# 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

### VOQRWAARDES 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 opgedatear 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 gevatideer 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 kopiee van die protokolle vir die toets van die massalot en die vullot sowel as ses kopiee van die vrystellingsertifikaat wat uitgereik is deur die verantwoordelike beheerliggaarn 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**

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| 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

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|---|---|
| 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

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|---|---|
| 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

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|---|---|
| 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

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|---|---|
| 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 EQIJIVALENT 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

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|---|---|
| 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>QUINAPIUL 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

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|---|---|
| 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 SERTRALTNE 50 mg |
| Dosage form: | TABLET |
| Active ingredients: | EACH TABLET CONTAINS:<br>SERTRALINE HYDROCHLORIDE EQUIVALENT TO 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

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|---|---|
| Registration number: | A38/1.210483 |
| Name of medicine: | ASPEN SERTRALINE 100 mg |
| Dosage form: | TABLET |
| Active ingredients: | EACH TABLET CONTAINS:<br>SERTRALINE HYDROCHLORIDE EQUIVALENT TO 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

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|---|---|
| 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

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|---|---|
| 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 |
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| FPRC/FPRR: | PHARMACARE LTD, KORSTEN, PORT ELIZABETH |
| Shelf-life: | 24 months |
| Date of registration: | 6 OCTOBER 2006 |