

MRF 15

Registration number: 41/18/0300
Name of medicine: FOSRENOL 500 mg
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
LANTHANUM CARBONATE HYDRATE
EQUIVALENT TO LANTHANUM 500,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: ADCOCK INGRAM CRITICAL CARE (PTY) LTD
Manufacturer: BCM LTD, NOTTINGHAM, NOTTINGHAMSHIRE, UK
Packer: BCM LTD, NOTTINGHAM, NOTTINGHAMSHIRE, UK
Laboratory: FPRC: BCM LTD, NOTTINGHAM, NOTTINGHAMSHIRE, UK
READING SCIENTIFIC SERVICES LTD, READING, BERKSHIRE, UK
SOUTHERN TESTING & RESEARCH, WILSON, NORTH CAROLINA, USA
SSCI Inc, WEST LAFAYETTE, INDIANAPOLIS, USA
TEPNEL SCIENTIFIC SERVICES, EDINBURGH, YORKSHIRE, UK
M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
FPRR: ADCOCK INGRAM CRITICAL CARE, AEROTON, JOHANNESBURG
Shelf-life: 24 months (Provisional)
Date of registration: 15 AUGUST 2008

MRF 15

Registration number: 41/18/0301
Name of medicine: FOSRENOL 750 mg
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
LANTHANUM CARBONATE HYDRATE
EQUIVALENT TO LANTHANUM 750,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: ADCOCK INGRAM CRITICAL CARE (PTY) LTD
Manufacturer: BCM LTD, NOTTINGHAM, NOTTINGHAMSHIRE, UK
Packer: BCM LTD, NOTTINGHAM, NOTTINGHAMSHIRE, UK
Laboratory: FPRC: BCM LTD, NOTTINGHAM, NOTTINGHAMSHIRE, UK
READING SCIENTIFIC SERVICES LTD, READING, BERKSHIRE, UK
SOUTHERN TESTING & RESEARCH, WILSON, NORTH CAROLINA, USA
SSCI Inc, WEST LAFAYETTE, INDIANAPOLIS, USA
TEPNEL SCIENTIFIC SERVICES, EDINBURGH, YORKSHIRE, UK
M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
FPRR: ADCOCK INGRAM CRITICAL CARE, AEROTON, JOHANNESBURG
Shelf-life: 24 months (Provisional)
Date of registration: 15 AUGUST 2008

MRF 15

Registration number: 41/20.1.1/0389
 Name of medicine: AURO-CEFALEXIN TABLETS 1 000 mg
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 CEFALEXIN MONOHYDRATE EQUIVALENT TO
 CEFALEXIN 1 000,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
 Applicant: AUROBINDO PHARMA (PTY) LTD
 Manufacturer: AUROBINDO PHARMA LTD, UNIT VI, MEDAK
 DISTRICT, ANDHRA PRADESH, INDIA
 Packer: AUROBINDO PHARMA LTD, UNIT VI, MEDAK
 DISTRICT, ANDHRA PRADESH, INDIA
 Laboratory: FPRC: AUROBINDO PHARMA LTD, UNIT VI, MEDAK
 DISTRICT, ANDHRA PRADESH, INDIA
 FPRC/FPRR: AUROBINDO PHARMA, ROSEBANK,
 JOHANNESBURG
 Shelf-life: 24 months (Provisional)
 Date of registration: 15 AUGUST 2008

MRF 15

Registration number: 41/7.5/0409
 Name of medicine: COLITE 10 mg TABLETS
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 PRAVASTATIN SODIUM 10,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 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
 Date of registration: 15 AUGUST 2008

MRF 15

Registration number:	41/7.5/0410
Name of medicine:	COLITE 20 mg TABLETS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PRAVASTATIN SODIUM 20,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
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
Date of registration:	15 AUGUST 2008

MRF 15

Registration number:	41/7.5/0411
Name of medicine:	COLITE 40 mg TABLETS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PRAVASTATIN SODIUM 40,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
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
Date of registration:	15 AUGUST 2008

MRF 15

Registration number: 41/7.5/0412

Name of medicine: COLITE 80 mg TABLETS

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
PRAVASTATIN SODIUM 80,0 mg

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

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

Date of registration: 15 AUGUST 2008

MRF 15

Registration number: 41/1.2/0440

Name of medicine: ODIVEN 37,5

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
VENLAFAXINE HYDROCHLORIDE
EQUIVALENT TO VENLAFAXINE 37,5 mg

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

Applicant: ZYDUS HEALTHCARE SA (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: 15 AUGUST 2008

MRF 15

Registration number: 41/1.2/0441
Name of medicine: ODIVEN 50
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
VENLAFAXINE HYDROCHLORIDE EQUIVALENT
TO VENLAFAXINE 50,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: ZYDUS HEALTHCARE SA (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: 15 AUGUST 2008

MRF 15

Registration number: 41/1.2/0442
Name of medicine: ODIVEN 75
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
VENLAFAXINE HYDROCHLORIDE
EQUIVALENT TO VENLAFAXINE 75,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: ZYDUS HEALTHCARE SA (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: 15 AUGUST 2008

MRF 15

Registration number: 41/20.1.2/0532
Name of medicine: BINDOCLAV 375 mg
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
AMOXYCILLIN TRIHYDRATE EQUIVALENT TO
AMOXYCILLIN 250,0 mg
POTASSIUM CLAVULANATE EQUIVALENT TO
CLAVULANIC ACID 125,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: AUROBINDO PHARMA (PTY) LTD
Manufacturer: AUROBINDO PHARMA, UNIT XII,
HYDERABAD, ANDHRA PRADESH, INDIA
Packer: AUROBINDO PHARMA, UNIT XII,
HYDERABAD, ANDHRA PRADESH, INDIA
Laboratory: FPRC: AUROBINDO PHARMA, UNIT XII,
HYDERABAD, ANDHRA PRADESH, INDIA
FPRR: AUROBINDO PHARMA, ROSEBANK,
JOHANNESBURG
Shelf-life: 24 months (Provisional)
Date of registration: 15 AUGUST 2008

MRF 15

Registration number: 41/20.1.2/0533
Name of medicine: BINDOCLAV 625 mg
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
AMOXYCILLIN TRIHYDRATE EQUIVALENT TO
AMOXYCILLIN 500,0 mg
POTASSIUM CLAVULANATE EQUIVALENT TO
CLAVULANIC ACID 125,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: AUROBINDO PHARMA (PTY) LTD
Manufacturer: AUROBINDO PHARMA, UNIT XII, HYDERABAD,
ANDHRA PRADESH, INDIA
Packer: AUROBINDO PHARMA, UNIT XII, HYDERABAD,
ANDHRA PRADESH, INDIA
Laboratory: FPRC: AUROBINDO PHARMA, UNIT XII, HYDERABAD,
ANDHRA PRADESH, INDIA
FPRR: AUROBINDO PHARMA, ROSEBANK,
JOHANNESBURG
Shelf-life: 24 months (Provisional)
Date of registration: 15 AUGUST 2008

MRF 15

Registration number:	41/20.1.2/0534
Name of medicine:	BINDOCLAV 1 000 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: AMOXYCILLIN TRIHYDRATE EQUIVALENT TO AMOXYCILLIN 875,0 mg POTASSIUM CLAVULANATE EQUIVALENT TO CLAVULANIC ACID 125,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA, UNIT XII, HYDERABAD, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA, UNIT XII, HYDERABAD, ANDHRA PRADESH, INDIA
Laboratory:	FPRC: AUROBINDO PHARMA, UNIT XII, HYDERABAD, ANDHRA PRADESH, INDIA
	FPRR: AUROBINDO PHARMA, ROSEBANK, JOHANNESBURG
Shelf-life:	24 months (Provisional)
Date of registration:	15 AUGUST 2008

MRF 15

Registration number:	41/20.1.2/0535
Name of medicine:	AURO-AMOXICLAV 375 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: AMOXYCILLIN TRIHYDRATE EQUIVALENT TO AMOXYCILLIN 250,0 mg POTASSIUM CLAVULANATE EQUIVALENT TO CLAVULANIC ACID 125,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA, UNIT XII, HYDERABAD, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA, UNIT XII, HYDERABAD, ANDHRA PRADESH, INDIA
Laboratory:	FPRC: AUROBINDO PHARMA, UNIT XII, HYDERABAD, ANDHRA PRADESH, INDIA
	FPRR: AUROBINDO PHARMA, ROSEBANK, JOHANNESBURG
Shelf-life:	24 months (Provisional)
Date of registration:	15 AUGUST 2008

MRF 15

Registration number: 41/20.1.2/0536
 Name of medicine: AURO-AMOXICLAV 625 mg
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 AMOXYCILLIN TRIHYDRATE EQUIVALENT TO 500,0 mg
 POTASSIUM CLAVULANATE EQUIVALENT TO 125,0 mg
 CLAVULANIC ACID
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
 Applicant: AUROBINDO PHARMA (PTY) LTD
 Manufacturer: AUROBINDO PHARMA, UNIT XII, HYDERABAD,
 ANDHRA PRADESH, INDIA
 Packer: AUROBINDO PHARMA, UNIT XII, HYDERABAD,
 ANDHRA PRADESH, INDIA
 Laboratory: FPRC: AUROBINDO PHARMA, UNIT XII, HYDERABAD,
 ANDHRA PRADESH, INDIA
 FPRR: AUROBINDO PHARMA, ROSEBANK,
 JOHANNESBURG
 Shelf-life: 24 months (Provisional)
 Date of registration: 15 AUGUST 2008

MRF 15

Registration number: 41/20.1.2/0537
 Name of medicine: AURO-AMOXICLAV 1 000 mg
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 AMOXYCILLIN TRIHYDRATE EQUIVALENT TO 875,0 mg
 POTASSIUM CLAVULANATE EQUIVALENT TO 125,0 mg
 CLAVULANIC ACID
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
 Applicant: AUROBINDO PHARMA (PTY) LTD
 Manufacturer: AUROBINDO PHARMA, UNIT XII,
 HYDERABAD, ANDHRA PRADESH, INDIA
 Packer: AUROBINDO PHARMA, UNIT XII,
 HYDERABAD, ANDHRA PRADESH, INDIA
 Laboratory: FPRC: AUROBINDO PHARMA, UNIT XII,
 HYDERABAD, ANDHRA PRADESH, INDIA
 FPRC/FPRR: AUROBINDO PHARMA, ROSEBANK,
 JOHANNESBURG
 Shelf-life: 24 months (Provisional)
 Date of registration: 15 AUGUST 2008

MRF 15

Registration number: 41/20.1.2/0546
Name of medicine: BETACLAV 375
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
AMOXYCILLIN TRIHYDRATE EQUIVALENT TO
AMOXYCILLIN 250,0 mg
POTASSIUM CLAVULANATE EQUIVALENT TO
CLAVULANIC ACID 125,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: BE-TABS PHARMACEUTICALS (PTY) LTD
Manufacturer: AUROBINDO PHARMA LTD, UNIT XII,
HYDERABAD, ANDHRA PRADESH, INDIA
Packer: AUROBINDO PHARMA LTD, UNIT XII,
HYDERABAD, ANDHRA PRADESH, INDIA
Laboratory: FPRC: AUROBINDO PHARMA LTD, UNIT XII,
HYDERABAD, ANDHRA PRADESH, INDIA
FPRC/FPRR: BE-TABS PHARMACEUTICALS, ROODEPOORT
Shelf-life: 24 months
Date of registration: 15 AUGUST 2008

MRF 15

Registration number: 41/20.1.2/0547
Name of medicine: BETACLAV 625
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
AMOXYCILLIN TRIHYDRATE EQUIVALENT TO
AMOXYCILLIN 500,0 mg
POTASSIUM CLAVULANATE EQUIVALENT TO
CLAVULANIC ACID 125,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: BE-TABS PHARMACEUTICALS (PTY) LTD
Manufacturer: AUROBINDO PHARMA LTD, UNIT XII,
HYDERABAD, ANDHRA PRADESH, INDIA
Packer: AUROBINDO PHARMA LTD, UNIT XII,
HYDERABAD, ANDHRA PRADESH, INDIA
Laboratory: FPRC: AUROBINDO PHARMA LTD, UNIT XII,
HYDERABAD, ANDHRA PRADESH, INDIA
FPRR: BE-TABS PHARMACEUTICALS, ROODEPOORT
Shelf-life: 24 months
Date of registration: 15 AUGUST 2008

MRF 15

Registration number:	41/20.1.2/0548
Name of medicine:	BETACLAV 1 000
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: AMOXYCILLIN TRIHYDRATE EQUIVALENT TO AMOXYCILLIN 875,0 mg POTASSIUM CLAVULANATE EQUIVALENT TO CLAVULANIC ACID 125,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	BE-TABS PHARMACEUTICALS (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LTD, UNIT XII, HYDERABAD, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LTD, UNIT XII, HYDERABAD, ANDHRA PRADESH, INDIA
Laboratory:	FPRC: AUROBINDO PHARMA LTD, UNIT XII, HYDERABAD, ANDHRA PRADESH, INDIA
FPRC/FPRR:	BE-TABS PHARMACEUTICALS, ROODEPOORT
Shelf-life:	24 months
Date of registration:	15 AUGUST 2008

MRF 15

Registration number:	41/5.4.1/0604
Name of medicine:	REQUIP XL 2 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ROPINIROLE HYDROCHLORIDE EQUIVALENT TO ROPINIROLE 2,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	GLAXOSMITHKLINE SOUTH AFRICA (PTY) LTD
Manufacturer:	SMITHKLINE BEECHAM PLC, CRAWLEY, WEST SUSSEX, UK
Packer:	SMITHKLINE BEECHAM PLC, CRAWLEY, WEST SUSSEX, UK CARDINAL HEALTH LTD, GREAT OAKLEY, CORBY, NORTHAMPTONSHIRE, UK GLAXOSMITHKLINE, EPPING, CAPE TOWN
Laboratory:	FPRC: SMITHKLINE BEECHAM PLC, CRAWLEY, WEST SUSSEX, UK
FPRC/FPRR:	GLAXOSMITHKLINE, EPPING, CAPE TOWN
Shelf-life:	36 months
Date of registration:	15 AUGUST 2008

MRF 15

Registration number: 41/5.4.1/0605
Name of medicine: REQUIP XL 3 mg
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
ROPINIROLE HYDROCHLORIDE EQUIVALENT
TO
ROPINIROLE 3,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: GLAXOSMITHKLINE SOUTH AFRICA (PTY) LTD
Manufacturer: SMITHKLINE BEECHAM PLC, CRAWLEY, WEST
SUSSEX, UK
Packer: SMITHKLINE BEECHAM PLC, CRAWLEY, WEST
SUSSEX, UK
CARDINAL HEALTH LTD, GREAT OAKLEY,
CORBY, NORTHAMPTONSHIRE, UK
GLAXOSMITHKLINE, EPPING, CAPE TOWN
Laboratory: FPRC: SMITHKLINE BEECHAM PLC, CRAWLEY, WEST
SUSSEX, UK
FPRC/FPRR: GLAXOSMITHKLINE, EPPING, CAPE TOWN
Shelf-life: 36 months
Date of registration: 15 AUGUST 2008

MRF 15

Registration number: 41/5.4.1/0606
Name of medicine: REQUIP XL 4 mg
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
ROPINIROLE HYDROCHLORIDE EQUIVALENT
TO
ROPINIROLE 4,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: GLAXOSMITHKLINE SOUTH AFRICA (PTY)
LTD
Manufacturer: SMITHKLINE BEECHAM PLC, CRAWLEY,
WEST SUSSEX, UK
Packer: SMITHKLINE BEECHAM PLC, CRAWLEY,
WEST SUSSEX, UK
CARDINAL HEALTH LTD, GREAT OAKLEY,
CORBY, NORTHAMPTONSHIRE, UK
GLAXOSMITHKLINE, EPPING, CAPE TOWN
Laboratory: FPRC: SMITHKLINE BEECHAM PLC, CRAWLEY,
WEST SUSSEX, UK
FPRC/FPRR: GLAXOSMITHKLINE, EPPING, CAPE TOWN
Shelf-life: 36 months
Date of registration: 15 AUGUST 2008

MRF 15

Registration number: 41/5.4.1/0607
 Name of medicine: REQUIP XL 8 mg
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 ROPINIROLE HYDROCHLORIDE
 EQUIVALENT TO
 ROPINIROLE 8,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: GLAXOSMITHKLINE SOUTH AFRICA (PTY) LTD
 Manufacturer: SMITHKLINE BEECHAM PLC, CRAWLEY,
 WEST SUSSEX, UK
 Packer: SMITHKLINE BEECHAM PLC, CRAWLEY,
 WEST SUSSEX, UK
 CARDINAL HEALTH LTD, GREAT OAKLEY,
 CORBY, NORTHAMPTONSHIRE, UK
 GLAXOSMITHKLINE, EPPING, CAPE TOWN
 Laboratory: FPRC: SMITHKLINE BEECHAM PLC, CRAWLEY,
 WEST SUSSEX, UK
 FPRC/FPRR: GLAXOSMITHKLINE, EPPING, CAPE TOWN
 Shelf-life: 36 months
 Date of registration: 15 AUGUST 2008

MRF 15

Registration number: 41/20.2.8/0737
 Name of medicine: ADCO-ZIDOVUDINE 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: ADCOCK INGRAM HEALTHCARE, WADEVILLE,
 GERMISTON
 FPRC/FPRR: ADCOCK INGRAM LTD, AEROTON,
 JOHANNESBURG
 FPRR: ADCOCK INGRAM LTD, BRYANSTON,
 JOHANNESBURG
 Shelf-life: 24 months (Provisional)
 Date of registration: 15 AUGUST 2008

MRF 15

Registration number:	41/20.2.8/0738
Name of medicine:	ADCO-ZIDOVUDINE 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:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
FPRC/FPRR:	ADCOCK INGRAM LTD, AEROTON, JOHANNESBURG
FPRR:	ADCOCK INGRAM LTD, BRYANSTON, JOHANNESBURG
Shelf-life:	24 months (Provisional)
Date of registration:	15 AUGUST 2008

MRF 15

Registration number:	41/8.1/0812
Name of medicine:	GULF AMLODIPINE 5
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:	GULF DRUG COMPANY (PTY) LTD
Manufacturer:	ALEMBIC LTD, TAL-HALOL, PANCHMAHALS, GUJARAT, INDIA
Packer:	ALEMBIC LTD, TAL-HALOL, PANCHMAHALS, GUJARAT, INDIA
Laboratory: FPRC:	ALEMBIC LTD, TAL-HALOL, PANCHMAHALS, GUJARAT, INDIA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG PHARMA-Q, INDUSTRIA WEST, JOHANNESBURG INSTITUTE FOR PHARMACEUTICALS SERVICES, SILVERTONDALE, PRETORIA CONSULTING MICROBIOLOGICAL LABORATORIES, MOREWILL, BOKSBURG
FPRR:	GULF DRUG CO, MOUNT EDGECOMBE, KZN
Shelf-life:	24 months (Provisional)
Date of registration:	15 AUGUST 2008

MRF 15

Registration number: 41/8.1/0813
 Name of medicine: GULF AMLODIPINE 10
 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: GULF DRUG COMPANY (PTY) LTD
 Manufacturer: ALEMBIC LTD, TAL-HALOL, PANCHMAHALS,
 GUJARAT, INDIA
 Packer: ALEMBIC LTD, TAL-HALOL, PANCHMAHALS, GUJARAT,
 INDIA
 Laboratory: FPRC: ALEMBIC LTD, TAL-HALOL, PANCHMAHALS, GUJARAT,
 INDIA
 SOUTH AFRICAN BUREAU OF STANDARDS,
 GROENKLOOF, PRETORIA
 M&L LABORATORY SERVICES, ORMONDE,
 JOHANNESBURG
 CONSULTING CHEMICAL LABORATORIES,
 ATLASVILLE, BOKSBURG
 PHARMA-Q, INDUSTRIA WEST, JOHANNESBURG
 INSTITUTE FOR PHARMACEUTICALS SERVICES,
 SILVERTONDALE, PRETORIA
 CONSULTING MICROBIOLOGICAL LABORATORIES,
 MOREWILL, BOKSBURG
 FPRR: GULF DRUG CO, MOUNT EDGECOMBE, KZN
 Shelf-life: 24 months (Provisional)
 Date of registration: 15 AUGUST 2008

MRF 15

Registration number: 41/7.1.3/0820
 Name of medicine: CIPLAZAR 25
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 LOSARTAN POTASSIUM EQUIVALENT TO
 LOSARTAN 25,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: CIPLA MEDPRO (PTY) LTD
 Manufacturer: CIPLA LTD, (UNIT III), SALCETTE, GOA,
 INDIA
 Packer: CIPLA LTD, (UNIT III), SALCETTE, GOA,
 INDIA
 Laboratory: FPRC: CIPLA LTD, (UNIT III), SALCETTE, GOA,
 INDIA
 FPRR: CIPLA MEDPRO, ROSENPARK, BELLVILLE
 Shelf-life: 24 months
 Date of registration: 15 AUGUST 2008

MRF 15

Registration number: 41/7.1.3/0821
Name of medicine: CIPLAZAR 50
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
LOSARTAN POTASSIUM EQUIVALENT TO
LOSARTAN 50,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: CIPLA MEDPRO (PTY) LTD
Manufacturer: CIPLA LTD, (UNIT III), SALCETTE, GOA, INDIA
Packer: CIPLA LTD, (UNIT III), SALCETTE, GOA, INDIA
Laboratory: FPRC: CIPLA LTD, (UNIT III), SALCETTE, GOA, INDIA
FPRR: CIPLA MEDPRO, ROSENPARK, BELLVILLE
Shelf-life: 24 months
Date of registration: 15 AUGUST 2008

MRF 15

Registration number: 41/7.1.3/0822
Name of medicine: CIPLAZAR 100
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
LOSARTAN POTASSIUM EQUIVALENT TO
LOSARTAN 100,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: CIPLA MEDPRO (PTY) LTD
Manufacturer: CIPLA LTD, (UNIT III), SALCETTE, GOA, INDIA
Packer: CIPLA LTD, (UNIT III), SALCETTE, GOA, INDIA
Laboratory: FPRC: CIPLA LTD, (UNIT III), SALCETTE, GOA, INDIA
FPRR: CIPLA MEDPRO, ROSENPARK, BELLVILLE
Shelf-life: 24 months
Date of registration: 15 AUGUST 2008

MRF 15

Registration number: 41/1.2/0843
Name of medicine: CITRAZ 5
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: 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, CENTURION, RSA
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 (Provisional)
Date of registration: 15 AUGUST 2008

MRF 15

Registration number: 41/1.2/0844
Name of medicine: CITRAZ 10
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: 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, CENTURION,
RSA
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 (Provisional)
Date of registration: 15 AUGUST 2008

MRF 15

Registration number: 41/1.2/0845
Name of medicine: CITRAZ 20
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: 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, CENTURION, RSA
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 (Provisional)
Date of registration: 15 AUGUST 2008

MRF 15

Registration number: 41/7.1/0935
Name of medicine: ZANERIL 10/10
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
LERCANIDIPINE HYDROCHLORIDE 10,0 mg
ENALAPRIL MALEATE 10,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: PHARMAPLAN (PTY) LTD
Manufacturer: RECORDATI INDUSTRIA CHIMICA &
FARMACEUTICA S.p.A., MILAN, ITALY
Packer: RECORDATI INDUSTRIA CHIMICA &
FARMACEUTICA S.p.A., MILAN, ITALY
Laboratory: FPRC: RECORDATI INDUSTRIA CHIMICA &
FARMACEUTICA S.p.A., MILAN, ITALY
CONSULTING CHEMICAL LABORATORIES,
ATLASVILLE, BOKSBURG
FPRR: PHARMAPLAN, MIDRAND, JOHANNESBURG
Shelf-life: 24 months
Date of registration: 15 AUGUST 2008

MRF 15

Registration number: 41/7.1/0936
Name of medicine: ZANERIL 10/20
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
LERCANIDIPINE HYDROCHLORIDE 10,0 mg
ENALAPRIL MALEATE 20,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: PHARMAPLAN (PTY) LTD
Manufacturer: RECORDATI INDUSTRIA CHIMICA &
FARMACEUTICA S.p.A., MILAN, ITALY
Packer: RECORDATI INDUSTRIA CHIMICA &
FARMACEUTICA S.p.A., MILAN, ITALY
Laboratory: FPRC: RECORDATI INDUSTRIA CHIMICA &
FARMACEUTICA S.p.A., MILAN, ITALY
CONSULTING CHEMICAL LABORATORIES,
ATLASVILLE, BOKSBURG
FPRR: PHARMAPLAN, MIDRAND, JOHANNESBURG
Shelf-life: 24 months
Date of registration: 15 AUGUST 2008

MRF 15

Registration number: 41/1.2/1007
Name of medicine: VENELA 37,5
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
VENLAFAXINE HYDROCHLORIDE
EQUIVALENT TO VENLAFAXINE 37,5 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, RANGA
REDDY DISTRICT, ANDHRA PRADESH,
INDIA
Packer: DR REDDY'S LABORATORIES LTD, RANGA
REDDY DISTRICT, ANDHRA PRADESH,
INDIA
Laboratory: FPRC: DR REDDY'S LABORATORIES LTD, RANGA
REDDY DISTRICT, ANDHRA PRADESH,
INDIA
INSTITUTE FOR PHARMACEUTICALS
SERVICES, SILVERTONDALE, PRETORIA
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, NORTH-WEST UNIVERSITY,
POTCHEFSTROOM
FPRR: DR REDDY'S LABORATORIES,
MURRAYFIELD, PRETORIA
Shelf-life: 24 months (Provisional)
Date of registration: 15 AUGUST 2008

MRF 15

Registration number: 41/1.2/1008
Name of medicine: VENELA 50
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
VENLAFAXINE HYDROCHLORIDE
EQUIVALENT TO VENLAFAXINE 50 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, RANGA
PEDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer: DR REDDY'S LABORATORIES LTD, RANGA
REDDY DISTRICT, ANDHRA PRADESH, INDIA
Laboratory: FPRC: DR REDDY'S LABORATORIES LTD, RANGA
REDDY DISTRICT, ANDHRA PRADESH, INDIA
INSTITUTE FOR PHARMACEUTICALS
SERVICES, SILVERTONDALE, PRETORIA
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, NORTH-WEST UNIVERSITY,
POTCHEFSTROOM
FPRR: DR REDDY'S LABORATORIES,
MURRAYFIELD, PRETORIA
Shelf-life: 24 months (Provisional)
Date of registration: 15 AUGUST 2008

MRF 15

Registration number: 41/1.2/1009
Name of medicine: VENELA 75
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
VENLAFAXINE HYDROCHLORIDE
EQUIVALENT TO VENLAFAXINE 75 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, RANGA
REDDY DISTRICT, ANDHRA PRADESH,
INDIA
Packer: DR REDDY'S LABORATORIES LTD, RANGA
REDDY DISTRICT, ANDHRA PRADESH,
INDIA
Laboratory: FPRC: DR REDDY'S LABORATORIES LTD, RANGA
REDDY DISTRICT, ANDHRA PRADESH,
INDIA
INSTITUTE FOR PHARMACEUTICALS
SERVICES, SILVERTONDALE, PRETORIA
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, NORTH-WEST UNIVERSITY,
POTCHEFSTROOM
FPRR: DR REDDY'S LABORATORIES,
MURRAYFIELD, PRETORIA
Shelf-life: 24 months (Provisional)
Date of registration: 15 AUGUST 2008

MRF 15

Registration number: 41/21.2/1089
Name of medicine: METORED 500
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
METFORMIN HYDROCHLORIDE 500,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: PHARMAPLAN (PTY) LTD
Manufacturer: SUN PHARMACEUTICAL INDUSTRIES LTD,
HALOL, DISTRICT PANCHMAHAL, GUJARAT,
INDIA
Packer: SUN PHARMACEUTICAL INDUSTRIES LTD,
HALOL, DISTRICT PANCHMAHAL, GUJARAT,
INDIA
Laboratory: FPRC: SUN PHARMACEUTICAL INDUSTRIES LTD,
HALOL, DISTRICT PANCHMAHAL, GUJARAT,
INDIA
CONSULTING CHEMICAL LABORATORIES,
ATLASVILLE, BOKSBURG
FPRR: PHARMAPLAN, MIDRAND, RSA
Shelf-life: 24 months (Provisional)
Date of registration: 15 AUGUST 2008

MRF 15

Registration number: 41/21.2/1090
Name of medicine: METORED 850
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
METFORMIN HYDROCHLORIDE 850,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: PHARMAPLAN (PTY) LTD
Manufacturer: SUN PHARMACEUTICAL INDUSTRIES LTD,
HALOL, DISTRICT PANCHMAHAL,
GUJARAT, INDIA
Packer: SUN PHARMACEUTICAL INDUSTRIES LTD,
HALOL, DISTRICT PANCHMAHAL,
GUJARAT, INDIA
Laboratory: FPRC: SUN PHARMACEUTICAL INDUSTRIES LTD,
HALOL, DISTRICT PANCHMAHAL,
GUJARAT, INDIA
CONSULTING CHEMICAL LABORATORIES,
ATLASVILLE, BOKSBURG
FPRR: PHARMAPLAN, MIDRAND, RSA
Shelf-life: 24 months (Provisional)
Date of registration: 15 AUGUST 2008

MRF 15

Registration number: 41/21.2/1091
Name of medicine: METORED 1 000
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
METFORMIN HYDROCHLORIDE 1 000,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: PHARMAPLAN (PTY) LTD
Manufacturer: SUN PHARMACEUTICAL INDUSTRIES LTD,
HALOL, DISTRICT PANCHMAHAL, GUJARAT,
INDIA
Packer: SUN PHARMACEUTICAL INDUSTRIES LTD,
HALOL, DISTRICT PANCHMAHAL, GUJARAT,
INDIA
Laboratory: FPRC: SUN PHARMACEUTICAL INDUSTRIES LTD,
HALOL, DISTRICT PANCHMAHAL, GUJARAT,
INDIA
CONSULTING CHEMICAL LABORATORIES,
ATLASVILLE, BOKSBURG
FPRR: PHARMAPLAN, MIDRAND, RSA
Shelf-life: 24 months (Provisional)
Date of registration: 15 AUGUST 2008

MRF 15

Registration number: 34/30.2/0501
Name of medicine: OCTAGAM
Dosage form: INFUSION
Active ingredients: EACH 1,0 ml SOLUTION CONTAINS:
HUMAN NORMAL IMMUNOGLOBULIN G
50,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: JE ECKARD
Manufacturer: OCTAPHARMA PHARMAZEUTIKA, VIENNA,
AUSTRIA
Packer: OCTAPHARMA PHARMAZEUTIKA, VIENNA,
AUSTRIA
Laboratory: FPRC: OCTAPHARMA PHARMAZEUTIKA, VIENNA,
AUSTRIA
FPRR: JE ECKARD, MONUMENT PARK, PRETORIA,
RSA
Shelf-life: 24 months
Date of registration: 13 JUNE 2008
