: | 1, 2, 3, 4, 5, 6 |
| Applicant: | HEXAL PHARMA (S.A.) (PTY) LTD |
| Manufacturer: | IMPFSTOFFWERK DESSAU-TORNAU GmbH, RODLEBEN/ORTSTEIL TORNAU, GERMANY |
| Packer: | IMPFSTOFFWERK DESSAU-TORNAU GmbH, RODLEBEN/ORTSTEIL TORNAU, GERMANY<br>DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG |
| Laboratory:FPRC: | SALUTAS PHARMA GmbH, BARLEBEN, GERMANY<br>CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA<br>ANALYTICON, TERENURE, KEMPTON PARK |
| FPRR: | HEXAL PHARMA , PINETOWN, RSA |
| Shelf-life: | 24 months |
| Date of registration: | 6 OCTOBER 2006 |

MRF 15

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|---|---|
| Registration number: | A39/5.7.1/0395 |
| Name of medicine: | ALLERCHLOR 2 mg/5 ml LIQUID |
| Dosage form: | LIQUID |
| Active ingredients: | EACH 5,0 ml LIQUID CONTAINS:<br>CHLORPHENAMINE MALEATE 2,0 mg |
| Conditions of registration: | 1, 2, 3, 4, 5, 6 |
| Applicant: | PHARMACARE LIMITED |
| Manufacturer: | PHARMACARE LTD, KORSTEN, PORT ELIZABETH<br>ASPEN PHARMACARE, WILSONIA, EAST LONDON |
| Packer: | PHARMACARE LTD, KORSTEN, PORT ELIZABETH<br>ASPEN PHARMACARE, WILSONIA, EAST LONDON |
| Laboratory:FPRC: | SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA<br>RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY, POTCHEFSTROOM<br>ASPEN PHARMACARE, WILSONIA, EAST LONDON |
| FPRC/FPRR: | PHARMACARE LTD, KORSTEN, PORT ELIZABETH |
| Shelf-life: | 24 months (provisional) |
| Date of registration: | 6 OCTOBER 2006 |

MRF 15

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|---|---|
| Registration number: | A39/34/0412 |
| Name of medicine: | MENOPUR SOLVENT FOR SOLUTION FOR INJECTION |
| Dosage form: | SOLUTION |
| Active ingredients: | EACH AMPOULE CONTAINS:<br>WATER FOR INJECTIONS 1,0 ml |
| Conditions of registration: | 1, 2, 3, 4, 5, 6 |
| Applicant: | FERRING (PTY) LTD |
| Manufacturer: | WEIMAR PHARMA GmbH, RASTATT, GERMANY<br>WULFING PHARMA GmbH, GRONAU, GERMANY |
| Packer: | WEIMAR PHARMA GmbH, RASTATT, GERMANY<br>WULFING PHARMA GmbH, GRONAU, GERMANY |
| Laboratory:FPRC: | FERRING GmbH, KIEL, GERMANY<br>CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA |
| FPRR: | FERRING, IRENE, RSA |
| Shelf-life: | 36 months |
| Date of registration: | 6 OCTOBER 2006 |

MRF 15

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|---|---|
| Registration number: | A39/4/0436 |
| Name of medicine: | LIGNOCAINE-HCl B BRAUN 1 % 5 ml |
| Dosage form: | INJECTION |
| Active ingredients: | EACH 1,0 ml SOLUTION CONTAINS:<br>LIGNOCAINE HYDROCHLORIDE 10,0 mg |
| Conditions of registration: | 1, 2, 3, 4, 5, 6 |
| Applicant: | B BRAUN MEDICAL (PTY) LTD |
| Manufacturer: | B BRAUN MELSUNGEN AG, BERLIN, GERMANY |
| Packer: | B BRAUN MELSUNGEN AG, BERLIN, GERMANY |
| Laboratory:FPRC: | B BRAUN MELSUNGEN AG, BERLIN, GERMANY<br>CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA |
| FPRR: | B BRAUN MEDICAL, HONEYDEW, GAUTENG, RSA |
| Shelf-life: | 24 months |
| Date of registration: | 6 OCTOBER 2006 |

MRF 15

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|---|---|
| Registration number: | A39/4/0437 |
| Name of medicine: | LIGNOCAINE-HCl B BRAUN 2 % 5 ml |
| Dosage form: | INJECTION |
| Active ingredients: | EACH 1,0 ml SOLUTION CONTAINS:<br>LIGNOCAINE HYDROCHLORIDE 20,0 mg |
| Conditions of registration: | 1, 2, 3, 4, 5, 6 |
| Applicant: | B BRAUN MEDICAL (PTY) LTD |
| Manufacturer: | B BRAUN MELSUNGEN AG, BERLIN, GERMANY |
| Packer: | B BRAUN MELSUNGEN AG, BERLIN, GERMANY |
| Laboratory:FPRC: | B BRAUN MELSUNGEN AG, BERLIN, GERMANY<br>CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA |
| FPRR: | B BRAUN MEDICAL, HONEYDEW, GAUTENG, RSA |
| Shelf-life: | 24 months |
| Date of registration: | 6 OCTOBER 2006 |

MRF 15

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|---|---|
| Registration number: | A39/2.7/0440 |
| Name of medicine: | ZYDUS-PARACETAMOL 500 mg TABLETS |
| Dosage form: | TABLET |
| Active ingredients: | EACH TABLET CONTAINS:<br>PARACETAMOL 500,0 mg |
| Conditions of registration: | 1, 2, 3, 4, 5, 6 |
| Applicant: | ZYDUS HEALTHCARE S.A. (PTY) LTD |
| Manufacturer: | ZYDUS CADILA HEALTHCARE LTD, SANAND, AHMEDABAD, INDIA |
| Packer: | ZYDUS CADILA HEALTHCARE LTD, SANAND, AHMEDABAD, INDIA |
| Laboratory:FPRC: | ZYDUS CADILA HEALTHCARE LTD, SANAND, AHMEDABAD, INDIA<br>INSTITUTE FOR PHARMACEUTICAL & CHEMICAL SERVICES, SILVERTONDALE, RSA<br>INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY, POTCHEFSTROOM |
| FPRR: | ZYDUS HEALTHCARE, VAN DER HOFF PARK, POTCHEFSTROOM |
| Shelf-life: | 24 months |
| Date of registration: | 6 OCTOBER 2006 |

MRF 15

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|---|---|
| Registration number: | A39/7.1.3/0531 |
| Name of medicine: | MAVIK 4 mg |
| Dosage form: | CAPSULE |
| Active ingredients: | EACH CAPSULE CONTAINS:<br>TRANDOLAPRIL 4,0 mg |
| Conditions of registration: | 1, 2, 3, 4, 5, 6 |
| Applicant: | ABBOTT LABORATORIES S.A. (PTY) LTD |
| Manufacturer: | ABBOTT GmbH & Co, LUDWIGSHAFEN, GERMANY |
| Packer: | ABBOTT GmbH & Co, LUDWIGSHAFEN, GERMANY |
| Laboratory:FPRC:<br>FPRC/FPRR: | ABBOTT GmbH & Co, LUDWIGSHAFEN, GERMANY<br>ABBOTT LABORATORIES, CONSTANTIA KLOOF, RSA |
| Shelf-life: | 24 months (provisional) |
| Date of registration: | 6 OCTOBER 2006 |

MRF 15

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|---|---|
| Registration number: | A39/20.2.2/0617 |
| Name of medicine: | TRISPORAL |
| Dosage form: | CAPSULE |
| Active ingredients: | EACH CAPSULE CONTAINS:<br>ITRACONAZOLE 100,0 mg |
| Conditions of registration: | 1, 2, 3, 4, 5, 6 |
| Applicant: | JANSSEN PHARMACEUTICA (PTY) LTD |
| Manufacturer: | JANSSEN PHARMACEUTICA NV, BEERSE, BELGIUM<br>JANSSEN PHARMACEUTICA NV, OLEN, BELGIUM<br>ETHYPHARM INDUSTRIES, CHATEAUNEUF-en-THYMERAIS, FRANCE |
| Packer: | JANSSEN-CILAG SpA, LATINA, ITALY<br>JANSSEN PHARMACEUTICA, WOODMEAD, RSA |
| Laboratory:FPRC: | JANSSEN PHARMACEUTICA NV, BEERSE, BELGIUM |
| FPRR: | JANSSEN PHARMACEUTICA, WOODMEAD, RSA |
| Shelf-life: | 36 months |
| Date of registration: | 6 OCTOBER 2006 |

MRF 15

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|---|---|
| Registration number: | A40/28/0001 |
| Name of medicine: | PRIMOVIST 5 ml |
| Dosage form: | INJECTION |
| Active ingredients: | EACH 1,0 ml SOLUTION CONTAINS:<br>GADOXETIC ACID 181,43 mg |
| Conditions of registration: | 1, 2, 3, 4, 5, 6 |
| Applicant: | SCHERING (PTY) LTD |
| Manufacturer: | SCHERING AG CHARLOTTENBURG, BERLIN, GERMANY<br>SCHERING AG WEDDING, BERLIN, GERMANY |
| Packer: | SCHERING AG CHARLOTTENBURG, BERLIN, GERMANY<br>SCHERING AG WEDDING, BERLIN, GERMANY |
| Laboratory:FPRC: | SCHERING AG CHARLOTTENBURG, BERLIN, GERMANY<br>SCHERING AG WEDDING, BERLIN, GERMANY<br>SOUTH AFRICAN BUREUA OF STANDARDS, GROENKLOOF, PRETORIA |
| FPRR: | SCHERING, RANDJESPARK, MIDRAND |
| Shelf-life: | 24 months |
| Date of registration: | 6 OCTOBER 2006 |

MRF 15

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|---|---|
| Registration number: | A40/28/0002 |
| Name of medicine: | PRIMOVIST 7,5 ml |
| Dosage form: | INJECTION |
| Active ingredients: | EACH 1,0 ml SOLUTION CONTAINS:<br>GADOXETIC ACID 181,43 mg |
| Conditions of registration: | 1, 2, 3, 4, 5, 6 |
| Applicant: | SCHERING (PTY) LTD |
| Manufacturer: | SCHERING AG CHARLOTTENBURG, BERLIN, GERMANY<br>SCHERING AG WEDDING, BERLIN, GERMANY |
| Packer: | SCHERING AG CHARLOTTENBURG, BERLIN, GERMANY<br>SCHERING AG WEDDING, BERLIN, GERMANY |
| Laboratory:FPRC: | SCHERING AG CHARLOTTENBURG, BERLIN, GERMANY<br>SCHERING AG WEDDING, BERLIN, GERMANY<br>SOUTH AFRICAN BUREUA OF STANDARDS, GROENKLOOF, PRETORIA |
| FPRR: | SCHERING, RANDJESPARK, MIDRAND |
| Shelf-life: | 24 months |
| Date of registration: | 6 OCTOBER 2006 |

MRF 15

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|---|---|
| Registration number: | A40/28/0003 |
| Name of medicine: | PRIMOVIST 10 ml |
| Dosage form: | INJECTION |
| Active ingredients: | EACH 1,0 ml SOLUTION CONTAINS:<br>GADOXETIC ACID 181,43 mg |
| Conditions of registration: | 1, 2, 3, 4, 5, 6 |
| Applicant: | SCHERING (PTY) LTD |
| Manufacturer: | SCHERING AG CHARLOTTENBURG, BERLIN, GERMANY<br>SCHERING AG WEDDING, BERLIN, GERMANY |
| Packer: | SCHERING AG CHARLOTTENBURG, BERLIN, GERMANY<br>SCHERING AG WEDDING, BERLIN, GERMANY |
| Laboratory:FPRC: | SCHERING AG CHARLOTTENBURG, BERLIN, GERMANY<br>SCHERING AG WEDDING, BERLIN, GERMANY<br>SOUTH AFRICAN BUREUA OF STANDARDS, GROENKLOOF, PRETORIA |
| FPRR: | SCHERING, RANDJESPARK, MIDRAND |
| Shelf-life: | 24 months |
| Date of registration: | 6 OCTOBER 2006 |

MRF 15

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|---|---|
| Registration number: | A40/2.5/0158 |
| Name of medicine: | EPLEPTIN 100 mg |
| Dosage form: | CAPSULE |
| Active ingredients: | EACH CAPSULE CONTAINS:<br>GABAPENTIN 100,0 mg |
| Conditions of registration: | 1, 2, 3, 4, 5, 6 |
| Applicant: | PHARMAPLAN (PTY) LTD |
| Manufacturer: | MJ PHARMACEUTICALS LTD, PANCHMAHAL, GUJARAT, INDIA |
| Packer: | MJ PHARMACEUTICALS LTD, PANCHMAHAL, GUJARAT, INDIA |
| Laboratory:FPRC: | MJ PHARMACEUTICALS LTD, PANCHMAHAL, GUJARAT, INDIA<br>CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA |
| FPRR: | PHARMAPLAN, MIDRAND, RSA |
| Shelf-life: | 24 months (provisional) |
| Date of registration: | 6 OCTOBER 2006 |

MRF 15

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|---|---|
| Registration number: | A40/2.5/0159 |
| Name of medicine: | EPLEPTIN 300 mg |
| Dosage form: | CAPSULE |
| Active ingredients: | EACH CAPSULE CONTAINS:<br>GABAPENTIN 300,0 mg |
| Conditions of registration: | 1, 2, 3, 4, 5, 6 |
| Applicant: | PHARMAPLAN (PTY) LTD |
| Manufacturer: | MJ PHARMACEUTICALS LTD, PANCHMAHAL, GUJARAT, INDIA |
| Packer: | MJ PHARMACEUTICALS LTD, PANCHMAHAL, GUJARAT, INDIA |
| Laboratory:FPRC: | MJ PHARMACEUTICALS LTD, PANCHMAHAL, GUJARAT, INDIA<br>CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA |
| FPRR: | PHARMAPLAN, MIDRAND, RSA |
| Shelf-life: | 24 months (provisional) |
| Date of registration: | 6 OCTOBER 2006 |

MRF 15

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|---|---|
| Registration number: | A40/2.5/0160 |
| Name of medicine: | EPLEPTIN 400 mg |
| Dosage form: | CAPSULE |
| Active ingredients: | EACH CAPSULE CONTAINS:<br>GABAPENTIN 400,0 mg |
| Conditions of registration: | 1, 2, 3, 4, 5, 6 |
| Applicant: | PHARMAPLAN (PTY) LTD |
| Manufacturer: | MJ PHARMACEUTICALS LTD, PANCHMAHAL, GUJARAT, INDIA |
| Packer: | MJ PHARMACEUTICALS LTD, PANCHMAHAL, GUJARAT, INDIA |
| Laboratory:FPRC: | MJ PHARMACEUTICALS LTD, PANCHMAHAL, GUJARAT, INDIA<br>CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA |
| FPRR: | PHARMAPLAN, MIDRAND, RSA |
| Shelf-life: | 24 months (provisional) |
| Date of registration: | 6 OCTOBER 2006 |

MRF 15

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|---|---|
| Registration number: | A40/20.1.1/0212 |
| Name of medicine: | SANDOZ CEFUROXIME 125 mg/5 ml |
| Dosage form: | SUSPENSION |
| Active ingredients: | EACH 5,0 ml SUSPENSION CONTAINS:<br>CEFUROXIME AXETIL EQUIVALENT TO<br>CEFUROXIME 125,0 mg |
| Conditions of registration: | 1, 2, 3, 4, 5, 6 |
| Applicant: | SANDOZ (PTY) LTD |
| Manufacturer: | GfM GESELLSCHAFT FÜR MIKRONISIERUNG GmbH, BREMEN, GERMANY<br>PENCEF PHARMA GmbH, GOTTINGEN, GERMANY |
| Packer: | PENCEF PHARMA GmbH, GOTTINGEN, GERMANY<br>NOVARTIS, SPARTAN, KEMPTON PARK |
| Laboratory:FPRC: | PENCEF PHARMA GmbH, GOTTINGEN, GERMANY<br>NOVARTIS, SPARTAN, KEMPTON PARK<br>SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA |
| FPRR: | SANDOZ, SPARTAN, KEMPTON PARK |
| Shelf-life: | 24 months |
| Date of registration: | 6 OCTOBER 2006 |

MRF 15

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|---|---|
| Registration number: | A40/7.1/0283 |
| Name of medicine: | KLODIP-5 |
| Dosage form: | TABLET |
| Active ingredients: | EACH TABLET CONTAINS:<br>AMLODIPINE BESYLATE EQUIVALENT TO<br>AMLODIPINE 5,0 mg |
| Conditions of registration: | 1, 2, 3, 4, 5, 6 |
| Applicant: | DEZZO TRADING (PTY) LTD t/a INDO PHARMA |
| Manufacturer: | KOPRAN LTD, KHALAPUR, RAIGAD, INDIA |
| Packer: | KOPRAN LTD, KHALAPUR, RAIGAD, INDIA |
| Laboratory:FPRC: | KOPRAN LTD, KHALAPUR, RAIGAD, INDIA<br>CONSULTING CHEMICAL LABORATORIES,<br>ATLASVILLE, BOKSBURG, RSA |
| FPRR: | DEZZO TRADING, ANCHORVILLE,<br>LENASIA, JOHANNESBURG, RSA |
| Shelf-life: | 24 months (provisional) |
| Date of registration: | 6 OCTOBER 2006 |

MRF 15

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|---|---|
| Registration number: | A40/21.12/0304 |
| Name of medicine: | BICADEX |
| Dosage form: | TABLET |
| Active ingredients: | EACH TABLET CONTAINS:<br>BICALUTAMIDE 50,0 mg |
| Conditions of registration: | 1, 2, 3, 4, 5, 6 |
| Applicant: | CIPLA MEDPRO (PTY) LTD |
| Manufacturer: | CIPLA LTD, VIRGONAR, BANGALORE, INDIA<br>CIPLA LTD, UNIT VI, SALCETTE, GOA, INDIA |
| Packer: | CIPLA LTD, VIRGONAR, BANGALORE, INDIA<br>CIPLA LTD, UNIT VI, SALCETTE, GOA, INDIA |
| Laboratory:FPRC: | CIPLA LTD, VIRGONAR, BANGALORE, INDIA<br>CIPLA LTD, UNIT VI, SALCETTE, GOA, INDIA |
| FPRR: | CIPLA MEDPRO, ROSENPARK, BELLVILLE |
| Shelf-life: | 24 months (provisional) |
| Date of registration: | 6 OCTOBER 2006 |

MRF 15

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|---|---|
| Registration number: | A40/21.12/0305 |
| Name of medicine: | CIPLA-BICALUTAMIDE |
| Dosage form: | TABLET |
| Active ingredients: | EACH TABLET CONTAINS:<br>BICALUTAMIDE 50,0 mg |
| Conditions of registration: | 1, 2, 3, 4, 5, 6 |
| Applicant: | CIPLA LIFE SCIENCES (PTY) LTD |
| Manufacturer: | CIPLA LTD, VIRGONAR, BANGALORE, INDIA<br>CIPLA LTD, UNIT VI, SALCETTE, GOA, INDIA |
| Packer: | CIPLA LTD, VIRGONAR, BANGALORE, INDIA<br>CIPLA LTD, UNIT VI, SALCETTE, GOA, INDIA |
| Laboratory:FPRC: | CIPLA LTD, VIRGONAR, BANGALORE, INDIA<br>CIPLA LTD, UNIT VI, SALCETTE, GOA, INDIA |
| FPRR: | CIPLA LIFE SCIENCES, ROSENPARK, BELLVILLE |
| Shelf-life: | 24 months (provisional) |
| Date of registration: | 6 OCTOBER 2006 |

MRF 15

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|---|---|
| Registration number: | A40/20.1.2/0331 |
| Name of medicine: | AMYN 250 |
| Dosage form: | CAPSULE |
| Active ingredients: | EACH CAPSULE CONTAINS:<br>AMOXYCILLIN TRIHYDRATE EQUIVALENT TO<br>AMOXYCILLIN 250,0 mg |
| Conditions of registration: | 1, 2, 3, 4, 5, 6 |
| Applicant: | DEZZO TRADING (PTY) LTD t/a INDO PHARMA |
| Manufacturer: | KOPRAN LTD, KHALAPUR, RAIGAD, INDIA |
| Packer: | KOPRAN LTD, KHALAPUR, RAIGAD, INDIA |
| Laboratory:FPRC:<br>FPRR: | KOPRAN LTD, KHALAPUR, RAIGAD, INDIA<br>DEZZO TRADING, ANCHORVILLE, LENASIA, JOHANNESBURG, RSA |
| Shelf-life: | 36 months |
| Date of registration: | 6 OCTOBER 2006 |

MRF 15

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|---|---|
| Registration number: | A40/20.1.2/0332 |
| Name of medicine: | AMYN 500 |
| Dosage form: | CAPSULE |
| Active ingredients: | EACH CAPSULE CONTAINS:<br>AMOXYCILLIN TRIHYDRATE EQUIVALENT TO<br>AMOXYCILLIN 500,0 mg |
| Conditions of registration: | 1, 2, 3, 4, 5, 6 |
| Applicant: | DEZZO TRADING (PTY) LTD t/a INDO PHARMA |
| Manufacturer: | KOPRAN LTD, KHALAPUR, RAIGAD, INDIA |
| Packer: | KOPRAN LTD, KHALAPUR, RAIGAD, INDIA |
| Laboratory:FPRC:<br>FPRR: | KOPRAN LTD, KHALAPUR, RAIGAD, INDIA<br>DEZZO TRADING, ANCHORVILLE, LENASIA, JOHANNESBURG, RSA |
| Shelf-life: | 36 months |
| Date of registration: | 6 OCTOBER 2006 |

MRF 15

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|---|---|
| Registration number: | A40/7.5/0397 |
| Name of medicine: | CIPLA-SIMVASTATIN 10 |
| Dosage form: | TABLET |
| Active ingredients: | EACH TABLET CONTAINS:<br>SIMVASTATIN 10,0 mg |
| Conditions of registration: | 1, 2, 3, 4, 5, 6 |
| Applicant: | CIPLA LIFE SCIENCES (PTY) LTD |
| Manufacturer: | CIPLA LTD, KURKUMBH, PUNE, INDIA |
| Packer: | CIPLA LTD, KURKUMBH, PUNE, INDIA |
| Laboratory:FPRC:<br>FPRR: | CIPLA LTD, KURKUMBH, PUNE, INDIA<br>CIPLA LIFE SCIENCES, ROSENPARK, BELLVILE |
| Shelf-life: | 24 months |
| Date of registration: | 6 OCTOBER 2006 |

MRF 15

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|---|---|
| Registration number: | A40/7.5/0398 |
| Name of medicine: | CIPLA-SIMVASTATIN 20 |
| Dosage form: | TABLET |
| Active ingredients: | EACH TABLET CONTAINS:<br>SIMVASTATIN 20,0 mg |
| Conditions of registration: | 1, 2, 3, 4, 5, 6 |
| Applicant: | CIPLA LIFE SCIENCES (PTY) LTD |
| Manufacturer: | CIPLA LTD, KURKUMBH, PUNE, INDIA |
| Packer: | CIPLA LTD, KURKUMBH, PUNE, INDIA |
| Laboratory:FPRC:<br>FPRR: | CIPLA LTD, KURKUMBH, PUNE, INDIA<br>CIPLA LIFE SCIENCES, ROSENPARK, BELLVILE |
| Shelf-life: | 24 months |
| Date of registration: | 6 OCTOBER 2006 |

MRF 15

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|---|---|
| Registration number: | A40/26/0416 |
| Name of medicine: | MABCAMPATH 30 mg/ml |
| Dosage form: | SOLUTION |
| Active ingredients: | EACH 1,0 ml SOLUTION CONTAINS:<br>ALEMTUZUMAB 30,0 mg |
| Conditions of registration: | 1, 2, 3, 4, 5, 6 |
| Applicant: | SCHERING (PTY) LTD |
| Manufacturer: | BOEHRINGER INGELHEIM PHARMA GmbH,<br>BIBERACH AN DER RISS, GERMANY |
| Packer: | BOEHRINGER INGELHEIM PHARMA GmbH,<br>BIBERACH AN DER RISS, GERMANY<br>SCHERING AG, BERLIN, GERMANY |
| Laboratory:FPRC: | BOEHRINGER INGELHEIM PHARMA GmbH,<br>BIBERACH AN DER RISS, GERMANY<br>SCHERING AG, BERLIN, GERMANY |
| FPRR: | SCHERING, RANDJESPARK, MIDRAND, RSA |
| Shelf-life: | 24 months |
| Date of registration: | 6 OCTOBER 2006 |

MRF 15

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|---|---|
| Registration number: | A40/20.1.1/0525 |
| Name of medicine: | SANDOZ LEVOFLOXACIN 250 |
| Dosage form: | TABLET |
| Active ingredients: | EACH TABLET CONTAINS:<br>LEVOFLOXACIN HEMIHYDRATE EQUIVALENT TO<br>LEVOFLOXACIN 250,0 mg |
| Conditions of registration: | 1, 2, 3, 4, 5, 6 |
| Applicant: | SANDOZ (PTY) LTD |
| Manufacturer: | LEK PHARMACEUTICALS d.d., VEROVSKOVA, SLOVENIA |
| Packer: | LEK PHARMACEUTICALS d.d., VEROVSKOVA, SLOVENIA<br>NOVARTIS, SPARTAN, KEMPTON PARK |
| Laboratory:FPRC: | LEK PHARMACEUTICALS d.d., VEROVSKOVA, SLOVENIA<br>NOVARTIS, SPARTAN, KEMPTON PARK<br>SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA |
| FPRR: | SANDOZ, SPARTAN, KEMPTON PAR |
| Shelf-life: | 24 months |
| Date of registration: | 6 OCTOBER 2006 |

MRF 15

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|---|---|
| Registration number: | A40/20.1.1/0526 |
| Name of medicine: | SANDOZ LEVOFLOXACIN 500 |
| Dosage form: | TABLET |
| Active ingredients: | EACH TABLET CONTAINS:<br>LEVOFLOXACIN HEMIHYDRATE EQUIVALENT TO<br>LEVOFLOXACIN 500,0 mg |
| Conditions of registration: | 1, 2, 3, 4, 5, 6 |
| Applicant: | SANDOZ (PTY) LTD |
| Manufacturer: | LEK PHARMACEUTICALS d.d., VEROVSKOVA, SLOVENIA |
| Packer: | LEK PHARMACEUTICALS d.d., VEROVSKOVA, SLOVENIA<br>NOVARTIS, SPARTAN, KEMPTON PARK |
| Laboratory:FPRC: | LEK PHARMACEUTICALS d.d., VEROVSKOVA, SLOVENIA<br>NOVARTIS, SPARTAN, KEMPTON PARK<br>SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA |
| FPRR: | SANDOZ, SPARTAN, KEMPTON PARK |
| Shelf-life: | 24 months |
| Date of registration: | 6 OCTOBER 2006 |

MRF 15

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|---|---|
| Registration number: | A40/20.2.8/0531 |
| Name of medicine: | AURO-STAVUDINE CAPSULES 30 m |
| Dosage form: | CAPSULES |
| Active ingredients: | EACH CAPSULE CONTAINS:<br>STAVUDINE 30,0 mg |
| Conditions of registration: | 1, 2, 3, 4, 5, 6 |
| Applicant: | AUROBINDO PHARMA (PTY) LTD |
| Manufacturer: | AUROBINDO PHARMA LTD, ANDHRA PRADESH, INDIA |
| Packer: | AUROBINDO PHARMA LTD, ANDHRA PRADESH, INDIA |
| Laboratory:FPRC: | AUROBINDO PHARMA LTD, ANDHRA PRADESH, INDIA |
| FPRR: | AUROBINDO PHARMA, ROSEBANK, JOHANNESBURG, RSA |
| Shelf-life: | 24 months (provisional) |
| Date of registration: | 6 OCTOBER 2006 |

MRF 15

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|---|---|
| Registration number: | A40/20.2.8/0532 |
| Name of medicine: | AURO-STAVUDINE CAPSULES 40 mg |
| Dosage form: | CAPSULES |
| Active ingredients: | EACH CAPSULE CONTAINS:<br>STAVUDINE 40,0 mg |
| Conditions of registration: | 1, 2, 3, 4, 5, 6 |
| Applicant: | AUROBINDO PHARMA (PTY) LTD |
| Manufacturer: | AUROBINDO PHARMA LTD, ANDHRA PRADESH, INDIA |
| Packer: | AUROBINDO PHARMA LTD, ANDHRA PRADESH, INDIA |
| Laboratory:FPRC: | AUROBINDO PHARMA LTD, ANDHRA PRADESH, INDIA |
| FPRR: | AUROBINDO PHARMA, ROSEBANK, JOHANNESBURG, RSA |
| Shelf-life: | 24 months (provisional) |
| Date of registration: | 6 OCTOBER 2006 |

MRF 15

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|---|---|
| Registration number: | A40/20.1.2/0563 |
| Name of medicine: | AMYN S 250 |
| Dosage form: | SUSPENSION |
| Active ingredients: | EACH 5,0 ml SUSPENSION CONTAINS:<br>AMOXYCILLIN TRIHYDRATE EQUIVALENT TO<br>AMOXYCILLIN 250,0 mg |
| Conditions of registration: | 1, 2, 3, 4, 5, 6 |
| Applicant: | DEZZO TRADING (PTY) LTD t/a INDO PHARMA |
| Manufacturer: | KOPRAN LTD, KHALAPUR, RAIGAD, INDIA |
| Packer: | KOPRAN LTD, KHALAPUR, RAIGAD, INDIA |
| Laboratory:FPRC: | KOPRAN LTD, KHALAPUR, RAIGAD, INDIA<br>CONSULTING CHEMICAL LABORATORIES,<br>ATLASVILLE, BOKSBURG, RSA |
| FPRR: | DEZZO TRADING, LENASIA, JOHANNESBURG |
| Shelf-life: | 24 months (provisional) |
| Date of registration: | 6 OCTOBER 2006 |

MRF 15

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|---|---|
| Registration number: | 41/4/0063 |
| Name of medicine: | LIGNOCAINE-HCl B BRAUN 1 % 10 ml |
| Dosage form: | INJECTION |
| Active ingredients: | EACH 1,0 ml SOLUTION CONTAINS:<br>LIGNOCAINE HYDROCHLORIDE 10,0 mg |
| Conditions of registration: | 1, 2, 3, 4, 5, 6 |
| Applicant: | B BRAUN MEDICAL (PTY) LTD |
| Manufacturer: | B BRAUN MELSUNGEN AG, BERLIN, GERMANY |
| Packer: | B BRAUN MELSUNGEN AG, BERLIN, GERMANY |
| Laboratory:FPRC: | B BRAUN MELSUNGEN AG, BERLIN, GERMANY<br>CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA |
| FPRR: | B BRAUN MEDICAL, HONEYDEW, GAUTENG, RSA |
| Shelf-life: | 24 months |
| Date of registration: | 6 OCTOBER 2006 |

MRF 15

| | |
|---|---|
| Registration number: | 41/4/0064 |
| Name of medicine: | LIGNOCAINE-HCl B BRAUN 1 % 20 ml |
| Dosage form: | INJECTION |
| Active ingredients: | EACH 1,0 ml SOLUTION CONTAINS:<br>LIGNOCAINE HYDROCHLORIDE 10,0 mg |
| Conditions of registration: | 1, 2, 3, 4, 5, 6 |
| Applicant: | B BRAUN MEDICAL (PTY) LTD |
| Manufacturer: | B BRAUN MELSUNGEN AG, BERLIN, GERMANY |
| Packer: | B BRAUN MELSUNGEN AG, BERLIN, GERMANY |
| Laboratory:FPRC: | B BRAUN MELSUNGEN AG, BERLIN, GERMANY<br>CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA |
| FPRR: | B BRAUN MEDICAL, HONEYDEW, GAUTENG, RSA |
| Shelf-life: | 36 months |
| Date of registration: | 6 OCTOBER 2006 |

MRF 15

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|---|---|
| Registration number: | 41/4/0065 |
| Name of medicine: | LIGNOCAINE-HCl B BRAUN 2 % 10 ml |
| Dosage form: | INJECTION |
| Active ingredients: | EACH 1,0 ml SOLUTION CONTAINS:<br>LIGNOCAINE HYDROCHLORIDE 20,0 mg |
| Conditions of registration: | 1, 2, 3, 4, 5, 6 |
| Applicant: | B BRAUN MEDICAL (PTY) LTD |
| Manufacturer: | B BRAUN MELSUNGEN AG, BERLIN, GERMANY |
| Packer: | B BRAUN MELSUNGEN AG, BERLIN, GERMANY |
| Laboratory:FPRC: | B BRAUN MELSUNGEN AG, BERLIN, GERMANY<br>CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA |
| FPRR: | B BRAUN MEDICAL, HONEYDEW, GAUTENG, RSA |
| Shelf-life: | 24 months |
| Date of registration: | 6 OCTOBER 2006 |

MRF 15

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|---|---|
| Registration number: | 41/4/0066 |
| Name of medicine: | LIGNOCAINE-HCl B BRAUN 2 % 20 ml |
| Dosage form: | INJECTION |
| Active ingredients: | EACH 1,0 ml SOLUTION CONTAINS:<br>LIGNOCAINE HYDROCHLORIDE 20,0 mg |
| Conditions of registration: | 1, 2, 3, 4, 5, 6 |
| Applicant: | B BRAUN MEDICAL (PTY) LTD |
| Manufacturer: | B BRAUN MELSUNGEN AG, BERLIN, GERMANY |
| Packer: | B BRAUN MELSUNGEN AG, BERLIN, GERMANY |
| Laboratory:FPRC: | B BRAUN MELSUNGEN AG, BERLIN, GERMANY<br>CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA |
| FPRR: | B BRAUN MEDICAL, HONEYDEW, GAUTENG, RSA |
| Shelf-life: | 36 months |
| Date of registration: | 6 OCTOBER 2006 |