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CONTENTS**INHOUD**

<i>No.</i>	<i>Page No.</i>	<i>Gazette No.</i>	<i>No.</i>	<i>Bladsy No.</i>	<i>Koerant No.</i>
GENERAL NOTICE			ALGEMENE KENNISGEWING		
Health, Department of			Gesondheid, Departement van		
<i>General Notice</i>			<i>Algemene Kennisgewing</i>		
163			163		
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	31881	Wet op Beheer van Medisyne en Verwante Stowwe (101/1965): Medi- synebeheerraad: Voorwaardes vir die registrasie van 'n medisyne in terme van die bepalings van artikel 15 (7).....	4	31881

GENERAL NOTICE ALGEMENE KENNISGEWING

NOTICE 163 OF 2009

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 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. 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 163 VAN 2009**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 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 25 van die Wet, om die nakoming van Goeie Vervaardigingspraktyke te bepaal.
3. Die inligting soos vervat in the 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 101 van 1965).
5. Die registrasie van hierdie medisyne is onderhewig aan gereelde hersiening met tussenpose soos deur die Raad bepaal, rakende kwaliteit, veiligheid en effektiwiteit, en die registrasie van hierdie medisyne kan gewysig word onderhewig aan kwessies na goedduke van 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 produk mag slegs aan die beroepe geadverteer word.
8. 'n Na-registrasie-inspeksie moet op die eerste produksielot van die plaaslik vervaardigde produk uitgevoer word.
9. 'n Na-registrasie-inspeksie moet op die eerste produksielot van elke plaaslike vervaardiger uitgevoer word.
10. 'n Na-registrasie-inspeksie moet op die eerste produksielot van die ingevoerde produk uitgevoer word.
11. Bemaking van die produk mag slegs 'n aanvang neem nadat 'n bevredigende na-registrasie-inspeksieverslag gedien het.
12. Een monster van elke lot moet tesame met vier kopieë van die protokolle vir die toets van die massalot en die vullot sowel as ses kopieë van die vrystellingstifikaat wat uitgereik is deur die verantwoordelike beheerliggaam in die land waar die produk vervaardig word, ingedien word by die Raad vir lotvrystellingsdoeleindes.
13. Die vervaldatum toegeken, sal gewysig word deur 'n verklaring by te voeg dat die virusstamme tans vir Suid-Afrikaanse gebruik gedurende die gespesifiseerde jaar aanbeveel word.
14. Die stamme van die oorspronklike saadvirusse moet elke jaar deur die Departement van Gesondheid goedgekeur word.

MRF 15

Registration number: 34/7.1.3/0334
Name of medicine: ENVAS 2,5
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
ENALAPRIL MALEATE 2,5 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: THEBE MEDICARE (PTY) LTD
Manufacturer: CADILA PHARMACEUTICALS, DHOLKA,
AHMEDABAD, GUJARAT, INDIA
Packer: CADILA PHARMACEUTICALS, DHOLKA,
AHMEDABAD, GUJARAT, INDIA
Laboratory: FPRC: CADILA PHARMACEUTICALS, DHOLKA,
AHMEDABAD, GUJARAT, INDIA
CONSULTING CHEMICAL LABORATORIES,
ATLASVILLE, BOKSBURG
FPRR: THEBE MEDICARE, NORTHRIDING, RANDBURG
Shelf-life: 24 months
Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: 34/7.1.3/0335
Name of medicine: ENVAS 5
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
ENALAPRIL MALEATE 5,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: THEBE MEDICARE (PTY) LTD
Manufacturer: CADILA PHARMACEUTICALS, DHOLKA,
AHMEDABAD, GUJARAT, INDIA
Packer: CADILA PHARMACEUTICALS, DHOLKA,
AHMEDABAD, GUJARAT, INDIA
Laboratory: FPRC: CADILA PHARMACEUTICALS, DHOLKA,
AHMEDABAD, GUJARAT, INDIA
CONSULTING CHEMICAL LABORATORIES,
ATLASVILLE, BOKSBURG
FPRR: THEBE MEDICARE, NORTHRIDING,
RANDBURG
Shelf-life: 24 months
Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: 34/7.1.3/0336
Name of medicine: ENVAS 10
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
ENALAPRIL MALEATE 10,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: THEBE MEDICARE (PTY) LTD
Manufacturer: CADILA PHARMACEUTICALS, DHOLKA,
AHMEDABAD, GUJARAT, INDIA
Packer: CADILA PHARMACEUTICALS, DHOLKA,
AHMEDABAD, GUJARAT, INDIA
Laboratory: FPRC: CADILA PHARMACEUTICALS, DHOLKA,
AHMEDABAD, GUJARAT, INDIA
CONSULTING CHEMICAL LABORATORIES,
ATLASVILLE, BOKSBURG

FPRR: THEBE MEDICARE, NORTHRIDING, RANDBURG

Shelf-life: 24 months
Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: 37/3.1/0229
Name of medicine: CPL ALLIANCE DICLOFENAC 75 INJECTION
Dosage form: INJECTION
Active ingredients: EACH 1,0 ml SOLUTION CONTAINS:
DICLOFENAC SODIUM 25,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: THEBE MEDICARE (PTY) LTD
Manufacturer: CADILA PHARMACEUTICALS LTD,
AHMEDABAD, GUJARAT, INDIA
Packer: CADILA PHARMACEUTICALS LTD,
AHMEDABAD, GUJARAT, INDIA
Laboratory: FPRC: CADILA PHARMACEUTICALS LTD,
AHMEDABAD, GUJARAT, INDIA
CONSULTING CHEMICAL LABORATORIES,
ATLASVILLE, BOKSBURG

FPRR: THEBE MEDICARE, NORTHRIDING,
RANDBURG

Shelf-life: 24 months
Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: A38/2.5/0454
Name of medicine: LAMOTEP 25
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
LAMOTRIGINE 25,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: HEXAL PHARMA S.A. (PTY) LTD
Manufacturer: WELLSPRING PHARMACEUTICAL CANADA,
OAKVILLE, ONTARIO, CANADA
Packer: WELLSPRING PHARMACEUTICAL CANADA,
OAKVILLE, ONTARIO, CANADA
DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, JOHANNESBURG
Laboratory: FPRC: WELLSPRING PHARMACEUTICAL CANADA,
OAKVILLE, ONTARIO, CANADA
CONSULTING CHEMICAL LABORATORIES,
ATLASVILLE, BOKSBURG
FPRR: HEXAL PHARMA, PINETOWN, KZN
Shelf-life: 24 months
Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: A38/2.5/0455
Name of medicine: LAMOTEP 50
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
LAMOTRIGINE 50,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: HEXAL PHARMA S.A. (PTY) LTD
Manufacturer: WELLSPRING PHARMACEUTICAL CANADA,
OAKVILLE, ONTARIO, CANADA
Packer: WELLSPRING PHARMACEUTICAL CANADA,
OAKVILLE, ONTARIO, CANADA
DIVPHARM MANUFACTURING &
PACKAGING, LONGDALE, JOHANNESBURG
Laboratory: FPRC: WELLSPRING PHARMACEUTICAL CANADA,
OAKVILLE, ONTARIO, CANADA
CONSULTING CHEMICAL LABORATORIES,
ATLASVILLE, BOKSBURG
FPRR: HEXAL PHARMA, PINETOWN, KZN
Shelf-life: 24 months
Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: A38/2.5/0456
Name of medicine: LAMOTEP 100
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
 LAMOTRIGINE 100,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: HEXAL PHARMA S.A. (PTY) LTD
Manufacturer: WELLSRING PHARMACEUTICAL CANADA,
 OAKVILLE, ONTARIO, CANADA
Packer: WELLSRING PHARMACEUTICAL CANADA,
 OAKVILLE, ONTARIO, CANADA
 DIVPHARM MANUFACTURING & PACKAGING,
 LONGDALE, JOHANNESBURG
Laboratory: FPRC: WELLSRING PHARMACEUTICAL CANADA,
 OAKVILLE, ONTARIO, CANADA
 CONSULTING CHEMICAL LABORATORIES,
 ATLASVILLE, BOKSBURG

FPRR: HEXAL PHARMA, PINETOWN, KZN
Shelf-life: 24 months
Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: A38/2.5/0457
Name of medicine: LAMOTEP 200
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
 LAMOTRIGINE 200,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: HEXAL PHARMA S.A. (PTY) LTD
Manufacturer: WELLSRING PHARMACEUTICAL CANADA,
 OAKVILLE, ONTARIO, CANADA
Packer: WELLSRING PHARMACEUTICAL CANADA,
 OAKVILLE, ONTARIO, CANADA
 DIVPHARM MANUFACTURING &
 PACKAGING, LONGDALE, JOHANNESBURG
Laboratory: FPRC: WELLSRING PHARMACEUTICAL CANADA,
 OAKVILLE, ONTARIO, CANADA
 CONSULTING CHEMICAL LABORATORIES,
 ATLASVILLE, BOKSBURG

FPRR: HEXAL PHARMA, PINETOWN, KZN
Shelf-life: 24 months
Date of registration: 9 DECEMBER 2008

MRF 15

Registration number:	A39/34/0310
Name of medicine:	XOLAIR 75 mg
Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: OMALIZUMAB 75,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	NOVARTIS SOUTH AFRICA (PTY) LTD
Manufacturer:	GENENTECH INC, SOUTH SAN FRANCISCO, CALIFORNIA, USA
Packer:	GENENTECH INC, SOUTH SAN FRANCISCO, CALIFORNIA, USA NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND
Laboratory: FPRC:	GENENTECH INC, SOUTH SAN FRANCISCO, CALIFORNIA, USA NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
FPRC/FPRR	NOVARTIS SA, SPARTAN, KEMPTON PARK
Shelf-life:	48 months
Date of registration:	9 DECEMBER 2008

MRF 15

Registration number:	A39/34/0311
Name of medicine:	XOLAIR 150 mg
Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: OMALIZUMAB 150,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	NOVARTIS SOUTH AFRICA (PTY) LTD
Manufacturer:	GENENTECH INC, SOUTH SAN FRANCISCO, CALIFORNIA, USA
Packer:	GENENTECH INC, SOUTH SAN FRANCISCO, CALIFORNIA, USA NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND
Laboratory: FPRC:	GENENTECH INC, SOUTH SAN FRANCISCO, CALIFORNIA, USA NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
FPRC/FPRR:	NOVARTIS SA, SPARTAN, KEMPTON PARK
Shelf-life:	48 months
Date of registration:	9 DECEMBER 2008

MRF 15

Registration number: A39/20.1.1/0382
 Name of medicine: AZITHROMYCIN HEXAL 500 mg TABLET
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 AZITHROMYCIN DIHYDRATE EQUIVALENT TO
 AZITHROMYCIN 500,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
 Applicant: HEXAL PHARMA (S.A.) (PTY) LTD
 Manufacturer: ILSAN ILTAS, GEBZE-KOCAELI, TURKEY
 HEXAL AG, HOLZKIRCHEN, GERMANY
 Packer: ILSAN ILTAS, GEBZE-KOCAELI, TURKEY
 SALUTAS PHARMA GmbH, BARLEBEN, GERMANY
 DIVPHARM MANUFACTURING & PACKAGING,
 LONGDALE, JOHANNESBURG
 NOVARTIS PHARMA, SPARTAN, KEMPTON PARK
 Laboratory: FPRC: ILSAN ILTAS, GEBZE-KOCAELI, TURKEY
 HEXAL AG, HOLZKIRCHEN, GERMANY
 SALUTAS PHARMA GmbH, BARLEBEN, GERMANY
 CONSULTING CHEMICAL LABORATORIES,
 ATLASVILLE, BOKSBURG, RSA
 FPRR HEXAL PHARMA, PINETOWN, RSA
 Shelf-life: 24 months (provisional)
 Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: A39/7.1.4/0408
 Name of medicine: CARANOR 5,0 mg
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 IVABRADINE HYDROCHLORIDE EQUIVALENT
 TO IVABRADINE 5,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: BIOGARAN SOUTH AFRICA (PTY) LTD
 Manufacturer: LES LABORATOIRES SERVIER INDUSTRIE,
 GIDY, FRANCE
 SERVIER (IRELAND) INDUSTRIES WICKLOW,
 ARKLOW, IRELAND
 Packer: LES LABORATOIRES SERVIER INDUSTRIE,
 GIDY, FRANCE
 SERVIER (IRELAND) INDUSTRIES WICKLOW,
 ARKLOW, IRELAND
 TECHNIKON LABORATORIES, ROBERTVILLE,
 FLORIDA
 Laboratory: FPRC LES LABORATOIRES SERVIER INDUSTRIE,
 GIDY, FRANCE
 SERVIER (IRELAND) INDUSTRIES WICKLOW,
 ARKLOW, IRELAND
 M&L LABORATORY SERVICES, ORMONDE,
 JOHANNESBURG
 FPRC/FPRR BIOGARAN S.A., RIVONIA, JOHANNESBURG
 Shelf-life: 36 months
 Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: A39/7.1.4/0409
Name of medicine: CARANOR 7,5 mg
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
IVABRADINE HYDROCHLORIDE EQUIVALENT TO
IVABRADINE 7,5 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: BIOGARAN SOUTH AFRICA (PTY) LTD
Manufacturer: LES LABORATOIRES SERVIER INDUSTRIE, GIDY,
FRANCE
SERVIER (IRELAND) INDUSTRIES WICKLOW,
ARKLOW, IRELAND
Packer: LES LABORATOIRES SERVIER INDUSTRIE, GIDY,
FRANCE
SERVIER (IRELAND) INDUSTRIES WICKLOW,
ARKLOW, IRELAND
TECHNIKON LABORATORIES, ROBERTVILLE,
FLORIDA
Laboratory: FPRC: LES LABORATOIRES SERVIER INDUSTRIE, GIDY,
FRANCE
SERVIER (IRELAND) INDUSTRIES WICKLOW,
ARKLOW, IRELAND
M&L LABORATORY SERVICES, ORMONDE,
JOHANNESBURG
FPRR: BIOGARAN S.A., RIVONIA, JOHANNESBURG
Shelf-life: 36 months
Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: A39/7.1.4/0410
Name of medicine: CORALAN 5,0 mg
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
IVABRADINE HYDROCHLORIDE
EQUIVALENT TO IVABRADINE
5,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: SERVIER LABORATORIES SOUTH AFRICA
(PTY) LTD
Manufacturer: LES LABORATOIRES SERVIER INDUSTRIE,
GIDY, FRANCE
SERVIER (IRELAND) INDUSTRIES
WICKLOW, ARKLOW, IRELAND
Packer: LES LABORATOIRES SERVIER INDUSTRIE,
GIDY, FRANCE
SERVIER (IRELAND) INDUSTRIES
WICKLOW, ARKLOW, IRELAND
TECHNIKON LABORATORIES,
ROBERTVILLE, FLORIDA
Laboratory: FPRC: LES LABORATOIRES SERVIER INDUSTRIE,
GIDY, FRANCE
SERVIER (IRELAND) INDUSTRIES
WICKLOW, ARKLOW, IRELAND
M&L LABORATORY SERVICES, ORMONDE,
JOHANNESBURG
FPRR: SERVIER LABORATORIES S.A., RIVONIA,
JOHANNESBURG
Shelf-life: 36 months
Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: A39/7.1.4/0411
 Name of medicine: CORALAN 7,5 mg
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 IVABRADINE HYDROCHLORIDE EQUIVALENT TO
 IVABRADINE 7,5 mg

 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: SERVIER LABORATORIES SOUTH AFRICA (PTY) LTD
 Manufacturer: LES LABORATOIRES SERVIER INDUSTRIE, GIDY,
 FRANCE
 SERVIER (IRELAND) INDUSTRIES WICKLOW, ARKLOW,
 IRELAND
 Packer: LES LABORATOIRES SERVIER INDUSTRIE, GIDY,
 FRANCE
 SERVIER (IRELAND) INDUSTRIES WICKLOW, ARKLOW,
 IRELAND
 TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA
 Laboratory:: FPRC LES LABORATOIRES SERVIER INDUSTRIE, GIDY,
 FRANCE
 SERVIER (IRELAND) INDUSTRIES WICKLOW, ARKLOW,
 IRELAND
 M&L LABORATORY SERVICES, ORMONDE,
 JOHANNESBURG

 FPRR SERVIER LABORATORIES S.A., RIVONIA,
 JOHANNESBURG
 Shelf-life: 36 months
 Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: A39/8.2/0444
 Name of medicine: ADCO-ARAVIX
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 CLOPIDOGREL BISULPHATE EQUIVALENT TO
 CLOPIDOGREL 75,0 mg

 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: ADCOCK INGRAM LIMITED
 Manufacturer: CADILA HEALTHCARE LTD, SANAND, AHMEDABAD,
 INDIA
 Packer: CADILA HEALTHCARE LTD, SANAND, AHMEDABAD,
 INDIA
 ADCOCK INGRAM HEALTHCARE, WADEVILLE,
 GERMISTON
 Laboratory: FPRC: CADILA HEALTHCARE LTD, SANAND, AHMEDABAD,
 INDIA

 FPRC/FPRR: ADCOCK INGRAM HEALTHCARE, WADEVILLE,
 GERMISTON
 FPRR: ADCOCK INGRAM LTD, ERAND GARDENS, MIDRAND
 Shelf-life: 24 months
 Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: A39/11.4.3/0466
Name of medicine: ADCO-OMEPRAZOLE 10
Dosage form: CAPSULE
Active ingredients: EACH CAPSULE CONTAINS:
OMEPRAZOLE 10,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: ADCOCK INGRAM LIMITED
Manufacturer: LICONSA SA, AZUQUECA DE HENARES,
GUADALAJARA, SPAIN
Packer: LICONSA SA, AZUQUECA DE HENARES,
GUADALAJARA, SPAIN
ADCOCK INGRAM HEALTHCARE LTD,
WADEVILLE, GERMISTON
Laboratory: FPRC: LICONSA SA, AZUQUECA DE HENARES,
GUADALAJARA, SPAIN

FPRC/FPRR: ADCOCK INGRAM HEALTHCARE LTD,
WADEVILLE, GERMISTON
FPRR: ADCOCK INGRAM LTD, ERAND GARDENS,
MIDRAND

Shelf-life: 24 months (Provisional)

Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: A39/11.4.3/0467
Name of medicine: ADCO-OMEPRAZOLE 40
Dosage form: CAPSULE
Active ingredients: EACH CAPSULE CONTAINS:
OMEPRAZOLE 40,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: ADCOCK INGRAM LIMITED
Manufacturer: LICONSA SA, AZUQUECA DE HENARES,
GUADALAJARA, SPAIN
Packer: LICONSA SA, AZUQUECA DE HENARES,
GUADALAJARA, SPAIN
ADCOCK INGRAM HEALTHCARE LTD,
WADEVILLE, GERMISTON
Laboratory: FPRC: LICONSA SA, AZUQUECA DE HENARES,
GUADALAJARA, SPAIN

FPRC/FPRR: ADCOCK INGRAM HEALTHCARE LTD,
WADEVILLE, GERMISTON
FPRR: ADCOCK INGRAM LTD, ERAND GARDENS,
MIDRAND

Shelf-life: 24 months (Provisional)

Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: A39/20.2.2/0572
 Name of medicine: ASPEN FLUCONAZOLE IV
 Dosage form: INFUSION
 Active ingredients: EACH 1,0 ml SOLUTION CONTAINS:
 FLUCONAZOLE 2,0 mg

 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
 Applicant: PHARMACARE LIMITED
 Manufacturer: REIG JOFRE, S.A, SANT JOAN DESPI,
 BARCELONA, SPAIN
 Packer: REIG JOFRE, S.A, SANT JOAN DESPI,
 BARCELONA, SPAIN

 Laboratory: FPRC: REIG JOFRE, S.A, SANT JOAN
 DESPI, BARCELONA, SPAIN
 SOUTH AFRICAN BUREAU OF STANDARDS,
 GROENKLOOF, PRETORIA
 RESEARCH INSTITUTE FOR INDUSTRIAL
 PHARMACY, NORTH-WEST UNIVERSITY,
 POTCHEFSTROOM

 FPRR: PHARMACARE LTD, WOODMEAD, SANDTON

 Shelf-life: 24 months (Provisional)
 Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: A39/20.1.1/0577
 Name of medicine: LEVOFLOXACIN-WINTHROP I.V. 250
 Dosage form: INJECTION
 Active ingredients: EACH 50,0 ml VIAL CONTAINS:
 LEVOFLOXACIN HEMIHYDRATE
 EQUIVALENT TO
 LEVOFLOXACIN 250,0 mg

 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: AVENTIS PHARMA (PTY) LTD
 Manufacturer: AVENTIS PHARMA DEUTSCHLAND GmbH,
 FRANKFURT, GERMANY
 Packer: AVENTIS PHARMA DEUTSCHLAND GmbH,
 FRANKFURT, GERMANY
 WINTHROP PHARMACEUTICALS,
 WALTLOO, PRETORIA

 Laboratory: FPRC: AVENTIS PHARMA SPECIALITES,
 COMPEIGNE, FRANCE
 AVENTIS PHARMA DEUTSCHLAND GmbH,
 FRANKFURT, GERMANY

 FPRC/FPRR: WINTHROP PHARMACEUTICALS,
 WALTLOO, PRETORIA

 FPRR: AVENTIS PHARMA, MIDRAND, RSA

 Shelf-life: 24 months
 Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: A39/20.1.1/0578
Name of medicine: LEVOFLOXACIN-WINTHROP I.V. 500
Dosage form: INJECTION
Active ingredients: EACH 100,0 ml VIAL CONTAINS:
LEVOFLOXACIN HEMIHYDRATE EQUIVALENT TO
LEVOFLOXACIN 500,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: AVENTIS PHARMA (PTY) LTD
Manufacturer: AVENTIS PHARMA DEUTSCHLAND GmbH,
FRANKFURT, GERMANY
Packer: AVENTIS PHARMA DEUTSCHLAND GmbH,
FRANKFURT, GERMANY
WINTHROP PHARMACEUTICALS, WALTLOO,
PRETORIA
Laboratory: FPRC: AVENTIS PHARMA DEUTSCHLAND GmbH,
FRANKFURT, GERMANY
FPRC/FPRR: WINTHROP PHARMACEUTICALS, WALTLOO,
PRETORIA
FPRR: AVENTIS PHARMA, MIDRAND, RSA
Shelf-life: 24 months
Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: A39/7.1/0634
Name of medicine: ADALAT XL 20
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
NIFEDIPINE 20,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: BAYER (PTY) LTD
Manufacturer: BAYER AG, LEVERKUSEN, GERMANY
Packer: BAYER AG, LEVERKUSEN, GERMANY
DIVPHARM MANUFACTURING &
PACKAGING, LONGDALE, JOHANNESBURG
PHARMACEUTICAL CONTRACTORS,
ISANDO, RSA
BAYER ANIMAL HEALTH, WILLOWTON,
PIETERMARITZBURG
Laboratory: FPRC: BAYER AG, LEVERKUSEN, GERMANY
BAYER ANIMAL HEALTH, WILLOWTON,
PIETERMARITZBURG
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, NORTH-WEST UNIVERSITY,
POTCHEFSTROOM
FPRR: BAYER, ISANDO, RSA
Shelf-life: 36 months
Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: A40/20.2.2/0070
Name of medicine: ITRACOL
Dosage form: CAPSULE
Active ingredients: EACH CAPSULE CONTAINS:
 ITRACONAZOLE 100,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: HEXAL PHARMA (SA) (PTY) LTD
Manufacturer: ILSAN ILTAS, GEBZE-KOCAELI, TURKEY
Packer: ILSAN ILTAS, GEBZE-KOCAELI, TURKEY
 SALUTAS PHARMA GmbH, BARLEBEN, GERMANY
 DIVPHARM MANUFACTURING & PACKAGING,
 LONGDALE, JOHANNESBURG
 TECHNIKON LABORATORIES, FLORIDA, RSA

Laboratory: FPRC: ILSAN ILTAS, GEBZE-KOCAELI, TURKEY
 SALUTAS PHARMA GmbH, BARLEBEN, GERMANY
 CONSULTING CHEMICAL LABORATORIES, STAR
 STREET, BOKSBURG, RSA

 FPRR: HEXAL PHARMA, PINETOWN, RSA
Shelf-life: 24 months (Provisional)
Date of registration: 9 DECEMBER 2009

MRF 15

Registration number: A40/20.2.2/0071
Name of medicine: ITRACONAZOLE HEXAL
Dosage form: CAPSULE
Active ingredients: EACH CAPSULE CONTAINS:
 ITRACONAZOLE 100,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: HEXAL PHARMA (SA) (PTY) LTD
Manufacturer: ILSAN ILTAS, GEBZE-KOCAELI, TURKEY
Packer: ILSAN ILTAS, GEBZE-KOCAELI, TURKEY
 SALUTAS PHARMA GmbH, BARLEBEN,
 GERMANY
 DIVPHARM MANUFACTURING &
 PACKAGING, LONGDALE, JOHANNESBURG
 TECHNIKON LABORATORIES, FLORIDA,
 RSA

Laboratory: FPRC: ILSAN ILTAS, GEBZE-KOCAELI, TURKEY
 SALUTAS PHARMA GmbH, BARLEBEN,
 GERMANY
 CONSULTING CHEMICAL LABORATORIES,
 STAR STREET, BOKSBURG, RSA

 FPRR: HEXAL PHARMA, PINETOWN, RSA
Shelf-life: 24 months (Provisional)
Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: A40/16.5/0136
Name of medicine: MEDI-KEEL ANTISEPTIC AND ANTI-INFLAMMATORY THROAT SPRAY
Dosage form: SPRAY
Active ingredients: EACH 15,0 ml SOLUTION CONTAINS:
BENZYLAMINE HYDROCHLORIDE 22,50 mg
CETYLPYRIDINIUM CHLORIDE 7,5 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 8
Applicant: ADCOCK INGRAM LIMITED
Manufacturer: ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Packer: ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Laboratory: FPRC/FPRR: ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
FPRR: ADCOCK INGRAM LTD, BRYANSTON, JOHANNESBURG
Shelf-life: 24 months (Provisional)
Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: A40/20.2.6/0165
Name of medicine: MALANIL PAEDIATRIC
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
ATOVAQUONE 62,5 mg
PROGUANIL HYDROCHLORIDE 25,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: GLAXOSMITHKLINE SOUTH AFRICA (PTY) LTD
Manufacturer: GLAXOSMITHKLINE INC, MISSISSAUGA, ONTARIO, CANADA
Packer: GLAXOSMITHKLINE INC, MISSISSAUGA, ONTARIO, CANADA
GLAXOSMITHKLINE SA, EPPING, CAPE TOWN
Laboratory: FPRC: GLAXOSMITHKLINE INC, MISSISSAUGA, ONTARIO, CANADA
FPRC/FPRR: GLAXOSMITHKLINE SA, EPPING, CAPE TOWN
Shelf-life: 60 months
Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: A40/34/0211
Name of medicine: CONTIFLO SR
Dosage form: CAPSULE
Active ingredients: EACH CAPSULE CONTAINS:
TAMSULOSIN HYDROCHLORIDE 0,4 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: RANBAXY (SA) (PTY) LTD
Manufacturer: RANBAXY LABORATORIES LTD, DEWAS,
MADHYA PRADESH, INDIA
Packer: RANBAXY LABORATORIES LTD, DEWAS,
MADHYA PRADESH, INDIA
Laboratory: FPRC: RANBAXY LABORATORIES LTD, DEWAS,
MADHYA PRADESH, INDIA
KHULULEKANI LABORATORY SERVICES,
COVENTRY PARK, MIDRAND
FPRR: RANBAXY (SA), CENTURION, RSA
Shelf-life: 24 months (Provisional)
Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: A40/20.1.1/0321
Name of medicine: SMARTSET GHV GENTAMICIN BONE
CEMENT
Dosage form: BONE CEMENT
Active ingredients: EACH 40,0 g CONTAINS:
GENTAMICIN SULPHATE EQUIVALENT TO
GENTAMICIN 1,0 g
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: ORTHOMEDICS PHARMACEUTICALS (PTY)
LTD
Manufacturer: DEPUY CMW, BLACKPOOL, LANCASHIRE,
UK
Packer: DEPUY CMW, BLACKPOOL, LANCASHIRE,
UK
Laboratory: FPRC: DEPUY CMW, BLACKPOOL, LANCASHIRE,
UK
FPRR: ORTHOMEDICS PHARMACEUTICALS,
SYBRAND PARK, CAPE TOWN
Shelf-life: 24 months
Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: A40/20.2.2/0614
Name of medicine: LAMISPOR 250
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
TERBINAFINE HYDROCHLORIDE EQUIVALENT
TO
TERBINAFINE 250,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: CIPLA MEDPRO (PTY) LTD
Manufacturer: CIPLA LTD, PLOT A, PATALGANGA, RAIGAD,
MAHARASHTRA, INDIA
Packer: CIPLA LTD, PLOT A, PATALGANGA, RAIGAD,
MAHARASHTRA, INDIA
Laboratory: FPRC: CIPLA LTD, PLOT A, PATALGANGA, RAIGAD,
MAHARASHTRA, INDIA
FPRR: CIPLA MEDPRO, ROSENPARK, BELLVILLE
Shelf-life: 24 months (Provisional)
Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: A40/20.2.2/0615
Name of medicine: CIPLA-TERBINAFINE 250
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
TERBINAFINE HYDROCHLORIDE
EQUIVALENT TO
TERBINAFINE 250,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: CIPLA LIFE SCIENCES (PTY) LTD
Manufacturer: CIPLA LTD, PLOT A, PATALGANGA,
RAIGAD, MAHARASHTRA, INDIA
Packer: CIPLA LTD, PLOT A, PATALGANGA,
RAIGAD, MAHARASHTRA, INDIA
Laboratory: FPRC: CIPLA LTD, PLOT A, PATALGANGA,
RAIGAD, MAHARASHTRA, INDIA
FPRR: CIPLA LIFE SCIENCES, ROSENPARK,
BELLVILLE
Shelf-life: 24 months (Provisional)
Date of registration: 9 DECEMBER 2008

MRF 15

Registration number:	A40/8.2/0673
Name of medicine:	PLAGROL
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CLOPIDOGREL BISULFATE EQUIVALENT TO CLOPIDOGREL 75,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	DR REDDY'S LABORATORIES (PTY) LTD
Manufacturer:	DR REDDY'S LABORATORIES LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:	DR REDDY'S LABORATORIES LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA DRA PHARMACEUTICALS, IRENE, CENTURION
Laboratory:	FPRC: DR REDDY'S LABORATORIES LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR: DR REDDY'S LABORATORIES, MURRAYFIELD, PRETORIA
Shelf-life:	36 months
Date of registration:	9 DECEMBER 2008

MRF 15

Registration number:	A40/2.6.5/0706
Name of medicine:	PERIZAL 0,5 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RISPERIDONE 0,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SPECPHARM (PTY) LTD
Manufacturer:	PHARMA INTERNATIONAL COMPANY, AMMAN, JORDAN
Packer:	PHARMA INTERNATIONAL COMPANY, AMMAN, JORDAN
Laboratory:	FPRC: PHARMA INTERNATIONAL COMPANY, AMMAN, JORDAN
	FPRR: SPECPHARM, SANDTON, JOHANNESBURG
Shelf-life:	24 months
Date of registration:	9 DECEMBER 2008

MRF 15

Registration number:	A40/2.6.5/0707
Name of medicine:	PERIZAL 1 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RISPERIDONE 1,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SPECPHARM (PTY) LTD
Manufacturer:	PHARMA INTERNATIONAL COMPANY, AMMAN, JORDAN
Packer:	PHARMA INTERNATIONAL COMPANY, AMMAN, JORDAN
Laboratory:	FPRC: PHARMA INTERNATIONAL COMPANY, AMMAN, JORDAN
	FPRR: SPECPHARM, SANDTON, JOHANNESBURG
Shelf-life:	24 months
Date of registration:	9 DECEMBER 2008

MRF 15

Registration number:	A40/2.6.5/0708
Name of medicine:	PERIZAL 2 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RISPERIDONE 2,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SPECPHARM (PTY) LTD
Manufacturer:	PHARMA INTERNATIONAL COMPANY, AMMAN, JORDAN
Packer:	PHARMA INTERNATIONAL COMPANY, AMMAN, JORDAN
Laboratory:	FPRC: PHARMA INTERNATIONAL COMPANY, AMMAN, JORDAN
	FPRR: SPECPHARM, SANDTON, JOHANNESBURG
Shelf-life:	24 months
Date of registration:	9 DECEMBER 2008

MRF 15

Registration number: A40/2.6.5/0709
Name of medicine: PERIZAL 3 mg
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
RISPERIDONE 3,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: SPECPHARM (PTY) LTD
Manufacturer: PHARMA INTERNATIONAL COMPANY, AMMAN,
JORDAN
Packer: PHARMA INTERNATIONAL COMPANY, AMMAN,
JORDAN
Laboratory: FPRC: PHARMA INTERNATIONAL COMPANY, AMMAN,
JORDAN
FPRR: SPECPHARM, SANDTON, JOHANNESBURG
Shelf-life: 24 months
Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: A40/2.6.5/0710
Name of medicine: PERIZAL 4 mg
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
RISPERIDONE 4,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: SPECPHARM (PTY) LTD
Manufacturer: PHARMA INTERNATIONAL COMPANY,
AMMAN, JORDAN
Packer: PHARMA INTERNATIONAL COMPANY,
AMMAN, JORDAN
Laboratory: FPRC: PHARMA INTERNATIONAL COMPANY,
AMMAN, JORDAN
FPRR: SPECPHARM, SANDTON, JOHANNESBURG
Shelf-life: 24 months
Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: A40/2.6.5/0727
Name of medicine: RISPERLET 0,5 mg
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
RISPERIDONE 0,5 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: JANSSEN PHARMACEUTICA (PTY) LTD
Manufacturer: JANSSEN-CILAG, BORGIO SAN MICHELE, LATINA,
ITALY
Packer: JANSSEN-CILAG, BORGIO SAN MICHELE, LATINA,
ITALY
JANSSEN PHARMACEUTICA, WOODMEAD,
SANDTON
Laboratory: FPRC: JANSSEN-CILAG, BORGIO SAN MICHELE, LATINA,
ITALY
FPRC/FPRR: JANSSEN PHARMACEUTICA, WOODMEAD,
SANDTON
Shelf-life: 24 months in HDPE bottles
36 months in foil blisters
Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: A40/2.6.5/0728
Name of medicine: RISPERLET 1 mg
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
RISPERIDONE 1,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: JANSSEN PHARMACEUTICA (PTY) LTD
Manufacturer: JANSSEN-CILAG, BORGIO SAN MICHELE,
LATINA, ITALY
Packer: JANSSEN-CILAG, BORGIO SAN MICHELE,
LATINA, ITALY
JANSSEN PHARMACEUTICA, WOODMEAD,
SANDTON
Laboratory: FPRC: JANSSEN-CILAG, BORGIO SAN MICHELE,
LATINA, ITALY
FPRR: JANSSEN PHARMACEUTICA, WOODMEAD,
SANDTON
Shelf-life: 24 months in HDPE bottles
36 months in foil blisters
Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: A40/2.6.5/0729
Name of medicine: RISPERLET 2 mg
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
 RISPERIDONE 2,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: JANSSEN PHARMACEUTICA (PTY) LTD
Manufacturer: JANSSEN-CILAG, BORGIO SAN MICHELE, LATINA,
 ITALY
Packer: JANSSEN-CILAG, BORGIO SAN MICHELE, LATINA,
 ITALY
 JANSSEN PHARMACEUTICA, WOODMEAD,
 SANDTON
Laboratory: FPRC: JANSSEN-CILAG, BORGIO SAN MICHELE, LATINA,
 ITALY

 FPRR: JANSSEN PHARMACEUTICA, WOODMEAD,
 SANDTON
Shelf-life: 24 months in HDPE bottles
 36 months in foil blisters
Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: A40/2.2/0760
Name of medicine: SPEC MIDAZOLAM
Dosage form: INJECTION
Active ingredients: EACH 3,0 ml AMPOULE CONTAINS:
 MIDAZOLAM HYDROCHLORIDE
 EQUIVALENT TO
 MIDAZOLAM 15,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: SPEC PHARM (PTY) LTD
Manufacturer: HAMELN PHARMACEUTICALS, HAMELN,
 GERMANY
Packer: HAMELN PHARMACEUTICALS, HAMELN,
 GERMANY

Laboratory: FPRC: HAMELN PHARMACEUTICALS, HAMELN,
 GERMANY

 FPRR: SPEC PHARM, HALFWAY HOUSE, MIDRAND
Shelf-life: 24 months (Provisional)
Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: 41/26/0028
Name of medicine: SANDOZ IRINOTECAN 40
Dosage form: INFUSION
Active ingredients: EACH 2,0 ml SOLUTION CONTAINS:
IRINOTECAN HYDROCHLORIDE 40,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: SANDOZ S.A. (PTY) LTD
Manufacturer: SANDOZ S.A., BUENOS AIRES, ARGENTINA
Packer: SANDOZ S.A., BUENOS AIRES, ARGENTINA
NOVARTIS S.A., SPARTAN, KEMPTON PARK

Laboratory: FPRC: SANDOZ S.A., BUENOS AIRES, ARGENTINA
NOVARTIS S.A., SPARTAN, KEMPTON PARK
LEK dd, VEROVSKOVA, LJUBLJANA, SLOVENIA
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA

FPRR: SANDOZ S.A., SPARTAN, KEMPTON PARK

Shelf-life: 24 months (Provisional)
Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: 41/26/0029
Name of medicine: SANDOZ IRINOTECAN 100
Dosage form: INFUSION
Active ingredients: EACH 5,0 ml SOLUTION CONTAINS:
IRINOTECAN HYDROCHLORIDE 100,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: SANDOZ S.A. (PTY) LTD
Manufacturer: SANDOZ S.A., BUENOS AIRES, ARGENTINA
Packer: SANDOZ S.A., BUENOS AIRES, ARGENTINA
NOVARTIS S.A., SPARTAN, KEMPTON PARK

Laboratory: FPRC: SANDOZ S.A., BUENOS AIRES, ARGENTINA
NOVARTIS S.A., SPARTAN, KEMPTON PARK
LEK dd, VEROVSKOVA, LJUBLJANA, SLOVENIA
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA

FPRR: SANDOZ S.A., SPARTAN, KEMPTON PARK

Shelf-life: 24 months (Provisional)
Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: 41/26/0030
 Name of medicine: TECORIN 40
 Dosage form: INFUSION
 Active ingredients: EACH 2,0 ml SOLUTION CONTAINS:
 IRINOTECAN HYDROCHLORIDE 40,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
 Applicant: SANDOZ S.A. (PTY) LTD
 Manufacturer: SANDOZ S.A., BUENOS AIRES, ARGENTINA
 Packer: SANDOZ S.A., BUENOS AIRES, ARGENTINA
 NOVARTIS S.A., SPARTAN, KEMPTON PARK
 Laboratory: FPRC: SANDOZ S.A., BUENOS AIRES, ARGENTINA
 NOVARTIS S.A., SPARTAN, KEMPTON PARK
 LEK dd, VEROVSKOVA, LJUBLJANA, SLOVENIA
 SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA
 FPRR: SANDOZ S.A., SPARTAN, KEMPTON PARK
 Shelf-life: 24 months (Provisional)
 Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: 41/26/0031
 Name of medicine: TECORIN 100
 Dosage form: INFUSION
 Active ingredients: EACH 5,0 ml SOLUTION CONTAINS:
 IRINOTECAN HYDROCHLORIDE 100,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
 Applicant: SANDOZ S.A. (PTY) LTD
 Manufacturer: SANDOZ S.A., BUENOS AIRES, ARGENTINA
 Packer: SANDOZ S.A., BUENOS AIRES, ARGENTINA
 NOVARTIS S.A., SPARTAN, KEMPTON PARK
 Laboratory: FPRC: SANDOZ S.A., BUENOS AIRES, ARGENTINA
 NOVARTIS S.A., SPARTAN, KEMPTON PARK
 LEK dd, VEROVSKOVA, LJUBLJANA, SLOVENIA
 SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA
 FPRR: SANDOZ S.A., SPARTAN, KEMPTON PARK
 Shelf-life: 24 months (Provisional)
 Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: 41/8.2/0051
Name of medicine: CLOPIDOGREL-WINTHROP
Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
CLOPIDOGREL HYDROGEN SULPHATE
EQUIVALENT TO CLOPIDPGREL 75,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: SANOFI-SYNTHELABO (PTY) LTD
Manufacturer: SANOFI WINTHROP INDUSTRIE, CARBON BLANC,
CEDEX, FRANCE
SANOFI-SYNTHELABO LTD, FAWDON, NEWCASTLE
UPON TYNE, UK
Packer: SANOFI WINTHROP INDUSTRIE, CARBON BLANC,
CEDEX, FRANCE
SANOFI-SYNTHELABO LTD, FAWDON, NEWCASTLE
UPON TYNE, UK
WINTHROP PHARMACEUTICALS, WALTLOO,
PRETORIA
Laboratory: FPRC: SANOFI WINTHROP INDUSTRIE, CARBON BLANC,
CEDEX, FRANCE
SANOFI-SYNTHELABO LTD, FAWDON, NEWCASTLE
UPON TYNE, UK
WINTHROP PHARMACEUTICALS, WALTLOO,
PRETORIA
M&L LABORATORY SERVICES, ORMONDE,
JOHANNESBURG
PHARMACEUTICAL CONTRACTORS, ISANDO
FPRR: SANOFI-SYNTHELABO, MIDRAND
Shelf-life: 36 months
Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: 41/8.2/0052
Name of medicine: CLOPIDOGREL-SANOFI-AVENTIS
Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
CLOPIDOGREL HYDROGEN SULPHATE
EQUIVALENT TO CLOPIDOGREL 75,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: SANOFI-SYNTHELABO (PTY) LTD
Manufacturer: SANOFI WINTHROP INDUSTRIE, CARBON BLANC, CEDEX,
FRANCE
SANOFI-SYNTHELABO LTD, FAWDON, NEWCASTLE UPON
TYNE, UK
Packer: SANOFI WINTHROP INDUSTRIE, CARBON BLANC, CEDEX,
FRANCE
SANOFI-SYNTHELABO LTD, FAWDON, NEWCASTLE UPON
TYNE, UK
WINTHROP PHARMACEUTICALS, WALTLOO, PRETORIA
Laboratory: FPRC: SANOFI WINTHROP INDUSTRIE, CARBON BLANC, CEDEX,
FRANCE
SANOFI-SYNTHELABO LTD, FAWDON, NEWCASTLE UPON
TYNE, UK
WINTHROP PHARMACEUTICALS, WALTLOO, PRETORIA
M&L LABORATORY SERVICES, ORMONDE,
JOHANNESBURG
PHARMACEUTICAL CONTRACTORS, ISANDO
FPRR: SANOFI-SYNTHELABO, MIDRAND
Shelf-life: 36 months
Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: 41/34/0068
 Name of medicine: BYETTA 5 ug
 Dosage form: INJECTION
 Active ingredients: EACH 1,0 ml SOLUTION CONTAINS:
 EXENATIDE 250,0 ug
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
 Applicant: ELI LILLY (S.A.) (PTY) LTD
 Manufacturer: WOCKHARDT UK LTD, WREXHAM, UK
 BAXTER PHARMACEUTICAL SOLUTIONS,
 BLOOMINGTON, INDIANA, USA
 Packer: LILLY PHARMA FERTIGUNG &
 DISTRIBUTION GmbH & Co, GIESSEN,
 GERMANY
 Laboratory: FPRC: CHARLES RIVER LABORATORIES
 PRECLINICAL SERVICES, TRANENT,
 EDINBURGH, SCOTLAND, UK
 SGS INSTITUT FRESENIUS BERLIN GmbH &
 Co, BERLIN, GERMANY
 SGS INSTITUT FRESENIUS GmbH,
 TAUNUS-STEIN, GERMANY
 LILLY PHARMA FERTIGUNG &
 DISTRIBUTION GmbH & Co, GIESSEN,
 GERMANY
 SOUTH AFRICAN BUREAU OF
 STANDARDS, GROENKLOOF, PRETORIA
 FPRR: ELI LILLY, BRYANSTON, RSA
 Shelf-life: 24 months (Provisional)
 Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: 41/34/0069
 Name of medicine: BYETTA 10 ug
 Dosage form: INJECTION
 Active ingredients: EACH 1,0 ml SOLUTION CONTAINS:
 EXENATIDE 250,0 ug
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
 Applicant: ELI LILLY (S.A.) (PTY) LTD
 Manufacturer: WOCKHARDT UK LTD, WREXHAM, UK
 BAXTER PHARMACEUTICAL SOLUTIONS,
 BLOOMINGTON, INDIANA, USA
 Packer: LILLY PHARMA FERTIGUNG & DISTRIBUTION
 GmbH & Co, GIESSEN, GERMANY
 Laboratory: FPRC: CHARLES RIVER LABORATORIES PRECLINICAL
 SERVICES, TRANENT, EDINBURGH, SCOTLAND,
 UK
 SGS INSTITUT FRESENIUS BERLIN GmbH & Co,
 BERLIN, GERMANY
 SGS INSTITUT FRESENIUS GmbH, TAUNUS-
 STEIN, GERMANY
 LILLY PHARMA FERTIGUNG & DISTRIBUTION
 GmbH & Co, GIESSEN, GERMANY
 SOUTH AFRICAN BUREAU OF STANDARDS,
 GROENKLOOF, PRETORIA
 FPRR: ELI LILLY, BRYANSTON, RSA
 Shelf-life: 24 months (Provisional)
 Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: 41/8.2/0146
Name of medicine: MISTRO
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
CLOPIDOGREL BISULFATE EQUIVALENT TO
CLOPIDOGREL 75,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: DR REDDY'S LABORATORIES (PTY) LTD
Manufacturer: DR REDDY'S LABORATORIES LTD, RANGA
REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer: DR REDDY'S LABORATORIES LTD, RANGA
REDDY DISTRICT, ANDHRA PRADESH, INDIA
DRA PHARMACEUTICALS, IRENE, CENTURION
Laboratory: FPRC: DR REDDY'S LABORATORIES LTD, RANGA
REDDY DISTRICT, ANDHRA PRADESH, INDIA
INSTITUTE FOR PHARMACEUTICAL
SERVICES, SILVERTONDALE, PRETORIA
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, NORTH-WEST UNIVERSITY,
POTCHEFSTROOM
FPRR: DR REDDY'S LABORATORIES, MURRAYFIELD,
PRETORIA
Shelf-life: 24 months
Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: 41/2.1/0191
Name of medicine: TERRELL
Dosage form: LIQUID
Active ingredients: EACH GLASS BOTTLE CONTAINS:
ISOFLURANE 100,0 ml
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: SAFELINE PHARMACEUTICALS (PTY)
LTD
Manufacturer: MINRAD INC, BETHLEHEM,
PENNSYLVANIA, USA
Packer: MINRAD INC, BETHLEHEM,
PENNSYLVANIA, USA
Laboratory: FPRC: MINRAD INC, BETHLEHEM,
PENNSYLVANIA, USA
INSTITUTE FOR PHARMACEUTICAL
SERVICES, SILVERTONDALE, PRETORIA
FPRR: SAFELINE PHARMACEUTICALS,
FLORIDA, JOHANNESBURG
Shelf-life: 60 months
Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: 41/1.2/0209
Name of medicine: SERMAX 50
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
SERTRALINE HYDROCHLORIDE EQUIVALENT
TO SERTRALINE 50,0 mg

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

Applicant: BE-TABS PHARMACEUTICALS (PTY) LTD

Manufacturer: TORRENT PHARMACEUTICALS LTD,
MEHSANA, GUJARAT, INDIA

Packer: TORRENT PHARMACEUTICALS LTD,
MEHSANA, GUJARAT, INDIA

Laboratory: FPRC: TORRENT PHARMACEUTICALS LTD,
MEHSANA, GUJARAT, INDIA

FPRC/FPRR: BE-TABS PHARMACEUTICALS, ROODEPOORT,
RSA

Shelf-life: 36 months

Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: 41/1.2/0210
Name of medicine: SERMAX 100
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
SERTRALINE HYDROCHLORIDE
EQUIVALENT TO
SERTRALINE 100,0 mg

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

Applicant: BE-TABS PHARMACEUTICALS (PTY) LTD

Manufacturer: TORRENT PHARMACEUTICALS LTD,
MEHSANA, GUJARAT, INDIA

Packer: TORRENT PHARMACEUTICALS LTD,
MEHSANA, GUJARAT, INDIA

Laboratory: FPRC: TORRENT PHARMACEUTICALS LTD,
MEHSANA, GUJARAT, INDIA

FPRC/FPRR: BE-TABS PHARMACEUTICALS,
ROODEPOORT, RSA

Shelf-life: 36 months

Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: 41/20.2.8/0218
Name of medicine: CIPLA DUOVIR AND EFAVIRENZ CO-PACK
Dosage form: TABLET
Active ingredients: EACH PACK CONTAINS:
DUOVIR TABLETS CONTAINING:
LAMIVUDINE 150,0 mg
ZIDOVUDINE 300,0 mg
EFAVIR 600 TABLETS CONTAINING:
EFAVIRENZ 600,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: CIPLA MEDPRO (PTY) LTD
Manufacturer: CIPLA LTD, VIKHROLI, MUMBAI, INDIA
CIPLA LTD, UNIT IV, SALCETTE, GOA, INDIA
Packer: CIPLA LTD, UNIT IV, SALCETTE, GOA, INDIA
Laboratory: FPRC: CIPLA LTD, VIKHROLI, MUMBAI, INDIA
CIPLA LTD, UNIT IV, SALCETTE, GOA, INDIA
FPRR: CIPLA MEDPRO, ROSENPARK, BELLVILLE
Shelf-life: 24 months (Provisional)
Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: 41/21.5.1/0238
Name of medicine: INFLANAZE 100
Dosage form: NASAL SPRAY
Active ingredients: EACH METERED DOSE CONTAINS:
BUDESONIDE 100,0 ug
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: INGELHEIM PHARMACEUTICALS (PTY) LTD
Manufacturer: MIPHARM S.p.A., MILAN, ITALY
Packer: MIPHARM S.p.A., MILAN, ITALY
Laboratory: FPRC: MIPHARM S.p.A., MILAN, ITALY
WINTHROP PHARMACEUTICALS,
WALTLOO, PRETORIA
FPRR: INGELHEIM PHARMACEUTICALS,
RANDBURG, RSA
Shelf-life: 24 months (Provisional)
Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: 41/2.6.5/0264
 Name of medicine: AUROPIDONE 1 mg
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 RISPERIDONE 1,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: AUROBINDO PHARMA (PTY) LTD
 Manufacturer: AUROBINDO PHARMA LTD, UNIT III, RANGA
 REDDY DISTRICT, ANDHRA PRADESH, INDIA
 Packer: AUROBINDO PHARMA LTD, UNIT III, RANGA
 REDDY DISTRICT, ANDHRA PRADESH, INDIA
 Laboratory: FPRC: AUROBINDO PHARMA LTD, UNIT III, RANGA
 REDDY DISTRICT, ANDHRA PRADESH, INDIA
 FPRR: AUROBINDO PHARMA, MEYERSDAL,
 JOHANNESBURG
 Shelf-life: 24 months
 Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: 41/2.6.5/0265
 Name of medicine: AUROPIDONE 2 mg
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 RISPERIDONE 2,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: AUROBINDO PHARMA (PTY) LTD
 Manufacturer: AUROBINDO PHARMA LTD, UNIT III,
 RANGA REDDY DISTRICT, ANDHRA
 PRADESH, INDIA
 Packer: AUROBINDO PHARMA LTD, UNIT III,
 RANGA REDDY DISTRICT, ANDHRA
 PRADESH, INDIA
 Laboratory: FPRC: AUROBINDO PHARMA LTD, UNIT III,
 RANGA REDDY DISTRICT, ANDHRA
 PRADESH, INDIA
 FPRR: AUROBINDO PHARMA, MEYERSDAL,
 JOHANNESBURG
 Shelf-life: 24 months
 Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: 41/2.6.5/0266
Name of medicine: AUROPIDONE 3 mg
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
RISPERIDONE 3,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: AUROBINDO PHARMA (PTY) LTD
Manufacturer: AUROBINDO PHARMA LTD, UNIT III, RANGA
REDDY DISTRICT, ANDHRA PRADESH,
INDIA
Packer: AUROBINDO PHARMA LTD, UNIT III, RANGA
REDDY DISTRICT, ANDHRA PRADESH,
INDIA
Laboratory: FPRC: AUROBINDO PHARMA LTD, UNIT III, RANGA
REDDY DISTRICT, ANDHRA PRADESH,
INDIA
FPRR: AUROBINDO PHARMA, MEYERSDAL,
JOHANNESBURG
Shelf-life: 24 months
Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: 41/2.6.5/0267
Name of medicine: AUROPIDONE 4 mg
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
RISPERIDONE 4,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: AUROBINDO PHARMA (PTY) LTD
Manufacturer: AUROBINDO PHARMA LTD, UNIT III, RANGA
REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer: AUROBINDO PHARMA LTD, UNIT III, RANGA
REDDY DISTRICT, ANDHRA PRADESH, INDIA
Laboratory: FPRC: AUROBINDO PHARMA LTD, UNIT III, RANGA
REDDY DISTRICT, ANDHRA PRADESH, INDIA
FPRR: AUROBINDO PHARMA, MEYERSDAL,
JOHANNESBURG
Shelf-life: 24 months
Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: 41/2.6.5/0339
Name of medicine: ASPEN RISPERIDONE 0,5 mg
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
RISPERIDONE 0,5 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: PHARMACARE LIMITED
Manufacturer: PHARMA INTERNATIONAL COMPANY, AL-
JUBEIHA, AMMAN, JORDAN
Packer: PHARMA INTERNATIONAL COMPANY, AL-
JUBEIHA, AMMAN, JORDAN
CHANELLE MEDICAL, LOUGHREA, COUNTY
GALWAY, IRELAND
Laboratory: FPRC: PHARMA INTERNATIONAL COMPANY, AL-
JUBEIHA, AMMAN, JORDAN
CHANELLE MEDICAL, LOUGHREA, COUNTY
GALWAY, IRELAND
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, SILVERTONDALE, PRETORIA
M&L LABORATORY SERVICES, ORMONDE,
JOHANNESBURG
FPRR: PHARMACARE LTD, WOODMEAD, SANDTON
Shelf-life: 24 months (Provisional)
Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: 41/2.6.5/0340
Name of medicine: ASPEN RISPERIDONE 1 mg
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
RISPERIDONE 1,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: PHARMACARE LIMITED
Manufacturer: PHARMA INTERNATIONAL COMPANY, AL-
JUBEIHA, AMMAN, JORDAN
Packer: PHARMA INTERNATIONAL COMPANY, AL-
JUBEIHA, AMMAN, JORDAN
CHANELLE MEDICAL, LOUGHREA, COUNTY
GALWAY, IRELAND
Laboratory: FPRC: PHARMA INTERNATIONAL COMPANY, AL-
JUBEIHA, AMMAN, JORDAN
CHANELLE MEDICAL, LOUGHREA, COUNTY
GALWAY, IRELAND
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, SILVERTONDALE, PRETORIA
M&L LABORATORY SERVICES, ORMONDE,
JOHANNESBURG
FPRR: PHARMACARE LTD, WOODMEAD, SANDTON
Shelf-life: 24 months (Provisional)
Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: 41/2.6.5/0341
Name of medicine: ASPEN RISPERIDONE 2 mg
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
RISPERIDONE 2,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: PHARMACARE LIMITED
Manufacturer: PHARMA INTERNATIONAL COMPANY, AL-
JUBEIHA, AMMAN, JORDAN
Packer: PHARMA INTERNATIONAL COMPANY, AL-
JUBEIHA, AMMAN, JORDAN
CHANELLE MEDICAL, LOUGHREA, COUNTY
GALWAY, IRELAND
Laboratory: FPRC: PHARMA INTERNATIONAL COMPANY, AL-
JUBEIHA, AMMAN, JORDAN
CHANELLE MEDICAL, LOUGHREA, COUNTY
GALWAY, IRELAND
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, SILVERTONDALE, PRETORIA
M&L LABORATORY SERVICES, ORMONDE,
JOHANNESBURG
FPRR: PHARMACARE LTD, WOODMEAD, SANDTON
Shelf-life: 24 months (Provisional)
Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: 41/2.6.5/0346
Name of medicine: ASPEN RISPERIDONE 3 mg
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
RISPERIDONE 3,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: PHARMACARE LIMITED
Manufacturer: PHARMA INTERNATIONAL COMPANY,
AL-JUBEIHA, AMMAN, JORDAN
Packer: PHARMA INTERNATIONAL COMPANY,
AL-JUBEIHA, AMMAN, JORDAN
CHANELLE MEDICAL, LOUGHREA,
COUNTY GALWAY, IRELAND
Laboratory: FPRC: PHARMA INTERNATIONAL COMPANY,
AL-JUBEIHA, AMMAN, JORDAN
CHANELLE MEDICAL, LOUGHREA,
COUNTY GALWAY, IRELAND
SOUTH AFRICAN BUREAU OF
STANDARDS, GROENKLOOF, PRETORIA
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, SILVERTONDALE,
PRETORIA
M&L LABORATORY SERVICES,
ORMONDE, JOHANNESBURG
FPRR: PHARMACARE LTD, WOODMEAD,
SANDTON
Shelf-life: 24 months (Provisional)
Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: 41/2.6.5/0347
Name of medicine: ASPEN RISPERIDONE 4 mg
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
 RISPERIDONE 4,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: PHARMACARE LIMITED
Manufacturer: PHARMA INTERNATIONAL COMPANY, AL-
 JUBEIHA, AMMAN, JORDAN
Packer: PHARMA INTERNATIONAL COMPANY, AL-
 JUBEIHA, AMMAN, JORDAN
 CHANELLE MEDICAL, LOUGHREA, COUNTY
 GALWAY, IRELAND
Laboratory: FPRC: PHARMA INTERNATIONAL COMPANY, AL-
 JUBEIHA, AMMAN, JORDAN
 CHANELLE MEDICAL, LOUGHREA, COUNTY
 GALWAY, IRELAND
 SOUTH AFRICAN BUREAU OF STANDARDS,
 GROENKLOOF, PRETORIA
 RESEARCH INSTITUTE FOR INDUSTRIAL
 PHARMACY, SILVERTONDALE, PRETORIA
 M&L LABORATORY SERVICES, ORMONDE,
 JOHANNESBURG
 FPRR: PHARMACARE LTD, WOODMEAD, SANDTON
Shelf-life: 24 months (Provisional)
Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: 41/21.12/0351
Name of medicine: FINAP 5 mg
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
 FINASTERIDE 5,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: PHARMACARE LIMITED
Manufacturer: FAMAR S.A., ANTHOUSSA, ATTIKIS,
 GREECE
Packer: FAMAR S.A., ANTHOUSSA, ATTIKIS,
 GREECE
Laboratory: FPRC: FAMAR S.A., ANTHOUSSA, ATTIKIS,
 GREECE
 PHARMATHEN S.A., PALLINI ATTIKIS,
 GREECE
 SOUTH AFRICAN BUREAU OF
 STANDARDS, GROENKLOOF, PRETORIA
 M&L LABORATORY SERVICES,
 ORMONDE, JOHANNESBURG
 RESEARCH INSTITUTE FOR INDUSTRIAL
 PHARMACY, NORTH WEST UNIVERSITY,
 POTCHEFSTROOM
 FPRR: PHARMACARE LTD, WOODMEAD,
 SANDTON
Shelf-life: 24 months
Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: 41/5.7.1/0352
Name of medicine: TELLERGE 120 mg
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
FEXOFENADINE HYDROCHLORIDE 120,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: PHARMACARE LIMITED
Manufacturer: CIPLA LTD, PLOT A, PATALGANGA,
MAHARASHTRA, INDIA
CHANELLE MEDICAL, GALWAY, IRELAND
Packer: CIPLA LTD, PLOT A, PATALGANGA,
MAHARASHTRA, INDIA
CHANELLE MEDICAL, GALWAY, IRELAND
Laboratory: FPRC: CIPLA LTD, PLOT A, PATALGANGA,
MAHARASHTRA, INDIA
CHANELLE MEDICAL, GALWAY, IRELAND
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, NORTH-WEST UNIVERSITY,
POTCHEFSTROOM
M&L LABORATOTY SERVICES, ORMONDE,
JOHANNESBURG
FPRR: PHARMACARE LTD, WOODMEAD, SANDTON
Shelf-life: 24 months
Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: 41/5.7.1/0353
Name of medicine: TELLERGE 180 mg
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
FEXOFENADINE HYDROCHLORIDE
180,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: PHARMACARE LIMITED
Manufacturer: CIPLA LTD, PLOT A, PATALGANGA,
MAHARASHTRA, INDIA
CHANELLE MEDICAL, GALWAY, IRELAND
Packer: CIPLA LTD, PLOT A, PATALGANGA,
MAHARASHTRA, INDIA
CHANELLE MEDICAL, GALWAY, IRELAND
Laboratory: FPRC: CIPLA LTD, PLOT A, PATALGANGA,
MAHARASHTRA, INDIA
CHANELLE MEDICAL, GALWAY, IRELAND
SOUTH AFRICAN BUREAU OF
STANDARDS, GROENKLOOF, PRETORIA
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, NORTH-WEST UNIVERSITY,
POTCHEFSTROOM
M&L LABORATOTY SERVICES,
ORMONDE, JOHANNESBURG
FPRR: PHARMACARE LTD, WOODMEAD,
SANDTON
Shelf-life: 24 months
Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: 41/2.5/0375
 Name of medicine: LAMITOR-200
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 LAMOTRIGINE 200,0 mg

 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: DR REDDY'S LABORATORIES (PTY) LTD
 Manufacturer: TORRENT PHARMACEUTICALS LTD,
 MEHSANA, INDIA
 Packer: TORRENT PHARMACEUTICALS LTD,
 MEHSANA, INDIA
 DRA PHARMACEUTICALS, IRENE,
 CENTURION
 Laboratory: FPRC: TORRENT PHARMACEUTICALS LTD,
 MEHSANA, INDIA
 INSTITUTE FOR PHARMACEUTICAL
 SERVICES, SILVERTONDALE, PRETORIA
 RESEARCH INSTITUTE FOR INDUSTRIAL
 PHARMACY, NORTH-WEST UNIVERSITY,
 POTCHEFSTROOM, RSA
 FPRR: DR REDDY'S LABORATORIES,
 MURRAYFIELD, PRETORIA
 Shelf-life: 24 months
 Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: 41/3.2/0431
 Name of medicine: BONIRAN 10
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 SODIUM ALENDRONATE EQUIVALENT TO
 ALENDRONIC ACID 10,0 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
 CONSULTING CHEMICAL LABORATORIES,
 ATLASVILLE, BOKSBURG
 KHULULEKANI LABORATORY SERVICES,
 COVENTRY PARK, MIDRAND
 FPRR: RANBAXY (SA), CENTURION, RSA
 Shelf-life: 24 months (Provisional)
 Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: 41/2.6.5/0445
Name of medicine: ZOxadon 1 mg
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
RISPERIDONE 1,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: PHARMA DYNAMICS (PTY) LTD
Manufacturer: ACTAVIS hf, KOPAVOGUR, ICELAND
ACTAVIS hf, HAFNARFJORDUR, ICELAND
ACTAVIS LTD, ZEJTUN, MALTA
Packer: ACTAVIS hf, KOPAVOGUR, ICELAND
ACTAVIS hf, HAFNARFJORDUR, ICELAND
ACTAVIS LTD, ZEJTUN, MALTA
TECHNIKON LABORATORIES, ROBERTVILLE,
FLORIDA
DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, JOHANNESBURG
PHARMACEUTICAL ENTERPRISES, N'DABENI,
KZN
Laboratory: FPRC: ACTAVIS hf, KOPAVOGUR, ICELAND
ACTAVIS hf, HAFNARFJORDUR, ICELAND
ACTAVIS LTD, ZEJTUN, MALTA
TECHNIKON LABORATORIES, ROBERTVILLE,
FLORIDA
CONSULTING CHEMICAL LABORATORIES,
ATLASVILLE, BOKSBURG
FPRR: PHARMA DYNAMICS, SILVERWOOD,
WESTLAKE
Shelf-life: 24 months
Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: 41/2.6.5/0446
Name of medicine: ZOxadon 2 mg
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
RISPERIDONE 2,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: PHARMA DYNAMICS (PTY) LTD
Manufacturer: ACTAVIS hf, KOPAVOGUR, ICELAND
ACTAVIS hf, HAFNARFJORDUR, ICELAND
ACTAVIS LTD, ZEJTUN, MALTA
Packer: ACTAVIS hf, KOPAVOGUR, ICELAND
ACTAVIS hf, HAFNARFJORDUR, ICELAND
ACTAVIS LTD, ZEJTUN, MALTA
TECHNIKON LABORATORIES,
ROBERTVILLE, FLORIDA
DIVPHARM MANUFACTURING &
PACKAGING, LONGDALE, JOHANNESBURG
PHARMACEUTICAL ENTERPRISES,
N'DABENI, KZN
Laboratory: FPRC: ACTAVIS hf, KOPAVOGUR, ICELAND
ACTAVIS hf, HAFNARFJORDUR, ICELAND
ACTAVIS LTD, ZEJTUN, MALTA
TECHNIKON LABORATORIES,
ROBERTVILLE, FLORIDA
CONSULTING CHEMICAL LABORATORIES,
ATLASVILLE, BOKSBURG
FPRR: PHARMA DYNAMICS, SILVERWOOD,
WESTLAKE
Shelf-life: 24 months
Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: 41/2.6.5/0447
Name of medicine: ZOxadon 6 mg
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
RISPERIDONE 6,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: PHARMA DYNAMICS (PTY) LTD
Manufacturer: ACTAVIS hf, KOPAVOGUR, ICELAND
ACTAVIS hf, HAFNARFJORDUR, ICELAND
ACTAVIS LTD, ZEJTUN, MALTA

Packer: ACTAVIS hf, KOPAVOGUR, ICELAND
ACTAVIS hf, HAFNARFJORDUR, ICELAND
ACTAVIS LTD, ZEJTUN, MALTA
TECHNIKON LABORATORIES, ROBERTVILLE,
FLORIDA
DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, JOHANNESBURG
PHARMACEUTICAL ENTERPRISES, N'DABENI, KZN

Laboratory: FPRC: ACTAVIS hf, KOPAVOGUR, ICELAND
ACTAVIS hf, HAFNARFJORDUR, ICELAND
ACTAVIS LTD, ZEJTUN, MALTA
TECHNIKON LABORATORIES, ROBERTVILLE,
FLORIDA
CONSULTING CHEMICAL LABORATORIES,
ATLASVILLE, BOKSBURG

FPRR: PHARMA DYNAMICS, SILVERWOOD, WESTLAKE

Shelf-life: 24 months
Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: 41/2.6.5/0468
Name of medicine: ZOxadon 0,5 mg
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
RISPERIDONE 0,5 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: PHARMA DYNAMICS (PTY) LTD
Manufacturer: ACTAVIS hf, KOPAVOGUR, ICELAND
ACTAVIS hf, HAFNARFJORDUR, ICELAND
ACTAVIS LTD, ZEJTUN, MALTA

Packer: ACTAVIS hf, KOPAVOGUR, ICELAND
ACTAVIS hf, HAFNARFJORDUR, ICELAND
ACTAVIS LTD, ZEJTUN, MALTA
TECHNIKON LABORATORIES, ROBERTVILLE,
FLORIDA
DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, JOHANNESBURG
PHARMACEUTICAL ENTERPRISES, N'DABENI,
KZN

Laboratory: FPRC: ACTAVIS hf, KOPAVOGUR, ICELAND
ACTAVIS hf, HAFNARFJORDUR, ICELAND
ACTAVIS LTD, ZEJTUN, MALTA
TECHNIKON LABORATORIES, ROBERTVILLE,
FLORIDA
CONSULTING CHEMICAL LABORATORIES,
ATLASVILLE, BOKSBURG

FPRR: PHARMA DYNAMICS, SILVERWOOD,
WESTLAKE

Shelf-life: 24 months
Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: 41/2.6.5/0469
Name of medicine: ZOAXADON 3 mg
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
RISPERIDONE 3,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: PHARMA DYNAMICS (PTY) LTD
Manufacturer: ACTAVIS hf, KOPAVOGUR, ICELAND
ACTAVIS hf, HAFNARFJORDUR, ICELAND
ACTAVIS LTD, ZEJTUN, MALTA
Packer: ACTAVIS hf, KOPAVOGUR, ICELAND
ACTAVIS hf, HAFNARFJORDUR, ICELAND
ACTAVIS LTD, ZEJTUN, MALTA
TECHNIKON LABORATORIES, ROBERTVILLE,
FLORIDA
DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, JOHANNESBURG
PHARMACEUTICAL ENTERPRISES, N'DABENI, KZN
Laboratory: FPRC: ACTAVIS hf, KOPAVOGUR, ICELAND
ACTAVIS hf, HAFNARFJORDUR, ICELAND
ACTAVIS LTD, ZEJTUN, MALTA
TECHNIKON LABORATORIES, ROBERTVILLE,
FLORIDA
CONSULTING CHEMICAL LABORATORIES,
ATLASVILLE, BOKSBURG
FPRR: PHARMA DYNAMICS, SILVERWOOD, WESTLAKE
Shelf-life: 24 months
Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: 41/2.6.5/0470
Name of medicine: ZOAXADON 4 mg
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
RISPERIDONE 4,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: PHARMA DYNAMICS (PTY) LTD
Manufacturer: ACTAVIS hf, KOPAVOGUR, ICELAND
ACTAVIS hf, HAFNARFJORDUR, ICELAND
ACTAVIS LTD, ZEJTUN, MALTA
Packer: ACTAVIS hf, KOPAVOGUR, ICELAND
ACTAVIS hf, HAFNARFJORDUR, ICELAND
ACTAVIS LTD, ZEJTUN, MALTA
TECHNIKON LABORATORIES, ROBERTVILLE,
FLORIDA
DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, JOHANNESBURG
PHARMACEUTICAL ENTERPRISES, N'DABENI,
KZN
Laboratory: FPRC: ACTAVIS hf, KOPAVOGUR, ICELAND
ACTAVIS hf, HAFNARFJORDUR, ICELAND
ACTAVIS LTD, ZEJTUN, MALTA
TECHNIKON LABORATORIES, ROBERTVILLE,
FLORIDA
CONSULTING CHEMICAL LABORATORIES,
ATLASVILLE, BOKSBURG
FPRR: PHARMA DYNAMICS, SILVERWOOD,
WESTLAKE
Shelf-life: 24 months
Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: 41/24/0553
Name of medicine: 0,9 % SODIUM CHLORIDE AND 5 % GLUCOSE
B BRAUN
Dosage form: INFUSION
Active ingredients: EACH 1000,0 ml SOLUTION CONTAINS:
GLUCOSE MONOHYDRATE EQUIVALENT TO
GLUCOSE 50,0 g
SODIUM CHLORIDE 9,0 g
Conditions of registration: 1, 2, 3, 4, 5, 6
Applicant: B BRAUN MEDICAL (PTY) LTD
Manufacturer: B BRAUN MELSUNGEN AG, MELSUNGEN, GERMANY
PRODUCTION PHARMA PFIEFFEWIESEN,
MELSUNGEN, GERMANY
B BRAUN MEDICAL S.A., BARCELONA, SPAIN
Packer: B BRAUN MELSUNGEN AG, MELSUNGEN, GERMANY
PRODUCTION PHARMA PFIEFFEWIESEN,
MELSUNGEN, GERMANY
B BRAUN MEDICAL S.A., BARCELONA, SPAIN
Laboratory: FPRC: B BRAUN MELSUNGEN AG, MELSUNGEN,
GERMANY
M&L LABORATORY SERVICES, ORMONDE,
JOHANNESBURG
COSI PHARMACEUTICALS, INDUSTRIA WEST,
JOHANNESBURG
CONSULTING CHEMICAL LABORATORIES,
ATLASVILLE, BOKSBURG
FPRR: B BRAUN MEDICAL, HONEYDEW, GAUTENG
Shelf-life: 36 months
Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: 41/7.1/0562
Name of medicine: DYNA AMLODIPINE BESYLATE 5 mg
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
AMLODIPINE BESYLATE EQUIVALENT TO
AMLODIPINE 5,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: PHARMA DYNAMICS (PTY) LTD
Manufacturer: KRKA , NOVO MESTO, SLOVENIA
Packer: KRKA , NOVO MESTO, SLOVENIA
TECHNIKON LABORATORIES, ROBERTVILLE,
FLORIDA
DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, JOHANNESBURG
PHARMACEUTICAL ENTERPRISES, N'DABENI,
PINELANDS
Laboratory: FPRC: KRKA , NOVO MESTO, SLOVENIA
TECHNIKON LABORATORIES, ROBERTVILLE,
FLORIDA
CONSULTING CHEMICAL LABORATORIES,
ATLASVILLE, BOKSBURG
FPRR: PHARMA DYNAMICS, SILVERWOOD,
WESTLAKE
Shelf-life: 24 months (Provisional)
Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: 41/7.1/0563
Name of medicine: DYNA AMLODIPINE BESYLATE 10 mg
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
AMLODIPINE BESYLATE EQUIVALENT TO
AMLODIPINE 10,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: PHARMA DYNAMICS (PTY) LTD
Manufacturer: KRKA , NOVO MESTO, SLOVENIA
Packer: KRKA , NOVO MESTO, SLOVENIA
TECHNIKON LABORATORIES, ROBERTVILLE,
FLORIDA
DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, JOHANNESBURG
PHARMACEUTICAL ENTERPRISES, N'DABENI,
PINELANDS
Laboratory: FPRC: KRKA , NOVO MESTO, SLOVENIA
TECHNIKON LABORATORIES, ROBERTVILLE,
FLORIDA
CONSULTING CHEMICAL LABORATORIES,
ATLASVILLE, BOKSBURG
FPRR: PHARMA DYNAMICS, SILVERWOOD,
WESTLAKE
Shelf-life: 24 months (Provisional)
Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: 41/20.2.8/0692
Name of medicine: CIPLA-ABACAVIR 300
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
ABACAVIR SULPHATE EQUIVALENT TO
ABACAVIR 300,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: CIPLA MEDPRO (PTY) LTD
Manufacturer: CIPLA LTD, PATALGANGA, RAIGAD,
MAHARASHTRA, INDIA
Packer: CIPLA LTD, PATALGANGA, RAIGAD,
MAHARASHTRA, INDIA
Laboratory: FPRC: CIPLA LTD, PATALGANGA, RAIGAD,
MAHARASHTRA, INDIA
FPRR: CIPLA MEDPRO, ROSENPARK,
BELLVILLE
Shelf-life: 24 months (Provisional)
Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: 41/20.2.8/0693
Name of medicine: ABAMUNE 300
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
 ABACAVIR SULPHATE EQUIVALENT TO
 ABACAVIR 300,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: CIPLA LIFE SCIENCES (PTY) LTD
Manufacturer: CIPLA LTD, PATALGANGA, RAIGAD,
 MAHARASHTRA, INDIA
Packer: CIPLA LTD, PATALGANGA, RAIGAD,
 MAHARASHTRA, INDIA
Laboratory: FPRC: CIPLA LTD, PATALGANGA, RAIGAD,
 MAHARASHTRA, INDIA
 FPRR: CIPLA LIFE SCIENCES, ROSEN PARK,
 BELLVILLE
Shelf-life: 24 months (Provisional)
Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: 41/20.2.8/0733
Name of medicine: ZETRODIN 100 mg
Dosage form: CAPSULE
Active ingredients: EACH CAPSULE CONTAINS:
 ZIDOVUDINE 100,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: ADCOCK INGRAM LIMITED
Manufacturer: ADCOCK INGRAM HEALTHCARE,
 WADEVILLE, GERMISTON
Packer: ADCOCK INGRAM HEALTHCARE,
 WADEVILLE, GERMISTON
 ADCOCK INGRAM LTD, AEROTON,
 JOHANNESBURG
Laboratory: FPRC/FPRR: ADCOCK INGRAM HEALTHCARE,
 WADEVILLE, GERMISTON
 ADCOCK INGRAM LTD, AEROTON,
 JOHANNESBURG
 FPRR: ADCOCK INGRAM LTD, ERAND
 GARDENS, MIDRAND
Shelf-life: 24 months (Provisional)
Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: 41/20.2.8/0734
Name of medicine: ZETRODIN 250 mg
Dosage form: CAPSULE
Active ingredients: EACH CAPSULE CONTAINS:
ZIDOVUDINE 250,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: ADCOCK INGRAM LIMITED
Manufacturer: ADCOCK INGRAM HEALTHCARE,
WADEVILLE, GERMISTON
Packer: ADCOCK INGRAM HEALTHCARE,
WADEVILLE, GERMISTON
ADCOCK INGRAM LTD, AEROTON,
JOHANNESBURG
Laboratory: FPRC/FPRR: ADCOCK INGRAM HEALTHCARE,
WADEVILLE, GERMISTON
ADCOCK INGRAM LTD, AEROTON,
JOHANNESBURG
FPRR: ADCOCK INGRAM LTD, ERAND GARDENS,
MIDRAND
Shelf-life: 24 months (Provisional)
Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: 41/8.2/0766
Name of medicine: CLOPIVAS
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
CLOPIDOGREL BISULPHATE EQUIVALENT TO
CLOPIDOGREL 75,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: CIPLA MEDPRO (PTY) LTD
Manufacturer: CIPLA LTD, UNIT VII, VERNA, GOA, INDIA
Packer: CIPLA LTD, UNIT VII, VERNA, GOA, INDIA
Laboratory: FPRC: CIPLA LTD, UNIT VII, VERNA, GOA, INDIA
FPRR: CIPLA MEDPRO, ROSENPARK, BELLVILLE
Shelf-life: 24 months (Provisional)
Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: 41/8.2/0767
 Name of medicine: CIPLA-CLOPIDOGREL
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 CLOPIDOGREL BISULPHATE EQUIVALENT TO
 CLOPIDOGREL 75,0 mg

 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
 Applicant: CIPLA LIFE SCIENCES (PTY) LTD
 Manufacturer: CIPLA LTD, UNIT VII, VERNA, GOA, INDIA
 Packer: CIPLA LTD, UNIT VII, VERNA, GOA, INDIA
 Laboratory: FPRC: CIPLA LTD, UNIT VII, VERNA, GOA, INDIA

FPRR: CIPLA LIFE SCIENCES, ROSEN PARK,
 BELLVILLE

Shelf-life: 24 months (Provisional)

Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: 41/8.2/0768
 Name of medicine: MEDPRO-CLOPIDOGREL
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 CLOPIDOGREL BISULPHATE
 EQUIVALENT TO
 CLOPIDOGREL 75,0
 mg

 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
 Applicant: MEDPRO PHARMACEUTICA (PTY) LTD
 Manufacturer: CIPLA LTD, UNIT VII, VERNA, GOA, INDIA
 Packer: CIPLA LTD, UNIT VII, VERNA, GOA, INDIA
 Laboratory: FPRC: CIPLA LTD, UNIT VII, VERNA, GOA, INDIA

FPRR: MEDPRO PHARMACEUTICA,
 ROSEN PARK, BELLVILLE

Shelf-life: 24 months (Provisional)

Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: 41/5.7.1/0780
Name of medicine: RHINETON SYRUP
Dosage form: SYRUP
Active ingredients: EACH 5,0 ml SYRUP CONTAINS:
CHLORPHENIRAMINE MALEATE 2,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: BE-TABS PHARMACEUTICALS (PTY) LTD
Manufacturer: BE-TABS PHARMACEUTICALS, ROODEPOORT
Packer: BE-TABS PHARMACEUTICALS, ROODEPOORT
Laboratory: FPRC/FPRR: BE-TABS PHARMACEUTICALS, ROODEPOORT

Shelf-life: 24 months (Provisional)
Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: 41/5.4.1/0781
Name of medicine: AZILECT 1 mg
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
RASAGILINE MESYLATE EQUIVALENT TO
RASAGILINE 1,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: H LUNDBECK (PTY) LTD
Manufacturer: TEVA PHARMACEUTICAL INDUSTRIES
LTD, KFAR-SABA, ISRAEL
Packer: TEVA PHARMACEUTICAL INDUSTRIES
LTD, KFAR-SABA, ISRAEL
Laboratory: FPRC: TEVA PHARMACEUTICAL INDUSTRIES
LTD, KFAR-SABA, ISRAEL

FPRR: H LUNDBECK, NORTH RIDING, RSA
Shelf-life: 24 months
Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: 41/20.2.8/0799
Name of medicine: CIPLA-OSELTAMIVIR

Dosage form: CAPSULE

Active ingredients: EACH CAPSULE CONTAINS:
 OSELTAMIVIR PHOSPHATE EQUIVALENT TO
 OSELTAMIVIR 75,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: CIPLA LIFE SCIENCES (PTY) LTD
Manufacturer: CIPLA LTD, VERNA, GOA, INDIA

Packer: CIPLA LTD, VERNA, GOA, INDIA

Laboratory: FPRC: CIPLA LTD, VERNA, GOA, INDIA

FPRR: CIPLA LIFE SCIENCES, ROSENPARK,
 BELLVILLE

Shelf-life: 24 months (Provisional)
Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: 41/20.2.8/0856
Name of medicine: ABAMUNE ORAL SOLUTION

Dosage form: SOLUTION

Active ingredients: EACH 1,0 ml SOLUTION CONTAINS:
 ABACAVIR SULPHATE EQUIVALENT TO
 ABACAVIR 20,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: CIPLA LIFE SCIENCES (PTY) LTD
Manufacturer: CIPLA LTD, UNIT I, VERNA, SALCETTE,
 GOA, INDIA

Packer: CIPLA LTD, UNIT I, VERNA, SALCETTE,
 GOA, INDIA

Laboratory: FPRC: CIPLA LTD, UNIT I, VERNA, SALCETTE,
 GOA, INDIA

FPRR: CIPLA LIFE SCIENCES, ROSENPARK,
 BELLVILLE

Shelf-life: 24 months (Provisional)
Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: 41/20.2.8/0857
Name of medicine: CIPLA-ABACAVIR ORAL SOLUTION
Dosage form: SOLUTION
Active ingredients: EACH 1,0 ml SOLUTION CONTAINS:
ABACAVIR SULPHATE EQUIVALENT TO
ABACAVIR 20,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: CIPLA MEDPRO (PTY) LTD
Manufacturer: CIPLA LTD, UNIT I, VERNA, SALCETTE, GOA,
INDIA
Packer: CIPLA LTD, UNIT I, VERNA, SALCETTE, GOA,
INDIA
Laboratory: FPRC: CIPLA LTD, UNIT I, VERNA, SALCETTE, GOA,
INDIA
FPRR: CIPLA MEDPRO, ROSENPAK, BELLVILLE
Shelf-life: 24 months (Provisional)
Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: 41/15.4/0860
Name of medicine: LUCENTIS
Dosage form: SOLUTION
Active ingredients: EACH 1,0 ml SOLUTION CONTAINS:
RANIBIZUMAB 10,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: NOVARTIS SOUTH AFRICA (PTY) LTD
Manufacturer: NOVARTIS PHARMA STEIN AG, STEIN,
SWITZERLAND
Packer: NOVARTIS PHARMA STEIN AG, STEIN,
SWITZERLAND
NOVARTIS S.A., SPARTAN, KEMPTON
PARK
Laboratory: FPRC: NOVARTIS PHARMA STEIN AG, STEIN,
SWITZERLAND
NOVARTIS PHARMA AG, BASLE,
SWITZERLAND
M&L LABORATORY SERVICES,
ORMONDE, JOHANNESBURG
FPRC/FPRR: NOVARTIS S.A., SPARTAN, KEMPTON
PARK
Shelf-life: 24 months (Provisional)
Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: 41/2.6.5/0874
Name of medicine: MERCK-RISPERIDONE 0,25
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
RISPERIDONE 0,25 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: MERCK GENERICS RSA (PTY) LTD
Manufacturer: PHARMA INTERNATIONAL CO, AL-JUBEIHA, AMMAN,
JORDAN
Packer: PHARMA INTERNATIONAL CO, AL-JUBEIHA, AMMAN,
JORDAN
CHANELLE MEDICAL, LOUGHREA, Co GALWAY,
IRELAND
GENERICS (UK) LTD, STATION CLOSE,
HERTFORDSHIRE, UK
GERARD LABORATORIES, DUBLIN, IRELAND
MERCK PHARMACEUTICAL MANUFACTURERS,
WADEVILLE, GERMISTON
Laboratory: FPRC: PHARMA INTERNATIONAL CO, AL-JUBEIHA, AMMAN,
JORDAN
CHANELLE MEDICAL, LOUGHREA, Co GALWAY,
IRELAND
GENERICS (UK) LTD, STATION CLOSE,
HERTFORDSHIRE, UK
GERARD LABORATORIES, DUBLIN, IRELAND
MERCK PHARMACEUTICAL MANUFACTURERS,
WADEVILLE, GERMISTON
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, NORTH-WEST UNIVERSITY,
POTCHEFSTROOM
FPRR: MERCK GENERICS RSA, MODDERFONTEIN, RSA
Shelf-life: 24 months
Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: 41/2.6.5/0875
Name of medicine: MERCK-RISPERIDONE 0,5
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
RISPERIDONE 0,5 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: MERCK GENERICS RSA (PTY) LTD
Manufacturer: PHARMA INTERNATIONAL CO, AL-JUBEIHA,
AMMAN, JORDAN
Packer: PHARMA INTERNATIONAL CO, AL-JUBEIHA,
AMMAN, JORDAN
CHANELLE MEDICAL, LOUGHREA, Co
GALWAY, IRELAND
GENERICS (UK) LTD, STATION CLOSE,
HERTFORDSHIRE, UK
GERARD LABORATORIES, DUBLIN, IRELAND
MERCK PHARMACEUTICAL
MANUFACTURERS, WADEVILLE, GERMISTON
Laboratory: FPRC: PHARMA INTERNATIONAL CO, AL-JUBEIHA,
AMMAN, JORDAN
CHANELLE MEDICAL, LOUGHREA, Co
GALWAY, IRELAND
GENERICS (UK) LTD, STATION CLOSE,
HERTFORDSHIRE, UK
GERARD LABORATORIES, DUBLIN, IRELAND
MERCK PHARMACEUTICAL
MANUFACTURERS, WADEVILLE, GERMISTON
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, NORTH-WEST UNIVERSITY,
POTCHEFSTROOM
FPRR: MERCK GENERICS RSA, MODDERFONTEIN,
RSA
Shelf-life: 24 months
Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: 41/2.6.5/0876
 Name of medicine: MERCK-RISPERIDONE 1
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 RISPERIDONE 1,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: MERCK GENERICS RSA (PTY) LTD
 Manufacturer: PHARMA INTERNATIONAL CO, AL-JUBEIHA, AMMAN,
 JORDAN
 Packer: PHARMA INTERNATIONAL CO, AL-JUBEIHA, AMMAN,
 JORDAN
 CHANELLE MEDICAL, LOUGHREA, Co GALWAY,
 IRELAND
 GENERICS (UK) LTD, STATION CLOSE,
 HERTFORDSHIRE, UK
 GERARD LABORATORIES, DUBLIN, IRELAND
 MERCK PHARMACEUTICAL MANUFACTURERS,
 WADEVILLE, GERMISTON
 Laboratory: FPRC: PHARMA INTERNATIONAL CO, AL-JUBEIHA, AMMAN,
 JORDAN
 CHANELLE MEDICAL, LOUGHREA, Co GALWAY,
 IRELAND
 GENERICS (UK) LTD, STATION CLOSE,
 HERTFORDSHIRE, UK
 GERARD LABORATORIES, DUBLIN, IRELAND
 MERCK PHARMACEUTICAL MANUFACTURERS,
 WADEVILLE, GERMISTON
 RESEARCH INSTITUTE FOR INDUSTRIAL
 PHARMACY, NORTH-WEST UNIVERSITY,
 POTCHEFSTROOM
 FPRR: MERCK GENERICS RSA, MODDERFONTEIN, RSA
 Shelf-life: 24 months
 Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: 41/2.6.5/0877
 Name of medicine: MERCK-RISPERIDONE 2
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 RISPERIDONE 2,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: MERCK GENERICS RSA (PTY) LTD
 Manufacturer: PHARMA INTERNATIONAL CO, AL-JUBEIHA,
 AMMAN, JORDAN
 Packer: PHARMA INTERNATIONAL CO, AL-JUBEIHA,
 AMMAN, JORDAN
 CHANELLE MEDICAL, LOUGHREA, Co
 GALWAY, IRELAND
 GENERICS (UK) LTD, STATION CLOSE,
 HERTFORDSHIRE, UK
 GERARD LABORATORIES, DUBLIN, IRELAND
 MERCK PHARMACEUTICAL
 MANUFACTURERS, WADEVILLE, GERMISTON
 Laboratory: FPRC: PHARMA INTERNATIONAL CO, AL-JUBEIHA,
 AMMAN, JORDAN
 CHANELLE MEDICAL, LOUGHREA, Co
 GALWAY, IRELAND
 GENERICS (UK) LTD, STATION CLOSE,
 HERTFORDSHIRE, UK
 GERARD LABORATORIES, DUBLIN, IRELAND
 MERCK PHARMACEUTICAL
 MANUFACTURERS, WADEVILLE, GERMISTON
 RESEARCH INSTITUTE FOR INDUSTRIAL
 PHARMACY, NORTH-WEST UNIVERSITY,
 POTCHEFSTROOM
 FPRR: MERCK GENERICS RSA, MODDERFONTEIN,
 RSA
 Shelf-life: 24 months
 Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: 41/2.6.5/0878
Name of medicine: MERCK-RISPERIDONE 3
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
 RISPERIDONE 3,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: MERCK GENERICS RSA (PTY) LTD
Manufacturer: PHARMA INTERNATIONAL CO, AL-JUBEIHA, AMMAN, JORDAN
Packer: PHARMA INTERNATIONAL CO, AL-JUBEIHA, AMMAN, JORDAN
 CHANELLE MEDICAL, LOUGHREA, Co GALWAY, IRELAND
 GENERICS (UK) LTD, STATION CLOSE, HERTFORDSHIRE, UK
 GERARD LABORATORIES, DUBLIN, IRELAND
 MERCK PHARMACEUTICAL MANUFACTURERS, WADEVILLE,
 GERMISTON
Laboratory: PHARMA INTERNATIONAL CO, AL-JUBEIHA, AMMAN, JORDAN
FPRC: CHANELLE MEDICAL, LOUGHREA, Co GALWAY, IRELAND
 GENERICS (UK) LTD, STATION CLOSE, HERTFORDSHIRE, UK
 GERARD LABORATORIES, DUBLIN, IRELAND
 MERCK PHARMACEUTICAL MANUFACTURERS, WADEVILLE,
 GERMISTON
 RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-
 WEST UNIVERSITY, POTCHEFSTROOM

FPRR: MERCK GENERICS RSA, MODDERFONTEIN, RSA
Shelf-life: 24 months
Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: 41/2.6.5/0879
Name of medicine: MERCK-RISPERIDONE 4
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
 RISPERIDONE 4,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: MERCK GENERICS RSA (PTY) LTD
Manufacturer: PHARMA INTERNATIONAL CO, AL-JUBEIHA, AMMAN, JORDAN
Packer: PHARMA INTERNATIONAL CO, AL-JUBEIHA, AMMAN, JORDAN
 CHANELLE MEDICAL, LOUGHREA, Co GALWAY, IRELAND
 GENERICS (UK) LTD, STATION CLOSE, HERTFORDSHIRE, UK
 GERARD LABORATORIES, DUBLIN, IRELAND
 MERCK PHARMACEUTICAL MANUFACTURERS, WADEVILLE,
 GERMISTON
Laboratory: PHARMA INTERNATIONAL CO, AL-JUBEIHA, AMMAN, JORDAN
FPRC: CHANELLE MEDICAL, LOUGHREA, Co GALWAY, IRELAND
 GENERICS (UK) LTD, STATION CLOSE, HERTFORDSHIRE, UK
 GERARD LABORATORIES, DUBLIN, IRELAND
 MERCK PHARMACEUTICAL MANUFACTURERS, WADEVILLE,
 GERMISTON
 RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-
 WEST UNIVERSITY, POTCHEFSTROOM

FPRR: MERCK GENERICS RSA, MODDERFONTEIN, RSA
Shelf-life: 24 months
Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: 41/2.6.5/0880
Name of medicine: MERCK-RISPERIDONE 6
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
RISPERIDONE 6,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: MERCK GENERICS RSA (PTY) LTD
Manufacturer: PHARMA INTERNATIONAL CO, AL-JUBEIHA, AMMAN,
JORDAN
Packer: PHARMA INTERNATIONAL CO, AL-JUBEIHA, AMMAN,
JORDAN
CHANELLE MEDICAL, LOUGHREA, Co GALWAY, IRELAND
GENERICS (UK) LTD, STATION CLOSE, HERTFORDSHIRE,
UK
GERARD LABORATORIES, DUBLIN, IRELAND
MERCK PHARMACEUTICAL MANUFACTURERS,
WADEVILLE, GERMISTON
Laboratory: FPRC: PHARMA INTERNATIONAL CO, AL-JUBEIHA, AMMAN,
JORDAN
CHANELLE MEDICAL, LOUGHREA, Co GALWAY, IRELAND
GENERICS (UK) LTD, STATION CLOSE, HERTFORDSHIRE,
UK
GERARD LABORATORIES, DUBLIN, IRELAND
MERCK PHARMACEUTICAL MANUFACTURERS,
WADEVILLE, GERMISTON
RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY,
NORTH-WEST UNIVERSITY, POTCHEFSTROOM
FPRR: MERCK GENERICS RSA, MODDERFONTEIN, RSA
Shelf-life: 24 months
Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: 41/1.2/0896
Name of medicine: ASPEN ESCITALOPRAM 5 mg
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
ESCITALOPRAM OXALATE EQUIVALENT TO
ESCITALOPRAM 5,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: PHARMACARE LIMITED
Manufacturer: ALPHAPHARM, CAROLE PARK, QUEENSLAND,
AUSTRALIA
MERCK PHARMA y QUIMICA, MOLLET DEL
VALLES, BARCELONA, SPAIN
Packer: ALPHAPHARM, CAROLE PARK, QUEENSLAND,
AUSTRALIA
MERCK PHARMA y QUIMICA, MOLLET DEL
VALLES, BARCELONA, SPAIN
GERARD LABORATORIES, DUBLIN, IRELAND
GENERICS (UK) LTD, STATION CLOSE,
HERTFORDSHIRE, UK
Laboratory: FPRC: ALPHAPHARM, CAROLE PARK, QUEENSLAND,
AUSTRALIA
MERCK PHARMA y QUIMICA, MOLLET DEL
VALLES, BARCELONA, SPAIN
GERARD LABORATORIES, DUBLIN, IRELAND
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA
M&L LABORATORY SERVICES, ORMONDE,
JOHANNESBURG
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, NORTH WEST UNIVERSITY,
POTCHEFSTROOM
FPRR: PHARMACARE LTD, WOODMEAD, SANDTON
Shelf-life: 24 months (Provisional)
Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: 41/1.2/0897
 Name of medicine: ASPEN ESCITALOPRAM 10 mg
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 ESCITALOPRAM OXALATE EQUIVALENT TO
 ESCITALOPRAM 10 ,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
 Applicant: PHARMACARE LIMITED
 Manufacturer: ALPHAPHARM, CAROLE PARK, QUEENSLAND,
 AUSTRALIA
 MERCK PHARMA y QUIMICA, MOLLET DEL VALLES,
 BARCELONA, SPAIN
 Packer: ALPHAPHARM, CAROLE PARK, QUEENSLAND,
 AUSTRALIA
 MERCK PHARMA y QUIMICA, MOLLET DEL VALLES,
 BARCELONA, SPAIN
 GERARD LABORATORIES, DUBLIN, IRELAND
 GENERICS (UK) LTD, STATION CLOSE,
 HERTFORDSHIRE, UK
 Laboratory: FPRC: ALPHAPHARM, CAROLE PARK, QUEENSLAND,
 AUSTRALIA
 MERCK PHARMA y QUIMICA, MOLLET DEL VALLES,
 BARCELONA, SPAIN
 GERARD LABORATORIES, DUBLIN, IRELAND
 SOUTH AFRICAN BUREAU OF STANDARDS,
 GROENKLOOF, PRETORIA
 M&L LABORATORY SERVICES, ORMONDE,
 JOHANNESBURG
 RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY,
 NORTH WEST UNIVERSITY, POTCHEFSTROOM
 FPRR: PHARMACARE LTD, WOODMEAD, SANDTON
 Shelf-life: 24 months (Provisional)
 Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: 41/1.2/0898
 Name of medicine: ASPEN ESCITALOPRAM 15 mg
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 ESCITALOPRAM OXALATE EQUIVALENT TO
 ESCITALOPRAM 15 ,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
 Applicant: PHARMACARE LIMITED
 Manufacturer: ALPHAPHARM, CAROLE PARK, QUEENSLAND,
 AUSTRALIA
 MERCK PHARMA y QUIMICA, MOLLET DEL
 VALLES, BARCELONA, SPAIN
 Packer: ALPHAPHARM, CAROLE PARK, QUEENSLAND,
 AUSTRALIA
 MERCK PHARMA y QUIMICA, MOLLET DEL
 VALLES, BARCELONA, SPAIN
 GERARD LABORATORIES, DUBLIN, IRELAND
 GENERICS (UK) LTD, STATION CLOSE,
 HERTFORDSHIRE, UK
 Laboratory: FPRC: ALPHAPHARM, CAROLE PARK, QUEENSLAND,
 AUSTRALIA
 MERCK PHARMA y QUIMICA, MOLLET DEL
 VALLES, BARCELONA, SPAIN
 GERARD LABORATORIES, DUBLIN, IRELAND
 SOUTH AFRICAN BUREAU OF STANDARDS,
 GROENKLOOF, PRETORIA
 M&L LABORATORY SERVICES, ORMONDE,
 JOHANNESBURG
 RESEARCH INSTITUTE FOR INDUSTRIAL
 PHARMACY, NORTH WEST UNIVERSITY,
 POTCHEFSTROOM
 FPRR: PHARMACARE LTD, WOODMEAD, SANDTON
 Shelf-life: 24 months (Provisional)
 Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: 41/1.2/0899
Name of medicine: ASPEN ESCITALOPRAM 20 mg
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
ESCITALOPRAM OXALATE EQUIVALENT TO
ESCITALOPRAM 20,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: PHARMACARE LIMITED
Manufacturer: ALPHAPHARM, CAROLE PARK, QUEENSLAND,
AUSTRALIA
MERCK PHARMA y QUIMICA, MOLLET DEL VALLES,
BARCELONA, SPAIN
Packer: ALPHAPHARM, CAROLE PARK, QUEENSLAND,
AUSTRALIA
MERCK PHARMA y QUIMICA, MOLLET DEL VALLES,
BARCELONA, SPAIN
GERARD LABORATORIES, DUBLIN, IRELAND
GENERICIS (UK) LTD, STATION CLOSE,
HERTFORDSHIRE, UK
Laboratory: FPRC: ALPHAPHARM, CAROLE PARK, QUEENSLAND,
AUSTRALIA
MERCK PHARMA y QUIMICA, MOLLET DEL VALLES,
BARCELONA, SPAIN
GERARD LABORATORIES, DUBLIN, IRELAND
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA
M&L LABORATORY SERVICES, ORMONDE,
JOHANNESBURG
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, NORTH WEST UNIVERSITY,
POTCHEFSTROOM
FPRR: PHARMACARE LTD, WOODMEAD, SANDTON
Shelf-life: 24 months (Provisional)
Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: 41/2.6.5/0937
Name of medicine: RISPONZ 1 TABLETS
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
RISPERIDONE 1,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
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
INSTITUTE FOR PHARMACEUTICAL
SERVICES, SILVERTONDALE, PRETORIA
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, NORTH-WEST UNIVERSITY,
POTCHEFSTROOM
FPRR: ZYDUS HEALTHCARE, VAN DER HOFF PARK,
POTCHEFSTROOM
Shelf-life: 24 months (Provisional)
Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: 41/2.6.5/0938
 Name of medicine: RISPOZ 2 TABLETS
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 RISPERIDONE 2,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
 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
 INSTITUTE FOR PHARMACEUTICAL SERVICES,
 SILVERTONDALE, PRETORIA
 RESEARCH INSTITUTE FOR INDUSTRIAL
 PHARMACY, NORTH-WEST UNIVERSITY,
 POTCHEFSTROOM
 FPRR: ZYDUS HEALTHCARE, VAN DER HOFF PARK,
 POTCHEFSTROOM
 Shelf-life: 24 months (Provisional)
 Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: 41/2.6.5/0939
 Name of medicine: RISPOZ 3 TABLETS
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 RISPERIDONE 3,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
 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
 INSTITUTE FOR PHARMACEUTICAL
 SERVICES, SILVERTONDALE, PRETORIA
 RESEARCH INSTITUTE FOR INDUSTRIAL
 PHARMACY, NORTH-WEST UNIVERSITY,
 POTCHEFSTROOM
 FPRR: ZYDUS HEALTHCARE, VAN DER HOFF
 PARK, POTCHEFSTROOM
 Shelf-life: 24 months (Provisional)
 Date of registration: 9 DECEMBER 2008

MRF 15	
Registration number:	41/2.6.5/0940
Name of medicine:	RISPONZ 4 TABLETS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RISPERIDONE 4,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
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 INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR: ZYDUS HEALTHCARE, VAN DER HOFF PARK, POTCHEFSTROOM
Shelf-life:	24 months (Provisional)
Date of registration:	9 DECEMBER 2008

MRF 15	
Registration number:	41/26/1039
Name of medicine:	SPRYCEL 20 mg TABLETS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: DASATINIB 20,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	BRISTOL-MYERS SQUIBB (PTY) LTD
Manufacturer:	BRISTOL-MYERS SQUIBB CO, VERNON, INDIANA, USA
Packer:	BRISTOL-MYERS SQUIBB CO, VERNON, INDIANA, USA BRISTOL-MYERS SQUIBB, EPERNON, FRANCE
Laboratory:	FPRC: BRISTOL-MYERS SQUIBB, EPERNON, FRANCE MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
	FPRR: BRISTOL-MYERS SQUIBB, BEDFORDVIEW, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	9 DECEMBER 2008

MRF 15

Registration number: 41/26/1040
 Name of medicine: SPRYCEL 50 mg TABLETS
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 DASATINIB 50,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
 Applicant: BRISTOL-MYERS SQUIBB (PTY) LTD
 Manufacturer: BRISTOL-MYERS SQUIBB CO, VERNON,
 INDIANA, USA
 Packer: BRISTOL-MYERS SQUIBB CO, VERNON,
 INDIANA, USA
 BRISTOL-MYERS SQUIBB, EPERNON, FRANCE
 Laboratory: FPRC: BRISTOL-MYERS SQUIBB, EPERNON, FRANCE
 MERCK PHARMACEUTICAL MANUFACTURING,
 WADEVILLE, GERMISTON
 CONSULTING CHEMICAL LABORATORIES,
 ATLASVILE, BOKSBURG
 FPRR: BRISTOL-MYERS SQUIBB, BEDFORDVIEW,
 RSA
 Shelf-life: 24 months (Provisional)
 Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: 41/26/1041
 Name of medicine: SPRYCEL 70 mg TABLETS
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 DASATINIB 70,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
 Applicant: BRISTOL-MYERS SQUIBB (PTY) LTD
 Manufacturer: BRISTOL-MYERS SQUIBB CO, VERNON,
 INDIANA, USA
 Packer: BRISTOL-MYERS SQUIBB CO, VERNON,
 INDIANA, USA
 BRISTOL-MYERS SQUIBB, EPERNON,
 FRANCE
 Laboratory: FPRC: BRISTOL-MYERS SQUIBB, EPERNON,
 FRANCE
 MERCK PHARMACEUTICAL
 MANUFACTURING, WADEVILLE,
 GERMISTON
 CONSULTING CHEMICAL
 LABORATORIES, ATLASVILE, BOKSBURG
 FPRR: BRISTOL-MYERS SQUIBB,
 BEDFORDVIEW, RSA
 Shelf-life: 24 months (Provisional)
 Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: 41/2.6.5/1056
Name of medicine: AUROPIDONE SOLUTION 1 mg/ml
Dosage form: SOLUTION
Active ingredients: EACH 1,0 ml SOLUTION CONTAINS:
RISPERIDONE 1,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: AUROBINDO PHARMA (PTY) LTD
Manufacturer: AUROBINDO PHARMA LTD, UNIT III, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer: AUROBINDO PHARMA LTD, UNIT III, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Laboratory: FPRC: AUROBINDO PHARMA LTD, UNIT III, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA

FPRR: AUROBINDO PHARMA, MEYERSDAL,
JOHANNESBURG

Shelf-life: 24 months (Provisional)

Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: 41/2.6.5/1057
Name of medicine: AURO-RISPERIDONE SOLUTION 1 mg/ml
Dosage form: SOLUTION
Active ingredients: EACH 1,0 ml SOLUTION CONTAINS:
RISPERIDONE 1,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: AUROBINDO PHARMA (PTY) LTD
Manufacturer: AUROBINDO PHARMA LTD, UNIT III, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer: AUROBINDO PHARMA LTD, UNIT III, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Laboratory: FPRC: AUROBINDO PHARMA LTD, UNIT III, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA

FPRR: AUROBINDO PHARMA, MEYERSDAL,
JOHANNESBURG

Shelf-life: 24 months (Provisional)

Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: 41/26/1092
Name of medicine: SANDOZ PACLITAXEL 30
Dosage form: INFUSION
Active ingredients: EACH VIAL CONTAINS:
 PACLITAXEL 30,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: SANDOZ S.A.(PTY) LTD
Manufacturer: HAUPT PHARMA WOLFRATSHAUSEN GmbH,
 WOLFRATSHAUSEN, GERMANY
Packer: HAUPT PHARMA WOLFRATSHAUSEN GmbH,
 WOLFRATSHAUSEN, GERMANY
Laboratory: FPRC: HAUPT PHARMA WOLFRATSHAUSEN GmbH,
 WOLFRATSHAUSEN, GERMANY
 SOUTH AFRICAN BUREAU OF STANDARDS,
 GROENKLOOF, PRETORIA

FPRC/FPRR: SANDOZ S.A., SPARTAN, KEMPTON PARK

Shelf-life: 24 months (Provisional)
Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: 41/26/1093
Name of medicine: SANDOZ PACLITAXEL 100
Dosage form: INFUSION
Active ingredients: EACH VIAL CONTAINS:
 PACLITAXEL 100,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: SANDOZ S.A.(PTY) LTD
Manufacturer: HAUPT PHARMA WOLFRATSHAUSEN GmbH,
 WOLFRATSHAUSEN, GERMANY
Packer: HAUPT PHARMA WOLFRATSHAUSEN GmbH,
 WOLFRATSHAUSEN, GERMANY
Laboratory: FPRC: HAUPT PHARMA WOLFRATSHAUSEN GmbH,
 WOLFRATSHAUSEN, GERMANY
 SOUTH AFRICAN BUREAU OF STANDARDS,
 GROENKLOOF, PRETORIA

FPRC/FPRR: SANDOZ S.A., SPARTAN, KEMPTON PARK

Shelf-life: 24 months (Provisional)
Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: 41/26/1094
Name of medicine: SANDOZ PACLITAXEL 300
Dosage form: INFUSION
Active ingredients: EACH VIAL CONTAINS:
PACLITAXEL 300,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: SANDOZ S.A.(PTY) LTD
Manufacturer: HAUPT PHARMA WOLFRATSHAUSEN GmbH,
WOLFRATSHAUSEN, GERMANY
Packer: HAUPT PHARMA WOLFRATSHAUSEN GmbH,
WOLFRATSHAUSEN, GERMANY
Laboratory: FPRC: HAUPT PHARMA WOLFRATSHAUSEN GmbH,
WOLFRATSHAUSEN, GERMANY
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA
FPRC/FPRR: SANDOZ S.A., SPARTAN, KEMPTON PARK
Shelf-life: 24 months (Provisional)
Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: 41/34/1125
Name of medicine: BICAVERA 1,5 % GLUCOSE (SOLUTION FOR
PERITONEAL DIALYSIS)
Dosage form: SOLUTION
Active ingredients: EACH 1000,0 ml SOLUTION CONTAINS:
SODIUM CHLORIDE 11,57 g
CALCIUM CHLORIDE DIHYDRATE 0,5145 g
MAGNESIUM CHLORIDE HEXA-HYDRATE
0,2033 g
GLUCOSE MONOHYDRATE EQUIVALENT TO
GLUCOSE 30,0 g
Conditions of registration: 1, 2, 3, 4, 5, 6
Applicant: FRESENIUS KABI SOUTH AFRICA (PTY) LTD
Manufacturer: FRESENIUS MEDICAL CARE DEUTSCHLAND
GmbH, WENDEL, GERMANY
Packer: FRESENIUS MEDICAL CARE DEUTSCHLAND
GmbH, WENDEL, GERMANY
Laboratory: FPRC: FRESENIUS MEDICAL CARE DEUTSCHLAND
GmbH, WENDEL, GERMANY
BODENE, t/a INTRAMED, KORSTEN, PORT
ELIZABETH
FPRR: FRESENIUS KABI SA, HALFWAY HOUSE, RSA
Shelf-life: 24 months
Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: 41/34/1126
Name of medicine: BICAVERA 2,3 % GLUCOSE (SOLUTION FOR PERITONEAL DIALYSIS)
Dosage form: SOLUTION
Active ingredients: EACH 1000,0 ml SOLUTION CONTAINS:
 SODIUM CHLORIDE 11,57 g
 CALCIUM CHLORIDE DIHYDRATE 0,5145 g
 MAGNESIUM CHLORIDE HEXA-HYDRATE 0,2033 g
 GLUCOSE MONOHYDRATE EQUIVALENT TO GLUCOSE 45,46 g
Conditions of registration: 1, 2, 3, 4, 5, 6
Applicant: FRESENIUS KABI SOUTH AFRICA (PTY) LTD
Manufacturer: FRESENIUS MEDICAL CARE DEUTSCHLAND GmbH, WENDEL, GERMANY
Packer: FRESENIUS MEDICAL CARE DEUTSCHLAND GmbH, WENDEL, GERMANY
Laboratory: FPRC: FRESENIUS MEDICAL CARE DEUTSCHLAND GmbH, WENDEL, GERMANY
 BODENE, 1/a INTRAMED, KORSTEN, PORT ELIZABETH
FPRR: FRESENIUS KABI SA, HALFWAY HOUSE, RSA
Shelf-life: 24 months
Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: 41/34/1127
Name of medicine: BICAVERA 4,25 % GLUCOSE (SOLUTION FOR PERITONEAL DIALYSIS)
Dosage form: SOLUTION
Active ingredients: EACH 1000,0 ml SOLUTION CONTAINS:
 SODIUM CHLORIDE 11,57 g
 CALCIUM CHLORIDE DIHYDRATE 0,5145 g
 MAGNESIUM CHLORIDE HEXA-HYDRATE 0,2033 g
 GLUCOSE MONOHYDRATE EQUIVALENT TO GLUCOSE 85,0 g
Conditions of registration: 1, 2, 3, 4, 5, 6
Applicant: FRESENIUS KABI SOUTH AFRICA (PTY) LTD
Manufacturer: FRESENIUS MEDICAL CARE DEUTSCHLAND GmbH, WENDEL, GERMANY
Packer: FRESENIUS MEDICAL CARE DEUTSCHLAND GmbH, WENDEL, GERMANY
Laboratory: FPRC: FRESENIUS MEDICAL CARE DEUTSCHLAND GmbH, WENDEL, GERMANY
 BODENE, 1/a INTRAMED, KORSTEN, PORT ELIZABETH
FPRR: FRESENIUS KABI SA, HALFWAY HOUSE, RSA
Shelf-life: 24 months
Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: 42/20.1.1/0004
Name of medicine: CURITAZ 4,5
Dosage form: INJECTION
Active ingredients: EACH VIAL CONTAINS:
PIPERACILLIN SODIUM EQUIVALENT TO 4,0 g
PIPERACILLIN
TAZOBACTAM SODIUM EQUIVALENT TO 500,0 mg
TAZOBACTAM
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: SANDOZ S.A. (PTY) LTD
Manufacturer: SANDOZ GmbH, KUNDL, AUSTRIA
Packer: SANDOZ GmbH, KUNDL, AUSTRIA
Laboratory: FPRC: SANDOZ GmbH, KUNDL, AUSTRIA
NOVARTIS S.A., SPARTAN, KEMPTON PARK
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA
FPRC: SANDOZ S.A., SPARTAN, KEMPTON PARK
Shelf-life: 24 months
Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: 42/26/0018
Name of medicine: ASPEN EPIRUBICIN 10 mg
Dosage form: INJECTION
Active ingredients: EACH VIAL CONTAINS:
EPIRUBICIN HYDROCHLORIDE 10,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: PHARMACARE LIMITED
Manufacturer: THYMOORGAN GmbH PHARMAZIE & CO,
VIENENBURG, GERMANY
S.C. SINDAN-PHARMA SRL, BUCHAREST,
ROMANIA
Packer: THYMOORGAN GmbH PHARMAZIE & CO,
VIENENBURG, GERMANY
S.C. SINDAN-PHARMA SRL, BUCHAREST,
ROMANIA
Laboratory: FPRC: THYMOORGAN GmbH PHARMAZIE & CO,
VIENENBURG, GERMANY
S.C. SINDAN-PHARMA SRL, BUCHAREST,
ROMANIA
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, NORTH-WEST UNIVERSITY,
POTCHEFSTROOM
M&L LABORATORY SERVICES, ORMONDE,
JOHANNESBURG
FPRC: PHARMACARE LTD, WOODMEAD, SANDTON
Shelf-life: 24 months
Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: 42/26/0019
Name of medicine: ASPEN EPIRUBICIN 50 mg
Dosage form: INJECTION
Active ingredients: EACH VIAL CONTAINS:
EPIRUBICIN HYDROCHLORIDE 50,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: PHARMACARE LIMITED
Manufacturer: THYMOORGAN GmbH PHARMAZIE & CO,
VIENENBURG, GERMANY
S.C. SINDAN-PHARMA SRL, BUCHAREST, ROMANIA
Packer: THYMOORGAN GmbH PHARMAZIE & CO,
VIENENBURG, GERMANY
S.C. SINDAN-PHARMA SRL, BUCHAREST, ROMANIA
Laboratory: FPRC: THYMOORGAN GmbH PHARMAZIE & CO,
VIENENBURG, GERMANY
S.C. SINDAN-PHARMA SRL, BUCHAREST, ROMANIA
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, NORTH-WEST UNIVERSITY,
POTCHEFSTROOM
M&L LABORATORY SERVICES, ORMONDE,
JOHANNESBURG
FPRR: PHARMACARE LTD, WOODMEAD, SANDTON
Shelf-life: 24 months
Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: 42/2.6.5/0101
Name of medicine: SANDOZ RISPERIDONE 0,5
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
RISPERIDONE 0,5 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: SANDOZ SA (PTY) LTD
Manufacturer: SALUTAS PHARMA GmbH, BARLEBEN,
GERMANY
Packer: SALUTAS PHARMA GmbH, BARLEBEN,
GERMANY
SANDOZ SA, SPARTAN, KEMPTON PARK
Laboratory: FPRC: SALUTAS PHARMA GmbH, BARLEBEN,
GERMANY
ANALYTICON, TERENURE, KEMPTON PARK
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA
FPRC/FPFR: SANDOZ SA, SPARTAN, KEMPTON PARK
Shelf-life: 24 months
Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: 42/7.3/0269
Name of medicine: AURO-SUMATRIPTAN TABLETS 50 mg

Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
SUMATRIPTAN SUCCINATE EQUIVALENT TO
SUMATRIPTAN 50,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: AUROBINDO PHARMA (PTY) LTD
Manufacturer: AUROBINDO PHARMA LTD, UNIT III, RANGA
REDDY DISTRICT, ANDHRA PRADESH, INDIA

Packer: AUROBINDO PHARMA LTD, UNIT III, RANGA
REDDY DISTRICT, ANDHRA PRADESH, INDIA

Laboratory: FPRC: AUROBINDO PHARMA LTD, UNIT III, RANGA
REDDY DISTRICT, ANDHRA PRADESH, INDIA

FPRC: AUROBINDO PHARMA, MEYERSDAL,
JOHANNESBURG

Shelf-life: 24 months (Provisional)
Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: 42/7.3/0270
Name of medicine: AURO-SUMATRIPTAN TABLETS 100 mg

Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
SUMATRIPTAN SUCCINATE EQUIVALENT
TO
SUMATRIPTAN 100,0
mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: AUROBINDO PHARMA (PTY) LTD
Manufacturer: AUROBINDO PHARMA LTD, UNIT III,
RANGA REDDY DISTRICT, ANDHRA
PRADESH, INDIA

Packer: AUROBINDO PHARMA LTD, UNIT III,
RANGA REDDY DISTRICT, ANDHRA
PRADESH, INDIA

Laboratory: FPRC: AUROBINDO PHARMA LTD, UNIT III,
RANGA REDDY DISTRICT, ANDHRA
PRADESH, INDIA

FPRC: AUROBINDO PHARMA, MEYERSDAL,
JOHANNESBURG

Shelf-life: 24 months (Provisional)
Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: A40/2.6.5/0688
Name of medicine: DRL RISPERIDONE 0,5
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
RISPERIDONE 0,5 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: DR REDDY'S LABORATORIES (PTY) LTD
Manufacturer: DR REDDY'S LABORATORIES LTD,
BACHUPALLY VILLAGE, QUTUBULLAPUR
MANDAL, RANGA REDDY DISTRICT, ANDHRA
PRADESH, INDIA
Packer: DR REDDY'S LABORATORIES LTD,
BACHUPALLY VILLAGE, QUTUBULLAPUR
MANDAL, RANGA REDDY DISTRICT, ANDHRA
PRADESH, INDIA
DRA PHARMACEUTICALS, IRENE, CENTURION
Laboratory: FPRC: DR REDDY'S LABORATORIES LTD,
BACHUPALLY VILLAGE, QUTUBULLAPUR
MANDAL, RANGA REDDY DISTRICT, ANDHRA
PRADESH, INDIA
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, NORTH-WEST UNIVERSITY,
POTCHEFSTROOM
FPRR: DR REDDY'S LABORATORIES, MURRAYFIELD,
PRETORIA
Shelf-life: 24 months (Provisional)
Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: A40/2.6.5/0689
Name of medicine: DRL RISPERIDONE 1
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
RISPERIDONE 1,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: DR REDDY'S LABORATORIES (PTY) LTD
Manufacturer: DR REDDY'S LABORATORIES LTD,
BACHUPALLY VILLAGE, QUTUBULLAPUR
MANDAL, RANGA REDDY DISTRICT,
ANDHRA PRADESH, INDIA
Packer: DR REDDY'S LABORATORIES LTD,
BACHUPALLY VILLAGE, QUTUBULLAPUR
MANDAL, RANGA REDDY DISTRICT,
ANDHRA PRADESH, INDIA
DRA PHARMACEUTICALS, IRENE,
CENTURION
Laboratory: FPRC: DR REDDY'S LABORATORIES LTD,
BACHUPALLY VILLAGE, QUTUBULLAPUR
MANDAL, RANGA REDDY DISTRICT,
ANDHRA PRADESH, INDIA
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, NORTH-WEST UNIVERSITY,
POTCHEFSTROOM
FPRR: DR REDDY'S LABORATORIES,
MURRAYFIELD, PRETORIA
Shelf-life: 24 months (Provisional)
Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: A40/2.6.5/0690
 Name of medicine: DRL RISPERIDONE 2
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 RISPERIDONE 2,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
 Applicant: DR REDDY'S LABORATORIES (PTY) LTD
 Manufacturer: DR REDDY'S LABORATORIES LTD,
 BACHUPALLY VILLAGE, QUTUBULLAPUR
 MANDAL, RANGA REDDY DISTRICT, ANDHRA
 PRADESH, INDIA
 Packer: DR REDDY'S LABORATORIES LTD,
 BACHUPALLY VILLAGE, QUTUBULLAPUR
 MANDAL, RANGA REDDY DISTRICT, ANDHRA
 PRADESH, INDIA
 DRA PHARMACEUTICALS, IRENE, CENTURION
 Laboratory: FPRC: DR REDDY'S LABORATORIES LTD,
 BACHUPALLY VILLAGE, QUTUBULLAPUR
 MANDAL, RANGA REDDY DISTRICT, ANDHRA
 PRADESH, INDIA
 RESEARCH INSTITUTE FOR INDUSTRIAL
 PHARMACY, NORTH-WEST UNIVERSITY,
 POTCHEFSTROOM
 FPRR: DR REDDY'S LABORATORIES, MURRAYFIELD,
 PRETORIA
 Shelf-life: 24 months (Provisional)
 Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: A40/2.6.5/0691
 Name of medicine: DRL RISPERIDONE 3
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 RISPERIDONE 3,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
 Applicant: DR REDDY'S LABORATORIES (PTY) LTD
 Manufacturer: DR REDDY'S LABORATORIES LTD,
 BACHUPALLY VILLAGE, QUTUBULLAPUR
 MANDAL, RANGA REDDY DISTRICT,
 ANDHRA PRADESH, INDIA
 Packer: DR REDDY'S LABORATORIES LTD,
 BACHUPALLY VILLAGE, QUTUBULLAPUR
 MANDAL, RANGA REDDY DISTRICT,
 ANDHRA PRADESH, INDIA
 DRA PHARMACEUTICALS, IRENE,
 CENTURION
 Laboratory: FPRC: DR REDDY'S LABORATORIES LTD,
 BACHUPALLY VILLAGE, QUTUBULLAPUR
 MANDAL, RANGA REDDY DISTRICT,
 ANDHRA PRADESH, INDIA
 RESEARCH INSTITUTE FOR INDUSTRIAL
 PHARMACY, NORTH-WEST UNIVERSITY,
 POTCHEFSTROOM
 FPRR: DR REDDY'S LABORATORIES,
 MURRAYFIELD, PRETORIA
 Shelf-life: 24 months (Provisional)
 Date of registration: 9 DECEMBER 2008

MRF 15

Registration number: A40/2.6.5/0692

Name of medicine: DRL RISPERIDONE 4

Dosage form: TABLET

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

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8

Applicant: DR REDDY'S LABORATORIES (PTY) LTD

Manufacturer: DR REDDY'S LABORATORIES LTD,
BACHUPALLY VILLAGE, QUTUBULLAPUR
MANDAL, RANGA REDDY DISTRICT, ANDHRA
PRADESH, INDIA

Packer: DR REDDY'S LABORATORIES LTD,
BACHUPALLY VILLAGE, QUTUBULLAPUR
MANDAL, RANGA REDDY DISTRICT, ANDHRA
PRADESH, INDIA
DRA PHARMACEUTICALS, IRENE, CENTURION

Laboratory: FPRC: DR REDDY'S LABORATORIES LTD,
BACHUPALLY VILLAGE, QUTUBULLAPUR
MANDAL, RANGA REDDY DISTRICT, ANDHRA
PRADESH, INDIA
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, NORTH-WEST UNIVERSITY,
POTCHEFSTROOM

FPRR: DR REDDY'S LABORATORIES, MURRAYFIELD,
PRETORIA

Shelf-life: 24 months (Provisional)

Date of registration: 9 DECEMBER 2008
