# GENERAL NOTICE
# ALGEMENE KENNISGEWING

## NOTICE 905 OF 2008

### CONDITIONS OF REGISTRATION OF A MEDICINE IN TERMS OF THE PROVISIONS OF SECTION 15(7) OF THE MEDICINES AND RELATED SUBSTANCES ACT, 1965 (ACT 101 OF 1965)

1. The applicant shall ensure that the medicine is manufactured and controlled in terms of the 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 101 of 1965).
5. The registration of this medicine shall be subject to review at intervals as determined by Council 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 product may be advertised to the professions only.
8. The provisional shelf-life allocated must be confirmed with stability data over the full shelf-life period on the first two production batches (well-known API) or first three production batches (NCE) in accordance with the Stability Guideline. Stability testing submitted on any pilot batches must also be completed and reported on. The stability report must be submitted within six months after completion of the stability trial. However, Council has to be informed immediately if any parameter shows a significant change or out-of-specification result during the stability trial.
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.

MRF 15

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|---|---|---|
| Registration number: | | 36/7.5/0281 |
| Name of medicine: | | BEZACHOLE SR |
| Dosage form: | | TABLET |
| Active ingredients: | | EACH TABLET CONTAINS:<br>BEZAFIBRATE 400,0 mg |
| Conditions of registration: | | 1, 2, 3, 4, 5, 6, 7 |
| Applicant: | | PHARMACARE LIMITED |
| Manufacturer: | | VALPHARMA INTERNATIONAL S.p.A., PENNABILLI, PERSARO-URBINO, ITALY |
| Packer: | | ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON<br>PHARMACARE LTD, KORSTEN, PORT ELIZABETH |
| Laboratory: | FPRC: | VALPHARMA INTERNATIONAL S.p.A., PENNABILLI, PERSARO-URBINO, ITALY<br>SEDEK AGRIKEM, KAMEELDRIFT EAST, PRETORIA<br>INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA<br>SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA<br>M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG<br>RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM<br>ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON |
| | FPRC/FPRR: | PHARMACARE LTD, KORSTEN, PORT ELIZABETH |
| Shelf-life: | | 24 months |
| Date of registration: | | 18 APRIL 2008 |

MRF 15

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|---|---|---|
| Registration number: | | 37/26/0483 |
| Name of medicine: | | NEOTALEM |
| Dosage form: | | INJECTION |
| Active ingredients: | | EACH 10,0 ml VIAL CONTAINS:<br>MITOXANTRONE HYDROCHLORIDE EQUIVALENT TO MITOXANTRONE 20,0 mg |
| Conditions of registration: | | 1, 2, 3, 4, 5, 6, 7 |
| Applicant: | | KEY ONCOLOGICS (PTY) LTD |
| Manufacturer: | | LEMERY S.A. de C.V, HUICHAPAN, XOCH, MEXICO |
| Packer: | | LEMERY S.A. de C.V, HUICHAPAN, XOCH, MEXICO |
| Laboratory: | FPRC: | LEMERY S.A. de C.V, HUICHAPAN, XOCH, MEXICO<br>INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA |
| | FPRR: | KEY ONCOLOGICS, SANDTON, JOHANNESBURG |
| Shelf-life: | | 24 months |
| Date of registration: | | 18 APRIL 2008 |

MRF 15

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|---|---|---|
| Registration number: | | 38/7.1.3/0032 |
| Name of medicine: | | AUSTELL-LISINOPRIL 10 mg |
| Dosage form: | | TABLET |
| Active ingredients: | | EACH TABLET CONTAINS:<br>LISINOPRIL DIHYDRATE EQUIVALENT TO<br>LISINOPRIL 10,0 mg |
| Conditions of registration: | | 1, 2, 3, 4, 5, 6, 7 |
| Applicant: | | AUSTELL LABORATORIES (PTY) LTD |
| Manufacturer: | | IPCA LABORATORIES LTD, SILVASSA, DADRA & NAGAR HAVELI, INDIA |
| Packer: | | IPCA LABORATORIES LTD, SILVASSA, DADRA & NAGAR HAVELI, INDIA |
| Laboratory: | FPRC: | IPCA LABORATORIES LTD, SILVASSA, DADRA & NAGAR HAVELI, INDIA<br>SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA |
| | FPRR: | AUSTELL LABORATORIES, SPRINGFIELD, JOHANNESBURG |
| Shelf-life: | | 36 months |
| Date of registration: | | 18 APRIL 2008 |

MRF 15

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|---|---|---|
| Registration number: | | 38/7.1.3/0033 |
| Name of medicine: | | AUSTELL-LISINOPRIL 5 mg |
| Dosage form: | | TABLET |
| Active ingredients: | | EACH TABLET CONTAINS:<br>LISINOPRIL DIHYDRATE EQUIVALENT TO<br>LISINOPRIL 5,0 mg |
| Conditions of registration: | | 1, 2, 3, 4, 5, 6, 7 |
| Applicant: | | AUSTELL LABORATORIES (PTY) LTD |
| Manufacturer: | | IPCA LABORATORIES LTD, SILVASSA, DADRA & NAGAR HAVELI, INDIA |
| Packer: | | IPCA LABORATORIES LTD, SILVASSA, DADRA & NAGAR HAVELI, INDIA |
| Laboratory: | FPRC: | IPCA LABORATORIES LTD, SILVASSA, DADRA & NAGAR HAVELI, INDIA<br>SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA |
| | FPRR: | AUSTELL LABORATORIES, SPRINGFIELD, JOHANNESBURG |
| Shelf-life: | | 36 months |
| Date of registration: | | 18 APRIL 2008 |

MRF 15

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|---|---|---|
| Registration number: | | 38/26/0057 |
| Name of medicine: | | LITAK 10 |
| Dosage form: | | INJECTION |
| Active ingredients: | | EACH 5,0 ml VIAL CONTAINS:<br>CLADRIBINE 10,0 mg |
| Conditions of registration: | | 1, 2, 3, 4, 5, 6, 7 |
| Applicant: | | KEY ONCOLOGICS (PTY) LTD |
| Manufacturer: | | HAUPT PHARMA GmbH, WOLFRATSHAUSEN, GERMANY |
| Packer: | | HAUPT PHARMA GmbH, WOLFRATSHAUSEN, GERMANY |
| Laboratory: | FPRC: | HAUPT PHARMA GmbH, WOLFRATSHAUSEN, GERMANY<br>LIPOMED AG, ARLESHEIM, SWITZERLAND<br>INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA |
| | FPRR: | KEY ONCOLOGICS, SANDTON, JOHANNESBURG |
| Shelf-life: | | 24 months |
| Date of registration: | | 18 APRIL 2008 |

MRF 15

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|---|---|---|
| Registration number: | | 38/20.1.1/0204 |
| Name of medicine: | | CEFUROXIME-SAFELINE 1,5 g |
| Dosage form: | | INJECTION |
| Active ingredients: | | EACH VIAL CONTAINS:<br>CEFUROXIME SODIUM EQUIVALENT TO CEFUROXIME 1,5 g |
| Conditions of registration: | | 1, 2, 3, 4, 5, 6, 7 |
| Applicant: | | SAFELINE PHARMACEUTICALS (PTY) LTD |
| Manufacturer: | | DEMO S.A. PHARMACEUTICAL, KRYONERI, ATHENS, GREECE |
| Packer: | | DEMO S.A. PHARMACEUTICAL, KRYONERI, ATHENS, GREECE |
| Laboratory: | FPRC: | DEMO S.A. PHARMACEUTICAL, KRYONERI, ATHENS, GREECE<br>INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA |
| | FPRR: | SAFELINE PHARMACEUTICALS, FLORIDA, JOHANNESBURG |
| Shelf-life: | | 24 months |
| Date of registration: | | 18 APRIL 2008 |

MRF 15

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|---|---|---|
| Registration number: | | 38/20.1.1/0205 |
| Name of medicine: | | CEFUROXIME-SAFELINE 750 mg |
| Dosage form: | | INJECTION |
| Active ingredients: | | EACH VIAL CONTAINS:<br>CEFUROXIME SODIUM EQUIVALENT TO<br>CEFUROXIME 750 mg |
| Conditions of registration: | | 1, 2, 3, 4, 5, 6, 7 |
| Applicant: | | SAFELINE PHARMACEUTICALS (PTY) LTD |
| Manufacturer: | | DEMO S.A. PHARMACEUTICAL, KRYONERI, ATHENS, GREECE |
| Packer: | | DEMO S.A. PHARMACEUTICAL, KRYONERI, ATHENS, GREECE |
| Laboratory: | FPRC: | DEMO S.A. PHARMACEUTICAL, KRYONERI, ATHENS, GREECE<br>INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA |
| | FPRR: | SAFELINE PHARMACEUTICALS, FLORIDA, JOHANNESBURG |
| Shelf-life: | | 24 months |
| Date of registration: | | 18 APRIL 2008 |

MRF 15

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|---|---|---|
| Registration number: | | A04/3.1.5/08 |
| Name of medicine: | | TILDREN |
| Dosage form: | | INJECTION |
| Active ingredients: | | EACH VIAL CONTAINS:<br>TILUDRONIC ACID 50,0 mg |
| Conditions of registration: | | 1, 2, 3, 4, 5, 6, 7 |
| Applicant: | | CEVA ANCHORPHARM ANIMAL HEALTH S.A (PTY) LTD |
| Manufacturer: | | CEVA SANTE ANIMALE SA, CEDEX, FRANCE<br>CEVA LABORATOIRES STERILYO, SANT AMAND LES EAUX, FRANCE |
| Packer: | | CEVA SANTE ANIMALE SA, CEDEX, FRANCE |
| Laboratory: | FPRC: | CEVA SANTE ANIMALE SA, CEDEX, FRANCE<br>CEVA LABORATOIRES STERILYO, SANT AMAND LES EAUX, FRANCE<br>CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG |
| | FPRR: | CEVA ANCHORPHARM ANIMAL HEALTH, BRAMLEY, JOHANNESBURG |
| Shelf-life: | | 36 months |
| Date of registration: | | 18 APRIL 2008 |

MRF 15

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|---|---|
| Registration number: | A05/22.6.2/10 |
| Name of medicine: | ALIZINE |
| Dosage form: | INJECTION |
| Active ingredients: | EACH 1,0 ml SOLUTION CONTAINS:<br>AGLEPRISTONE 30,0 mg |
| Conditions of registration: | 1, 2, 3, 4, 5, 6, 7 |
| Applicant: | VIRBAC RSA (PTY) LTD |
| Manufacturer: | VIRBAC SA, CEDEX, FRANCE |
| Packer: | VIRBAC SA, CEDEX, FRANCE<br>VIRBAC RSA, CENTURION, RSA |
| Laboratory: FPRC: | VIRBAC SA, CEDEX, FRANCE<br>M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG |
| FPRR | VIRBAC RSA, CENTURION, RSA |
| Shelf-life: | 36 months |
| Date of registration: | 18 APRIL 2008 |

MRF 15

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| Registration number: | A38/3.2/0381 |
| Name of medicine: | BONDRONAT 6 mg/6 ml |
| Dosage form: | INJECTION |
| Active ingredients: | EACH VIAL CONTAINS:<br>IBANDRONIC ACID 6,0 mg |
| Conditions of registration: | 1, 2, 3, 4, 5, 6, 7 |
| Applicant: | ROCHE PRODUCTS (PTY) LTD |
| Manufacturer: | ROCHE DIAGNOSTIC GmbH, MANNHEIM, GERMANY |
| Packer: | ROCHE DIAGNOSTIC GmbH, MANNHEIM, GERMANY<br>ROCHE PRODUCTS, ISANDO, RSA |
| Laboratory: FPRC: | ROCHE DIAGNOSTIC GmbH, MANNHEIM, GERMANY |
| FPRC/FPRR: | ROCHE PRODUCTS, ISANDO, RSA |
| Shelf-life: | 60 months |
| Date of registration: | 18 APRIL 2008 |

MRF 15

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| Registration number: | A39/21.12/0064 |
| Name of medicine: | CETROTIDE 0,25 mg |
| Dosage form: | INJECTION |
| Active ingredients: | EACH VIAL CONTAINS:<br>CETRORELIX ACETATE EQUIVALENT TO<br>CETRORELIX 0,25 mg |
| Conditions of registration: | 1, 2, 3, 4, 5, 6, 7 |
| Applicant: | MERCK (PTY) LTD |
| Manufacturer: | BAXTER ONCOLOGY GmbH, HALLE, GERMANY |
| Packer: | BAXTER ONCOLOGY GmbH, HALLE, GERMANY<br>SOLVAY PHARMACEUTICALS BV, OLST, THE NETHERLANDS |
| Laboratory: FPRC: | BAXTER ONCOLOGY GmbH, HALLE, GERMANY<br>SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA |
| FPRR | MERCK, MODDERFONTEIN, RSA |
| Shelf-life: | 24 months |
| Date of registration: | 18 APRIL 2008 |

MRF 15

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|---|---|
| Registration number: | A39/21.12/0065 |
| Name of medicine: | CETROTIDE 3 mg |
| Dosage form: | INJECTION |
| Active ingredients: | EACH VIAL CONTAINS:<br>CETRORELIX ACETATE EQUIVALENT TO<br>CETRORELIX 3,0 mg |
| Conditions of registration: | 1, 2, 3, 4, 5, 6, 7 |
| Applicant: | MERCK (PTY) LTD |
| Manufacturer: | BAXTER ONCOLOGY GmbH, HALLE, GERMANY |
| Packer: | BAXTER ONCOLOGY GmbH, HALLE, GERMANY<br>SOLVAY PHARMACEUTICALS BV, OLST, THE NETHERLANDS |
| Laboratory: FPRC | BAXTER ONCOLOGY GmbH, HALLE, GERMANY<br>SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA |
| FPRR | MERCK, MODDERFONTEIN, RSA |
| Shelf-life: | 24 months |
| Date of registration: | 18 APRIL 2008 |

MRF 15

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|---|---|---|
| Registration number: | | A39/2.1/0077 |
| Name of medicine: | | B. BRAUN PROPOFOL 1 % (10 mg/ml) |
| Dosage form: | | EMULSION |
| Active ingredients: | | EACH 1,0 ml EMULSION CONTAINS:<br>PROPOFOL 10,0 mg |
| Conditions of registration: | | 1, 2, 3, 4, 5, 6, 7 |
| 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, ATLASVILLE, BOKSBURG |
| | FPRR: | B BRAUN MEDICAL, HONEYDEW, RANDBURG |
| Shelf-life: | | 24 months |
| Date of registration: | | 18 APRIL 2008 |

MRF 15

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|---|---|---|
| Registration number: | | A39/30.4/0417 |
| Name of medicine: | | CEPROTIN 500 iu |
| Dosage form: | | INJECTION |
| Active ingredients: | | EACH VIAL CONTAINS:<br>PROTEIN C 500,0 iu |
| Conditions of registration: | | 1, 2, 3, 4, 5, 6, 7 |
| Applicant: | | ADCOCK INGRAM CRITICAL CARE (PTY) LTD |
| Manufacturer: | | BAXTER AG, INDUSTRIESTRASSE, VIENNA, AUSTRIA<br>BAXTER AG, BENATZKYGASSE, VIENNA, AUSTRIA<br>BAXTER S.p.A., RUFINA, ITALY |
| Packer: | | BAXTER AG, INDUSTRIESTRASSE, VIENNA, AUSTRIA<br>ADCOCK INGRAM CRITICAL CARE, AEROTON, JOHANNESBURG |
| Laboratory: | FPRC: | BAXTER AG, SMOLAGASSE, VIENNA, AUSTRIA |
| | FPRC/FPRR: | ADCOCK INGRAM CRITICAL CARE, AEROTON, JOHANNESBURG |
| Shelf-life: | | 24 months |
| Date of registration: | | 18 APRIL 2008 |

MRF 15

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| Registration number: | A39/30.4/0418 |
| Name of medicine: | CEPROTIN 1000 iu |
| Dosage form: | INJECTION |
| Active ingredients: | EACH VIAL CONTAINS:<br>PROTEIN C 1000,0 iu |
| Conditions of registration: | 1, 2, 3, 4, 5, 6, 7 |
| Applicant: | ADCOCK INGRAM CRITICAL CARE (PTY) LTD |
| Manufacturer: | BAXTER AG, INDUSTRIESTRASSE, VIENNA, AUSTRIA<br>BAXTER AG, BENATZKYGASSE, VIENNA, AUSTRIA<br>BAXTER S.p.A., RUFINA, ITALY |
| Packer: | BAXTER AG, INDUSTRIESTRASSE, VIENNA, AUSTRIA<br>ADCOCK INGRAM CRITICAL CARE, AEROTON, JOHANNESBURG |
| Laboratory: FPRC: | BAXTER AG, SMOLAGASSE, VIENNA, AUSTRIA |
| FPRC/FPRR: | ADCOCK INGRAM CRITICAL CARE, AEROTON, JOHANNESBURG |
| Shelf-life: | 24 months |
| Date of registration: | 18 APRIL 2008 |

MRF 15

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| Registration number: | A39/1.2/0500 |
| Name of medicine: | TAZERON 15 mg |
| Dosage form: | TABLET |
| Active ingredients: | EACH TABLET CONTAINS:<br>MIRTAZAPINE 15,0 mg |
| Conditions of registration: | 1, 2, 3, 4, 5, 6, 7 |
| Applicant: | PHARMAPLAN (PTY) LTD |
| Manufacturer: | KERN PHARMA S.L., TERRASSA, BARCELONA, SPAIN |
| Packer: | KERN PHARMA S.L., TERRASSA, BARCELONA, SPAIN |
| Laboratory: FPRC: | COMBINO PHARM S.L., SANT JOAN DESPI, BACELONA, SPAIN<br>CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG |
| FPRR: | PHARMAPLAN, MIDRAND, RSA |
| Shelf-life: | 24 months |
| Date of registration: | 18 APRIL 2008 |

MRF 15

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|---|---|---|
| Registration number: | | A39/1.2/0501 |
| Name of medicine: | | TAZERON 30 mg |
| Dosage form: | | TABLET |
| Active ingredients: | | EACH TABLET CONTAINS:<br>MIRTAZAPINE 30,0 mg |
| Conditions of registration: | | 1, 2, 3, 4, 5, 6, 7 |
| Applicant: | | PHARMAPLAN (PTY) LTD |
| Manufacturer: | | KERN PHARMA S.L., TERRASSA, BARCELONA, SPAIN |
| Packer: | | KERN PHARMA S.L., TERRASSA, BARCELONA, SPAIN |
| Laboratory: | FPRC: | COMBINO PHARM S.L., SANT JOAN DESPI, BACELONA, SPAIN<br>CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG |
| | FPRR: | PHARMAPLAN, MIDRAND, RSA |
| Shelf-life: | | 24 months |
| Date of registration: | | 18 APRIL 2008 |

MRF 15

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|---|---|---|
| Registration number: | | A39/21.5.1/0584 |
| Name of medicine: | | SANDOZ BECLOMETHASONE DIPROPIONATE AQ 100 |
| Dosage form: | | SUSPENSION |
| Active ingredients: | | EACH METERED NASAL SPRAY DOSE CONTAINS:<br>BECLOMETHASONE DIPROPIONATE 100,0 ug |
| Conditions of registration: | | 1, 2, 3, 4, 5, 6, 7 |
| Applicant: | | SANDOZ S.A. (PTY) LTD |
| Manufacturer: | | CHIESI FARMACEUTICI SpA, LEONARDO, PARMA, ITALY |
| Packer: | | CHIESI FARMACEUTICI SpA, LEONARDO, PARMA, ITALY<br>CHIESI FARMACEUTICI SpA, PALERMO, PARMA, ITALY<br>NOVARTIS S.A., SPARTAN, KEMPTON PARK |
| Laboratory: | FPRC: | CHIESI FARMACEUTICI SpA, LEONARDO, PARMA, ITALY<br>SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA<br>NOVARTIS S.A., SPARTAN, KEMPTON PARK |
| | FPRR: | SANDOZ S.A., SPARTAN, KEMPTON PARK |
| Shelf-life: | | 36 months |
| Date of registration: | | 18 APRIL 2008 |

MRF 15

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|---|---|---|
| Registration number: | | A40/13.4.1/0035 |
| Name of medicine: | | CLOBEX SHAMPOO |
| Dosage form: | | SHAMPOO |
| Active ingredients: | | EACH 1,0 g SHAMPOO CONTAINS:<br>CLOBETASOL PROPIONATE 0,5 mg |
| Conditions of registration: | | 1, 2, 3, 4, 5, 6, 7 |
| Applicant: | | GALDERMA LABORATORIES S.A. (PTY) LTD |
| Manufacturer: | | LABORATOIRES GALDERMA, MONTDESIR, ALBY-SUR-CHERAN, FRANCE |
| Packer: | | LABORATOIRES GALDERMA, MONTDESIR, ALBY-SUR-CHERAN, FRANCE |
| Laboratory: | FPRC: | LABORATOIRES GALDERMA, MONTDESIR, ALBY-SUR-CHERAN, FRANCE |
| | FPRR: | GALDERMA LABORATORIES S.A., BRYANSTON, JOHANNESBURG |
| Shelf-life: | | 36 months |
| Date of registration: | | 18 APRIL 2008 |

MRF 15

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|---|---|---|
| Registration number: | | A40/34/0045 |
| Name of medicine: | | CIPLA-TAMSULOSIN HYDROCHLORIDE |
| Dosage form: | | CAPSULE |
| Active ingredients: | | EACH CAPSULE CONTAINS:<br>TAMSULOSIN HYDROCHLORIDE 400,0 ug |
| Conditions of registration: | | 1, 2, 3, 4, 5, 6, 7 |
| Applicant: | | CIPLA LIFE SCIENCES (PTY) LTD |
| Manufacturer: | | CIPLA LTD, VIRGONAGAR, BANGALORE, INDIA |
| Packer: | | CIPLA LTD, VIRGONAGAR, BANGALORE, INDIA |
| Laboratory: | FPRC: | CIPLA LTD, VIRGONAGAR, BANGALORE, INDIA |
| | FPRR: | CIPLA LIFE SCIENCES, ROSENPARK, BELLVILLE |
| Shelf-life: | | 24 months |
| Date of registration: | | 18 APRIL 2008 |

MRF 15

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|---|---|---|
| Registration number: | | A40/34/0046 |
| Name of medicine: | | UROMAX |
| Dosage form: | | CAPSULE |
| Active ingredients: | | EACH CAPSULE CONTAINS:<br>TAMSULOSIN HYDROCHLORIDE 400,0 ug |
| Conditions of registration: | | 1, 2, 3, 4, 5, 6, 7 |
| Applicant: | | CIPLA MEDPRO (PTY) LTD |
| Manufacturer: | | CIPLA LTD, VIRGONAGAR, BANGALORE, INDIA |
| Packer: | | CIPLA LTD, VIRGONAGAR, BANGALORE, INDIA |
| Laboratory: | FPRC: | CIPLA LTD, VIRGONAGAR, BANGALORE, INDIA |
| | FPRR: | CIPLA MEDPRO, ROSENPARK, BELLVILLE |
| Shelf-life: | | 24 months |
| Date of registration: | | 18 APRIL 2008 |

MRF 15

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|---|---|---|
| Registration number: | | A40/20.1.1/0102 |
| Name of medicine: | | ZITHROMAX ONE |
| Dosage form: | | GRANULES |
| Active ingredients: | | EACH BOTTLE CONTAINS:<br>AZITHROMYCIN DIHYDRATE EQUIVALENT TO<br>AZITHROMYCIN 2,0 g |
| Conditions of registration: | | 1, 2, 3, 4, 5, 6, 7 |
| Applicant: | | PFIZER LABORATORIES (PTY) LTD |
| Manufacturer: | | PFIZER PHARMACEUTICALS LLC, VEGA BAJA, PUERTO RICO |
| Packer: | | PFIZER PHARMACEUTICALS LLC, VEGA BAJA, PUERTO RICO<br>PFIZER ITALIA s.r.l., LATINA, ITALY<br>PFIZER GLOBAL MANUFACTURING, RETREAT, CAPE TOWN |
| Laboratory: | FPRC: | PFIZER PHARMACEUTICALS LLC, VEGA BAJA, PUERTO RICO<br>PFIZER ITALIA s.r.l., LATINA, ITALY |
| | FPRC/FPRR: | PFIZER GLOBAL MANUFACTURING, RETREAT, CAPE TOWN |
| | FPRR | PFIZER LABORATORIES, SANDTON, JOHANNESBURG |
| Shelf-life: | | 24 months |
| Date of registration: | | 18 APRIL 2008 |

MRF 15

| | | |
|---|---|---|
| Registration number: | | A40/21.2/0132 |
| Name of medicine: | | GLIMPID 1 |
| Dosage form: | | TABLET |
| Active ingredients: | | EACH TABLET CONTAINS:<br>GLIMEPIRIDE 1,0 mg |
| Conditions of registration: | | 1, 2, 3, 4, 5, 6, 7, 8 |
| Applicant: | | RANBAXY (SA) (PTY) LTD |
| Manufacturer: | | RANBAXY LABORATORIES LTD, PAONTA SAHIB, HIMACHAL PRADESH, INDIA |
| Packer: | | RANBAXY LABORATORIES LTD, PAONTA SAHIB, HIMACHAL PRADESH, INDIA |
| Laboratory: | FPRC: | RANBAXY LABORATORIES LTD, PAONTA SAHIB, HIMACHAL PRADESH, INDIA<br>CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA |
| | FPRR: | RANBAXY (SA), CENTURION, RSA |
| Shelf-life: | | 24 months (Provisional) |
| Date of registration: | | 18 APRIL 2008 |

MRF 15

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|---|---|---|
| Registration number: | | A40/21.2/0133 |
| Name of medicine: | | GLIMPID 2 |
| Dosage form: | | TABLET |
| Active ingredients: | | EACH TABLET CONTAINS:<br>GLIMEPIRIDE 2,0 mg |
| Conditions of registration: | | 1, 2, 3, 4, 5, 6, 7, 8 |
| Applicant: | | RANBAXY (SA) (PTY) LTD |
| Manufacturer: | | RANBAXY LABORATORIES LTD, PAONTA SAHIB, HIMACHAL PRADESH, INDIA |
| Packer: | | RANBAXY LABORATORIES LTD, PAONTA SAHIB, HIMACHAL PRADESH, INDIA |
| Laboratory: | FPRC: | RANBAXY LABORATORIES LTD, PAONTA SAHIB, HIMACHAL PRADESH, INDIA<br>CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA |
| | FPRR: | RANBAXY (SA), CENTURION, RSA |
| Shelf-life: | | 24 months (Provisional) |
| Date of registration: | | 18 APRIL 2008 |

MRF 15

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|---|---|---|
| Registration number: | | A40/21.2/0134 |
| Name of medicine: | | GLIMPID 4 |
| Dosage form: | | TABLET |
| Active ingredients: | | EACH TABLET CONTAINS:<br>GLIMEPIRIDE 4,0 mg |
| Conditions of registration: | | 1, 2, 3, 4, 5, 6, 7, 8 |
| Applicant: | | RANBAXY (SA) (PTY) LTD |
| Manufacturer: | | RANBAXY LABORATORIES LTD, PAONTA SAHIB, HIMACHAL PRADESH, INDIA |
| Packer: | | RANBAXY LABORATORIES LTD, PAONTA SAHIB, HIMACHAL PRADESH, INDIA |
| Laboratory: | FPRC: | RANBAXY LABORATORIES LTD, PAONTA SAHIB, HIMACHAL PRADESH, INDIA<br>CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA |
| | FPRR: | RANBAXY (SA), CENTURION, RSA |
| Shelf-life: | | 24 months (Provisional) |
| Date of registration: | | 18 APRIL 2008 |

MRF 15

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|---|---|---|
| Registration number: | | A40/2.5/0166 |
| Name of medicine: | | DYNA-LAMOTRIGINE 100 mg |
| Dosage form: | | TABLET |
| Active ingredients: | | EACH TABLET CONTAINS:<br>LAMOTRIGINE 100,0 mg |
| Conditions of registration: | | 1, 2, 3, 4, 5, 6, 7 |
| Applicant: | | PHARMA DYNAMICS (PTY) LTD |
| Manufacturer: | | MEDOCHEMIE LTD, LIMASSOL, CYPRUS |
| Packer: | | MEDOCHEMIE LTD, LIMASSOL, CYPRUS<br>DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG<br>TECHNIKON LABORATORIES, FLORIDA, RSA<br>PHARMACEUTICAL ENTERPRISES, N'DABENI, KZN<br>IMPILO DRUGS, ISITHEBE, KZN |
| Laboratory: | FPRC: | MEDOCHEMIE LTD, LIMASSOL, CYPRUS<br>CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA<br>TECHNIKON LABORATORIES, FLORIDA, RSA |
| | FPRR: | PHARMA DYNAMICS, SILVERWOOD, WESTLAKE, RSA |
| Shelf-life: | | 24 months |
| Date of registration: | | 18 APRIL 2008 |

MRF 15

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|---|---|---|
| Registration number: | | A40/2.5/0167 |
| Name of medicine: | | DYNA-LAMOTRIGINE 200 mg |
| Dosage form: | | TABLET |
| Active ingredients: | | EACH TABLET CONTAINS:<br>LAMOTRIGINE 200,0 mg |
| Conditions of registration: | | 1, 2, 3, 4, 5, 6, 7 |
| Applicant: | | PHARMA DYNAMICS (PTY) LTD |
| Manufacturer: | | MEDOCHEMIE LTD, LIMASSOL, CYPRUS |
| Packer: | | MEDOCHEMIE LTD, LIMASSOL, CYPRUS<br>DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG<br>TECHNIKON LABORATORIES, FLORIDA, RSA<br>PHARMACEUTICAL ENTERPRISES, N'DABENI, KZN |
| Laboratory: | FPRC: | MEDOCHEMIE LTD, LIMASSOL, CYPRUS<br>CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA<br>TECHNIKON LABORATORIES, FLORIDA, RSA |
| | FPRR: | PHARMA DYNAMICS, SILVERWOOD, WESTLAKE, RSA |
| Shelf-life: | | 24 months |
| Date of registration: | | 18 APRIL 2008 |

MRF 15

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|---|---|---|
| Registration number: | | A40/2.5/0169 |
| Name of medicine: | | DYNA-LAMOTRIGINE 50 mg |
| Dosage form: | | TABLET |
| Active ingredients: | | EACH TABLET CONTAINS:<br>LAMOTRIGINE 50,0 mg |
| Conditions of registration: | | 1, 2, 3, 4, 5, 6, 7 |
| Applicant: | | PHARMA DYNAMICS (PTY) LTD |
| Manufacturer: | | MEDOCHEMIE LTD, LIMASSOL, CYPRUS |
| Packer: | | MEDOCHEMIE LTD, LIMASSOL, CYPRUS<br>DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG<br>TECHNIKON LABORATORIES, FLORIDA, RSA<br>PHARMACEUTICAL ENTERPRISES, N'DABENI, KZN |
| Laboratory: | FPRC: | MEDOCHEMIE LTD, LIMASSOL, CYPRUS<br>CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA<br>TECHNIKON LABORATORIES, FLORIDA, RSA |
| | FPRR: | PHARMA DYNAMICS, SILVERWOOD, WESTLAKE, RSA |
| Shelf-life: | | 24 months |
| Date of registration: | | 18 APRIL 2008 |

MRF 15

| | | |
|---|---|---|
| Registration number: | | A40/2.5/0173 |
| Name of medicine: | | DYNA-LAMOTRIGINE 25 mg |
| Dosage form: | | TABLET |
| Active ingredients: | | EACH TABLET CONTAINS:<br>LAMOTRIGINE 25,0 mg |
| Conditions of registration: | | 1, 2, 3, 4, 5, 6, 7 |
| Applicant: | | PHARMA DYNAMICS (PTY) LTD |
| Manufacturer: | | MEDOCHEMIE LTD, LIMASSOL, CYPRUS |
| Packer: | | MEDOCHEMIE LTD, LIMASSOL, CYPRUS<br>DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG<br>TECHNIKON LABORATORIES, FLORIDA, RSA<br>PHARMACEUTICAL ENTERPRISES, N'DABENI, KZN |
| Laboratory: | FPRC: | MEDOCHEMIE LTD, LIMASSOL, CYPRUS<br>CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA<br>TECHNIKON LABORATORIES, FLORIDA, RSA |
| | FPRR: | PHARMA DYNAMICS, SILVERWOOD, WESTLAKE, RSA |
| Shelf-life: | | 24 months |
| Date of registration: | | 18 APRIL 2008 |

MRF 15

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|---|---|---|
| Registration number: | | A40/3.1/0240 |
| Name of medicine: | | CATAFAST-D TABLETS |
| Dosage form: | | TABLET |
| Active ingredients: | | EACH TABLET CONTAINS:<br>DICLOFENAC SODIUM 50,0 mg |
| Conditions of registration: | | 1, 2, 3, 4, 5, 6, 7 |
| Applicant: | | NOVARTIS SOUTH AFRICA (PTY) LTD |
| Manufacturer: | | NOVARTIS PHARMA GmbH, WEHR, GERMANY |
| Packer: | | NOVARTIS PHARMA GmbH, WEHR, GERMANY<br>NOVARTIS S.A., SPARTAN, KEMPTON PARK |
| Laboratory: | FPRC: | NOVARTIS PHARMA GmbH, WEHR, GERMANY<br>M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG |
| | FPRC/FPRR: | NOVARTIS S.A., SPARTAN, KEMPTON PARK |
| Shelf-life: | | 24 months |
| Date of registration: | | 18 APRIL 2008 |

MRF 15

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|---|---|
| Registration number: | A40/7.1.3/0287 |
| Name of medicine: | COIRBESARTAN WINTHROP 300/12,5 |
| Dosage form: | TABLET |
| Active ingredients: | EACH TABLET CONTAINS:<br>IRBESARTAN 300,0 mg<br>HYDROCHLOROTHIAZIDE 12,5 mg |
| Conditions of registration: | 1, 2, 3, 4, 5, 6, 7 |
| Applicant: | SANOFI-SYNTHELABO (PTY) LTD |
| Manufacturer: | BRISTOL-MYERS SQUIBB CO., EVANSVILLE INDIANA, USA<br>SANOFI WINTHROP INDUSTRIE, AMBARES, FRANCE |
| Packer: | SANOFI WINTHROP INDUSTRIE, AMBARES, FRANCE<br>AVENTIS PHARMA, WALTLOO, PRETORIA<br>PHARMACEUTICAL CONTRACTORS, ISANDO |
| Laboratory: FPRC: | SANOFI WINTHROP INDUSTRIE, AMBARES, FRANCE<br>M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG |
| FPRC/FPRR: | AVENTIS PHARMA, WALTLOO, PRETORIA |
| FPRR: | SANOFI-SYNTHELABO, MIDRAND, RSA |
| Shelf-life: | 36 months |
| Date of registration: | 18 APRIL 2008 |

MRF 15

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|---|---|
| Registration number: | A40/7.1.3/0290 |
| Name of medicine: | COIRBESARTAN WINTHROP 150/12,5 |
| Dosage form: | TABLET |
| Active ingredients: | EACH TABLET CONTAINS:<br>IRBESARTAN 150,0 mg<br>HYDROCHLOROTHIAZIDE 12,5 mg |
| Conditions of registration: | 1, 2, 3, 4, 5, 6, 7 |
| Applicant: | SANOFI-SYNTHELABO (PTY) LTD |
| Manufacturer: | BRISTOL-MYERS SQUIBB CO., EVANSVILLE INDIANA, USA<br>SANOFI WINTHROP INDUSTRIE, AMBARES, FRANCE |
| Packer: | SANOFI WINTHROP INDUSTRIE, AMBARES, FRANCE<br>AVENTIS PHARMA, WALTLOO, PRETORIA<br>PHARMACEUTICAL CONTRACTORS, ISANDO |
| Laboratory: FPRC: | SANOFI WINTHROP INDUSTRIE, AMBARES, FRANCE<br>M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG |
| FPRR: | AVENTIS PHARMA, WALTLOO, PRETORIA |
| Shelf-life: | SANOFI-SYNTHELABO, MIDRAND, RSA |
| Date of registration: | 36 months<br>18 APRIL 2008 |

MRF 15

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|---|---|
| Registration number: | A40/34/0299 |
| Name of medicine: | CYCLEAN |
| Dosage form: | SOLUTION |
| Active ingredients: | EACH 1,0 ml SOLUTION CONTAINS:<br>POLYHEXANIDE 0,1 µg |
| Conditions of registration: | 1, 2, 3 ,4, 5, 6, 8 |
| Applicant: | REVISION S.A. (PTY) LTD |
| Manufacturer: | SAUFLON PHARMACEUTICALS LTD, TWICKENHAM, MIDDLESEX, U.K. |
| Packer: | SAUFLON PHARMACEUTICALS LTD, TWICKENHAM, MIDDLESEX, U.K |
| Laboratory: FPRC: | SAUFLON PHARMACEUTICALS LTD, TWICKENHAM, MIDDLESEX, U.K<br>TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA, RSA |
| FPRR: | REVISION S.A., BEDFORDVIEW, JOHANNESBURG, RSA |
| Shelf-life: | 24 months (Provisional) |
| Date of registration: | 18 APRIL 2008 |

MRF 15

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|---|---|
| Registration number: | A40/20.1.1/0309 |
| Name of medicine: | LEVOFLOXACIN-WINTHROP 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, 7 |
| Applicant: | AVENTIS PHARMA (PTY) LTD |
| Manufacturer: | AVENTIS PHARMA SPECIALITES, COMPEIGNE, FRANCE |
| Packer: | AVENTIS PHARMA DEUTSCHLAND GmbH, FRANKFURT, GERMANY |
| Laboratory: FPRC: | AVENTIS PHARMA SPECIALITES, COMPEIGNE, FRANCE<br>AVENTIS PHARMA DEUTSCHLAND GmbH, FRANKFURT, GERMANY |
| FPRC/FPRR: | WINTHROP PHARMACEUTICALS, WALTLOO, PRETORIA |
| FPRR: | AVENTIS PHARMA, MIDRAND, RSA |
| Shelf-life: | 24 months |
| Date of registration: | 18 APRIL 2008 |

MRF 15

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|---|---|
| Registration number: | A40/20.1.1/0310 |
| Name of medicine: | LEVOFLOXACIN-WINTHROP 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, 7 |
| Applicant: | AVENTIS PHARMA (PTY) LTD |
| Manufacturer: | AVENTIS PHARMA SPECIALITES, COMPEIGNE, FRANCE |
| Packer: | AVENTIS PHARMA DEUTSCHLAND GmbH, FRANKFURT, GERMANY |
| Laboratory: FPRC: | AVENTIS PHARMA SPECIALITES, COMPEIGNE, FRANCE<br>AVENTIS PHARMA DEUTSCHLAND GmbH, FRANKFURT, GERMANY |
| FPRC/FPRR: | WINTHROP PHARMACEUTICALS, WALTLOO, PRETORIA |
| FPRR: | AVENTIS PHARMA, MIDRAND, RSA |
| **Shelf-life:** | **60 months** |
| **Date of registration:** | **18 APRIL 2008** |

MRF 15

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|---|---|
| Registration number: | A40/34/0314 |
| Name of medicine: | OCTREOTIDE HEXAL 0,05 mg |
| Dosage form: | INJECTION |
| Active ingredients: | EACH 1,0 ml SOLUTION CONTAINS:<br>OCTREOTIDE 0,05 mg |
| Conditions of registration: | 1, 2, 3, 4, 5, 6, 7 |
| Applicant: | HEXAL PHARMA (SA) (PTY |
| Manufacturer: | WASSERBURGER ARZNEIMITTELWERK GmbH, WASSERBURG AM INN, GERMANY |
| Packer: | WASSERBURGER ARZNEIMITTELWERK GmbH, WASSERBURG AM INN, GERMANY<br>SALUTAS PHARMA GmbH, BARLEBEN, GERMANY<br>DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG<br>TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA<br>PHARMA-Q, INDUSTRIA, JOHANNESBURG |
| Laboratory: FPRC: | WASSERBURGER ARZNEIMITTELWERK GmbH, WASSERBURG AM INN, GERMANY<br>SALUTAS PHARMA GmbH, BARLEBEN, GERMANY<br>LABOR L+S AG, BAD BOCKLET-GROSSENBACH, GERMANY<br>CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG<br>ANALYTICON, TERENURE, KEMPTON PARK |
| FPRR: | HEXAL PHARMA, PINETOWN, KZN |
| **Shelf-life:** | **24 months** |
| **Date of registration:** | **18 APRIL 2008** |

MRF 15

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|---|---|---|
| Registration number: | | A40/34/0315 |
| Name of medicine: | | OCTREOTIDE HEXAL 0,1 mg |
| Dosage form: | | INJECTION |
| Active ingredients: | | EACH 1,0 ml SOLUTION CONTAINS:<br>OCTREOTIDE 0,1 mg |
| Conditions of registration: | | 1, 2, 3, 4, 5, 6, 7 |
| Applicant: | | HEXAL PHARMA (SA) (PTY |
| Manufacturer: | | WASSERBURGER ARZNEIMITTELWERK GmbH, WASSERBURG AM INN, GERMANY |
| Packer: | | WASSERBURGER ARZNEIMITTELWERK GmbH, WASSERBURG AM INN, GERMANY<br>SALUTAS PHARMA GmbH, BARLEBEN, GERMANY<br>DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG<br>TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA<br>PHARMA-Q, INDUSTRIA, JOHANNESBURG |
| Laboratory: | FPRC: | WASSERBURGER ARZNEIMITTELWERK GmbH, WASSERBURG AM INN, GERMANY<br>SALUTAS PHARMA GmbH, BARLEBEN, GERMANY<br>LABOR L+S AG, BAD BOCKLET-GROSSENBACH, GERMANY<br>CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG<br>ANALYTICON, TERENURE, KEMPTON PARK |
| | FPRR: | HEXAL PHARMA, PINETOWN, KZN |
| Shelf-life: | | 24 months |
| Date of registration: | | 18 APRIL 2008 |

MRF 15

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|---|---|---|
| Registration number: | | A40/20.1.1/0522 |
| Name of medicine: | | TOBI 300 mg/5 ml |
| Dosage form: | | SOLUTION |
| Active ingredients: | | EACH 5,0 ml SOLUTION CONTAINS:<br>TOBRAMYCIN 300,0 mg |
| Conditions of registration: | | 1, 2, 3, 4, 5, 6, 7 |
| Applicant: | | NOVARTIS SA (PTY) LTD |
| Manufacturer: | | CARDINAL HEALTH INC, WOODSTOCK, ILLINOIS, USA |
| Packer: | | CARDINAL HEALTH INC, WOODSTOCK, ILLINOIS, USA<br>CARDINAL HEALTH LTD, BOLTON, LANCASHIRE, UK |
| Laboratory: | FPRC: | CARDINAL HEALTH LTD, BOLTON, LANCASHIRE, UK<br>CHIRON CORPORATION, ANNANDALE, NEW JERSEY, USA<br>TEPNEL LIFE SCIENCES, EDINBURGH, UK<br>INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA |
| | FPRR: | NOVARTIS SA, SPARTAN, KEMPTON PARK |
| Shelf-life: | | 36 months |
| Date of registration: | | 18 APRIL 2008 |

MRF 15

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|---|---|
| Registration number: | A40/21.5.1/0524 |
| Name of medicine: | AP METHYLPRED |
| Dosage form: | INJECTION |
| Active ingredients: | EACH 8,0 ml SOLUTION CONTAINS:<br>METHYLPREDNISOLONE SODIUM SUCCINATE EQUIVALENT TO<br>METHYLPREDNISOLONE 500,0 mg |
| Conditions of registration: | 1, 2, 3, 4, 5, 6, 7, 8 |
| Applicant: | PHARMACARE LIMITED |
| Manufacturer: | STRIDES ARCOLAB, ANEKAL TALUK, BANGALORE, INDIA |
| Packer: | STRIDES ARCOLAB, ANEKAL TALUK, BANGALORE, INDIA<br>ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON<br>PHARMACARE LTD, KORSTEN, PORT ELIZABETH |
| Laboratory: FPRC: | STRIDES ARCOLAB, ANEKAL TALUK, BANGALORE, INDIA<br>M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG<br>SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA<br>RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM |
| FPRC/FPRR: | ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON<br>PHARMACARE LTD, KORSTEN, PORT ELIZABETH |
| Shelf-life: | 24 months (Provisional) |
| Date of registration: | 18 APRIL 2008 |

MRF 15

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|---|---|
| Registration number: | A40/20.2.8/0619 |
| Name of medicine: | SONKE-LASTAD 30 |
| Dosage form: | TABLET |
| Active ingredients: | EACH TABLET CONTAINS:<br>LAMIVUDINE 150,0 mg<br>STAVUDINE 30,0 mg |
| Conditions of registration: | 1, 2, 3, 4, 5, 6, 7, 8 |
| Applicant: | RANBAXY (S.A.) (PTY) LTD |
| Manufacturer: | RANBAXY LABORATORIES LTD, PAONTA SAHIB, DISTRICT SIRMOUR, HIMACHAL PRADESH, INDIA |
| Packer: | RANBAXY LABORATORIES LTD, PAONTA SAHIB, DISTRICT SIRMOUR, HIMACHAL PRADESH, INDIA |
| Laboratory: FPRC: | RANBAXY LABORATORIES LTD, PAONTA SAHIB, DISTRICT SIRMOUR, HIMACHAL PRADESH, INDIA<br>CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG |
| FPRR: | RANBAXY, CENTURION, RSA |
| Shelf-life: | 24 months (provisional) |
| Date of registration: | 18 APRIL 2008 |

MRF 15

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|---|---|---|
| Registration number: | | A40/20.2.8/0620 |
| Name of medicine: | | SONKE-LASTAD 40 |
| Dosage form: | | TABLET |
| Active ingredients: | | EACH TABLET CONTAINS:<br>LAMIVUDINE 150,0 mg<br>STAVUDINE 40,0 mg |
| Conditions of registration: | | 1, 2, 3, 4, 5, 6, 7, 8 |
| Applicant: | | RANBAXY (S.A.) (PTY) LTD |
| Manufacturer: | | RANBAXY LABORATORIES LTD, PAONTA SAHIB, DISTRICT SIRMOUR, HIMACHAL PRADESH, INDIA |
| Packer: | | RANBAXY LABORATORIES LTD, PAONTA SAHIB, DISTRICT SIRMOUR, HIMACHAL PRADESH, INDIA |
| Laboratory: | FPRC: | RANBAXY LABORATORIES LTD, PAONTA SAHIB, DISTRICT SIRMOUR, HIMACHAL PRADESH, INDIA<br>CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOSKBURG |
| | FPRR: | RANBAXY, CENTURION, RSA |
| Shelf-life: | | 24 months (provisional) |
| Date of registration: | | 18 APRIL 2008 |

MRF 15

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|---|---|---|
| Registration number: | | A40/3.1/0664 |
| Name of medicine: | | ARROW MELOXICAM 7,5 |
| Dosage form: | | TABLET |
| Active ingredients: | | EACH TABLET CONTAINS:<br>MELOXICAM 7,5 mg |
| Conditions of registration: | | 1, 2, 3, 4, 5, 6, 7 |
| Applicant: | | ARROW PHARMA SOUTH AFRICA (PTY) LTD |
| Manufacturer: | | RX MANUFACTURING INC, MISSISSAUGA, ONTARIO, CANADA |
| Packer: | | RX MANUFACTURING INC, MISSISSAUGA, ONTARIO, CANADA<br>DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG |
| Laboratory: | FPRC: | RX MANUFACTURING INC, MISSISSAUGA, ONTARIO, CANADA<br>RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM<br>SEDEK AGRIKEM CC, KAMEELDRIFT, PRETORIA |
| | FPRR: | ARROW PHARMA SA, WOODMEAD, JOHANNESBURG |
| Shelf-life: | | 24 months |
| Date of registration: | | 18 APRIL 2008 |

MRF 15

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|---|---|---|
| Registration number: | | A40/3.1/0665 |
| Name of medicine: | | ARROW MELOXICAM 15 |
| Dosage form: | | TABLET |
| Active ingredients: | | EACH TABLET CONTAINS:<br>MELOXICAM 15,0 mg |
| Conditions of registration: | | 1, 2, 3, 4, 5, 6, 7 |
| Applicant: | | ARROW PHARMA SOUTH AFRICA (PTY) LTD |
| Manufacturer: | | RX MANUFACTURING INC, MISSISSAUGA, ONTARIO, CANADA |
| Packer: | | RX MANUFACTURING INC, MISSISSAUGA, ONTARIO, CANADA<br>DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG |
| Laboratory: | FPRC: | RX MANUFACTURING INC, MISSISSAUGA, ONTARIO, CANADA<br>RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM<br>SEDEK AGRIKEM CC, KAMEELDRIFT, PRETORIA |
| | FPRR: | ARROW PHARMA SA, WOODMEAD, JOHANNESBURG |
| Shelf-life: | | 24 months |
| Date of registration: | | 18 APRIL 2008 |

MRF 15

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|---|---|---|
| Registration number: | | 41/7.1.3/0001 |
| Name of medicine: | | ASPEN CARVEDILOL 25 mg |
| Dosage form: | | TABLET |
| Active ingredients: | | EACH TABLET CONTAINS:<br>CARVEDILOL 25,0 mg |
| Conditions of registration: | | 1, 2, 3, 4, 5, 6, 7 |
| Applicant: | | PHARMACARE LIMITED |
| Manufacturer: | | PHARMASCIENCE INC, MONTREAL, CANADA<br>PHARMACARE LTD, KORSTEN, PORT ELIZABETH<br>ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON |
| Packer: | | PHARMASCIENCE INC, MONTREAL, CANADA<br>PHARMACARE LTD, KORSTEN, PORT ELIZABETH<br>ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON |
| Laboratory: | FPRC: | PHARMASCIENCE INC, MONTREAL, CANADA<br>SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA<br>RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM<br>M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG |
| | FPRR: | PHARMACARE LTD, WOODMEAD, JOHANNESBURG |
| | FPRC/FPRR: | PHARMACARE LTD, KORSTEN, PORT ELIZABETH<br>ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON |
| Shelf-life: | | 36 months |
| Date of registration: | | 18 APRIL 2008 |