
GENERAL NOTICE

NOTICE 1321 OF 2006

MEDICINES CONTROL COUNCIL

CONDITIONS OF REGISTRATION OF A MEDICINE IN TERMS OF THE PROVISIONS OF SECTION 15(7) OF THE MEDICINES AND RELATED SUBSTANCES ACT, 1965 (ACT No. 101 OF 1965)

1. The applicant shall ensure that the medicine is manufactured and controlled in terms of current Good Manufacturing Practices as determined by Council.
2. The manufacture of this medicine is subject to regular investigation and inspections by the inspectors appointed in terms of Section 26 of the Act, to assess compliance with current Good Manufacturing Practices.
3. The information in the package insert shall be updated on a regular basis to conform to the package insert recently approved by Council.
4. The applicant must comply with all the legal requirements of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965).
5. The registration of this medicine shall be subject to regular review regarding its quality, safety and efficacy, and the registration of this medicine may be varied subject to issues Council may deem fit.
6. The first two production batches must be fully validated in terms of the detailed process validation protocol submitted at the time of application for registration, and the validation report must be submitted within a month after completion of the validation.
7. The registration dossier is subject to review at intervals as determined by Council.
8. A post-registration inspection must be conducted in the first production batch of the locally manufactured product.
9. A post-registration inspection must be conducted on the first production batch manufactured by each local manufacturer.
10. A post-registration inspection must be conducted on the first production batch of the imported product.
11. Marketing of the product may only commence following a satisfactory post-registration inspection report.
12. One sample of every batch, together with four copies of the protocol for testing of the bulk lot and filling lot, and six copies of the certificate of release issued by a competent authority in the country in which the product was manufactured, must be submitted to the Council for lot release purposes.
13. The expiry date allocated shall be modified by adding a statement that the virus strains are currently recommended for South African usage in the specific year.
14. The strains of the master seed viruses must be approved by the Department of Health for each year.

MRF 15

Registration number: G/10.1/0640

Name of medicine: DIMETAPP COUGH EXPECTORANT

Dosage form: SYRUP

Active ingredients: EACH 5,0 ml SYRUP CONTAINS:
GUAIFENESIN 100,0 mg

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

Applicant: WYETH SOUTH AFRICA (PTY) LTD

Manufacturer: WHITEHALL-ROBINS, RICHMOND, VIRGINIA,
USA

Packer: WHITEHALL-ROBINS, RICHMOND, VIRGINIA,
USA

Laboratory:FPRC: WHITEHALL-ROBINS, RICHMOND, VIRGINIA,
USA
ASPEN PHARMACARE, WILSONIA,
EAST LONDON, RSA
CONSULTING CHEMICAL LABORATORIES,
STAR STREET, BOKSBURG, RSA
ANALYTICON, KEMPTON PARK, RSA
FPRR: WYETH S.A., MIDRAND, RSA

Shelf-life: 36 months

Date of registration: 7 JULY 2006

MRF 15

Registration number: 37/30.1/0047

Name of medicine: OKAVAX

Dosage form: INJECTION

Active ingredients: EACH 0,5 ml DOSE CONTAINS:
ATTENUATED LIVE VARICELLA-ZOSTER
VIRUS (OKA STRAIN) 1 000,0 PFU

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

Applicant: AVENTIS PHARMA (PTY) LTD

Manufacturer: KAN-ONJI INSTITUTE, KAN-ONJI CITY,
KAGAWA, JAPAN

Packer: KAN-ONJI INSTITUTE, KAN-ONJI CITY,
KAGAWA, JAPAN

Laboratory:FPRC: KAN-ONJI INSTITUTE, KAN-ONJI CITY,
KAGAWA, JAPAN
FPRR/FPRC: AVENTIS PHARMA, WALTLOO, PRETORIA

Shelf-life: 24 months

Date of registration: 7 JULY 2006

MRF 15

Registration number: 37/34/0140

Name of medicine: AIR PRODUCTS MEDICAL OXYGEN (GASEOUS)

Dosage form: GAS

Active ingredients: EACH CYLINDER CONTAINS:
OXYGEN 99,5 % v/v

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

Applicant: AIR PRODUCTS SOUTH AFRICA (PTY) LTD

Manufacturer: AIR PRODUCTS S.A., SPARTAN, KEMPTON PARK

Packer: AIR PRODUCTS S.A., SPARTAN, KEMPTON PARK

Laboratory:FPRC/FPRR: AIR PRODUCTS S.A., SPARTAN, KEMPTON PARK

Shelf-life: 36 months

Date of registration: 7 JULY 2006

MRF 15

Registration number: 37/34/0141

Name of medicine: AIR PRODUCTS MEDICAL OXYGEN (LIQUID)

Dosage form: LIQUID

Active ingredients: EACH CYLINDER CONTAINS:
OXYGEN 99,5 % v/v

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

Applicant: AIR PRODUCTS SOUTH AFRICA (PTY) LTD

Manufacturer: AIR PRODUCTS S.A., SPARTAN, KEMPTON PARK
AIR PRODUCTS S.A., VANDERBIJLPARK, RSA
AIR PRODUCTS S.A., ISCOR WORKS,
NEW CASTLE, RSA
AIR PRODUCTS S.A., STIKLAND TRIANGLE,
BELLVILLE

Packer: AIR PRODUCTS S.A., SPARTAN, KEMPTON PARK
AIR PRODUCTS S.A., VANDERBIJLPARK, RSA
AIR PRODUCTS S.A., ISCOR WORKS,
NEW CASTLE, RSA
AIR PRODUCTS S.A., STIKLAND TRIANGLE,
BELLVILLE

Laboratory:FPRC: AIR PRODUCTS S.A., VANDERBIJLPARK, RSA
AIR PRODUCTS S.A., ISCOR WORKS,
NEW CASTLE, RSA
AIR PRODUCTS S.A., STIKLAND TRIANGLE,
BELLVILLE

FPRC/FPRR: AIR PRODUCTS S.A., SPARTAN, KEMPTON PARK

Shelf-life: 36 months

Date of registration: 7 JULY 2006

MRF 15

Registration number:	37/2.6.5/0319
Name of medicine:	RISPERDAL QUICKLET 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 ORTHO LLC, GURABO, PUERTO RICO
Packer:	JANSSEN ORTHO LLC, GURABO, PUERTO RICO JANSSEN-CILAG FARMACEUTICA Lda, BACARENA, PORTUGAL JANSSEN PHARMACEUTICA, HALFWAY HOUSE, RSA
Laboratory:FPRC:	JANSSEN ORTHO LLC, GURABO, PUERTO RICO JANSSEN-CILAG FARMACEUTICA Lda, BACARENA, PORTUGAL JANSSEN PHARMACEUTICA N.V., BEERSE, BELGIUM
FPRC/FPRR:	JANSSEN PHARMACEUTICA, HALFWAY HOUSE, RSA
Shelf-life:	24 months
Date of registration:	7 JULY 2006

MRF 15

Registration number: 37/2.6.5/0320

Name of medicine: RISPERDAL QUICKLET 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 ORTHO LLC, GURABO, PUERTO RICO

Packer: JANSSEN ORTHO LLC, GURABO, PUERTO RICO
JANSSEN-CILAG FARMACEUTICA Lda, BACARENA,
PORTUGAL
JANSSEN PHARMACEUTICA, HALFWAY HOUSE,
RSA

Laboratory:FPRC: JANSSEN ORTHO LLC, GURABO, PUERTO RICO
JANSSEN-CILAG FARMACEUTICA Lda, BACARENA,
PORTUGAL
JANSSEN PHARMACEUTICA N.V., BEERSE,
BELGIUM

FPRC/FPRR: JANSSEN PHARMACEUTICA, HALFWAY HOUSE,
RSA

Shelf-life: 24 months

Date of registration: 7 JULY 2006

MRF 15

Registration number: 37/2.6.5/0321

Name of medicine: RISPERDAL QUICKLET 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 ORTHO LLC, GURABO, PUERTO RICO

Packer: JANSSEN ORTHO LLC, GURABO, PUERTO RICO
JANSSEN-CILAG FARMACEUTICA Lda, BACARENA,
PORTUGAL
JANSSEN PHARMACEUTICA, HALFWAY HOUSE,
RSA

Laboratory:FPRC: JANSSEN ORTHO LLC, GURABO, PUERTO RICO
JANSSEN-CILAG FARMACEUTICA Lda, BACARENA,
PORTUGAL
JANSSEN PHARMACEUTICA N.V., BEERSE,
BELGIUM

FPRC/FPRR: JANSSEN PHARMACEUTICA, HALFWAY HOUSE,
RSA

Shelf-life: 24 months

Date of registration: 7 JULY 2006

MRF 15

Registration number: 37/20.1.1/0382

Name of medicine: GENERIX-CEFAZOLIN 0,5 g INJECTION

Dosage form: INJECTION

Active ingredients: EACH VIAL CONTAINS:
CEFAZOLIN SODIUM EQUIVALENT TO
CEFAZOLIN 500,0 mg

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

Applicant: GENERIX INTERNATIONAL S.A. (PTY) LTD

Manufacturer: HARBIN GENERAL PHARMACEUTICAL FACTORY,
HARBIN, PEOPLE'S REPUBLIC OF CHINA

Packer: HARBIN GENERAL PHARMACEUTICAL FACTORY,
HARBIN, PEOPLE'S REPUBLIC OF CHINA

Laboratory:FPRC: HARBIN GENERAL PHARMACEUTICAL FACTORY,
HARBIN, PEOPLE'S REPUBLIC OF CHINA
CONSULTING CHEMICAL LABORATORIES, STAR
STREET, BOKSBURG
FPRR: GENERIX INTERNATIONAL S.A., ATHLONE,
CAPE TOWN

Shelf-life: 24 months

Date of registration: 7 JULY 2006

MRF 15

Registration number: 37/20.1.1/0383

Name of medicine: GENERIX-CEFAZOLIN 1,0 g INJECTION

Dosage form: INJECTION

Active ingredients: EACH VIAL CONTAINS:
CEFAZOLIN SODIUM EQUIVALENT TO
CEFAZOLIN 1,0 g

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

Applicant: GENERIX INTERNATIONAL S.A. (PTY) LTD

Manufacturer: HARBIN GENERAL PHARMACEUTICAL FACTORY,
HARBIN, PEOPLE'S REPUBLIC OF CHINA

Packer: HARBIN GENERAL PHARMACEUTICAL FACTORY,
HARBIN, PEOPLE'S REPUBLIC OF CHINA

Laboratory:FPRC: HARBIN GENERAL PHARMACEUTICAL FACTORY,
HARBIN, PEOPLE'S REPUBLIC OF CHINA
CONSULTING CHEMICAL LABORATORIES, STAR
STREET, BOKSBURG

FPRR: GENERIX INTERNATIONAL S.A., ATHLONE,
CAPE TOWN

Shelf-life: 24 months

Date of registration: 7 JULY 2006

MRF 15

Registration number: 37/2.5/0482

Name of medicine: PARTID-200

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
CARBAMAZEPINE 200,0 mg

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

Applicant: MDI CC

Manufacturer: EMCURE PHARMACEUTICALS LTD, HINJWADI,
PUNE, INDIA

Packer: EMCURE PHARMACEUTICALS LTD, HINJWADI,
PUNE, INDIA

Laboratory:FPRC: EMCURE PHARMACEUTICALS LTD, HINJWADI,
PUNE, INDIA
CONSULTING CHEMICAL LABORATORIES, STAR
STREET, BOKSBURG, RSA
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
FPRR: MDI CC, MENLO PARK, PRETORIA, RSA

Shelf-life: 24 months

Date of registration: 7 JULY 2006

MRF 15 (MBR 15)

Registration number: 37/25.2/0505

Name of medicine: OLICLINOMEL N4-550

Dosage form: INFUSION

Active ingredients: EACH BAG CONTAINS:
a) 5,5 % AMINO ACIDS SOLUTION compartment
b) 20 % GLUCOSE SOLUTION compartment
c) 10 % LIPID EMULSION compartment
SEE ADDENDUM

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

Applicant: ADCOCK INGRAM CRITICAL CARE (PTY) LTD

Manufacturer: CLINTEC PARENTERAL S.A., CEDEX, FRANCE
BAXTER S.A., LESSINES, BELGIUM

Packer: CLINTEC PARENTERAL S.A., CEDEX, FRANCE
BAXTER S.A., LESSINES, BELGIUM
ADCOCK INGRAM CRITICAL CARE, AEROTON,
JOHANNESBURG, RSA

Laboratory:FPRC: CLINTEC PARENTERAL S.A., CEDEX, FRANCE
BAXTER S.A., LESSINES, BELGIUM
FPRC/FPRR: ADCOCK INGRAM CRITICAL CARE, AEROTON,
JOHANNESBURG, RSA

Shelf-life: 24 months

Date of registration: 7 JULY 2006

ADDENDUM

- a) 5,5 % AMINO ACIDS SOLUTION compartment
containing per 1,0 litre:

L-alanine	11,39 g
L-arginine	6,33 g
Glycine	5,67 g
L-histidine	2,64 g
L-isoleucine	3,30 g
L-leucine	4,02 g
L-lysine	3,19 g
L-methionine	2,20 g
L-phenylalanine	3,08 g
L-proline	3,74 g
L-serine	2,75 g
L-threonine	2,31 g
L-tryptophan	0,99 g
L-tyrosine	0,22 g
L-valine	3,19 g

- b) 20 % GLUCOSE SOLUTION compartment
containing per 1,0 litre:

Glucose monohydrate equivalent to Glucose	200,00 g
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- c) 10 % LIPID EMULSION compartment containing per 1,0 litre:

Refined soya-bean oil + Refined olive oil	100,00 g
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MRF 15 (MBR 15)

Registration number:	37/25.2/0506
Name of medicine:	OLICLINOMEL N6-900
Dosage form:	INFUSION
Active ingredients:	EACH BAG CONTAINS: a) 8,5 % AMINO ACIDS SOLUTION compartment b) 30 % GLUCOSE SOLUTION compartment c) 20 % LIPID EMULSION compartment SEE ADDENDUM
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM CRITICAL CARE (PTY) LTD
Manufacturer:	CLINTEC PARENTERAL S.A., CEDEX, FRANCE BAXTER S.A., LESSINES, BELGIUM
Packer:	CLINTEC PARENTERAL S.A., CEDEX, FRANCE BAXTER S.A., LESSINES, BELGIUM ADCOCK INGRAM CRITICAL CARE, AEROTON, JOHANNESBURG, RSA
Laboratory:FPRC:	CLINTEC PARENTERAL S.A., CEDEX, FRANCE BAXTER S.A., LESSINES, BELGIUM
FPRC/FPRR:	ADCOCK INGRAM CRITICAL CARE, AEROTON, JOHANNESBURG, RSA
Shelf-life:	24 months
Date of registration:	7 JULY 2006

ADDENDUM

- a) 8,5 % AMINO ACIDS SOLUTION compartment
containing per 1,0 litre:

L-alanine	17,60 g
L-arginine	9,78 g
Glycine	8,76 g
L-histidine	4,08 g
L-isoleucine	5,10 g
L-leucine	6,21 g
L-lysine	4,93 g
L-methionine	3,40 g
L-phenylalanine	4,76 g
L-proline	5,78 g
L-serine	4,25 g
L-threonine	3,57 g
L-tryptophan	1,53 g
L-tyrosine	0,34 g
L-valine	4,93 g

- b) 30 % GLUCOSE SOLUTION compartment
containing per 1,0 litre:

Glucose monohydrate equivalent to Glucose	300,00 g
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- c) 20 % LIPID EMULSION compartment containing per 1,0 litre:

Refined soya-bean oil + Refined olive oil	200,00 g
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MRF 15 (MBR 15)

Registration number:	37/25.2/0507
Name of medicine:	OLICLINOMEL N7-1000
Dosage form:	INFUSION
Active ingredients:	EACH BAG CONTAINS: a) 10 % AMINO ACIDS SOLUTION compartment b) 40 % GLUCOSE SOLUTION compartment c) 20 % LIPID EMULSION compartment SEE ADDENDUM
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM CRITICAL CARE (PTY) LTD
Manufacturer:	CLINTEC PARENTERAL S.A., CEDEX, FRANCE BAXTER S.A., LESSINES, BELGIUM
Packer:	CLINTEC PARENTERAL S.A., CEDEX, FRANCE BAXTER S.A., LESSINES, BELGIUM ADCOCK INGRAM CRITICAL CARE, AEROTON, JOHANNESBURG, RSA
Laboratory:FPRC:	CLINTEC PARENTERAL S.A., CEDEX, FRANCE BAXTER S.A., LESSINES, BELGIUM
FPRC/FPRR:	ADCOCK INGRAM CRITICAL CARE, AEROTON, JOHANNESBURG, RSA
Shelf-life:	24 months
Date of registration:	7 JULY 2006

ADDENDUM

- a) 10 % AMINO ACIDS SOLUTION compartment containing per 1,0 litre:

L-alanine	20,70 g
L-arginine	11,50 g
Glycine	10,30 g
L-histidine	4,80 g
L-isoleucine	6,00 g
L-leucine	7,30 g
L-lysine	5,80 g
L-methionine	4,00 g
L-phenylalanine	5,60 g
L-proline	6,80 g
L-serine	5,00 g
L-threonine	4,20 g
L-tryptophan	1,80 g
L-tyrosine	0,40 g
L-valine	5,80 g

- b) 40 % GLUCOSE SOLUTION compartment containing per 1,0 litre:

Glucose monohydrate equivalent to Glucose	400,00 g
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- c) 20 % LIPID EMULSION compartment containing per 1,0 litre:

Refined soya-bean oil + Refined olive oil	200,00 g
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MRF 15

Registration number: 37/21.10/0560

Name of medicine: LUVERIS 75 I.U.

Dosage form: INJECTION

Active ingredients: EACH VIAL CONTAINS:
RECOMBINANT HUMAN LUTEINISING
HORMONE 75,0 I.U.

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

Applicant: SERONO S.A. (PTY) LTD

Manufacturer: LABORATOIRES SERONO S.A., AUBONNE,
SWITZERLAND

Packer: LABORATOIRES SERONO S.A., AUBONNE,
SWITZERLAND

Laboratory:FPRC: LABORATOIRES SERONO S.A., AUBONNE,
SWITZERLAND
FPRR: RBM, COLLERETO GIACOSA, ITALY
SERONO S.A., FOURWAYS, JOHANNESBURG

Shelf-life: 24 months

Date of registration: 7 JULY 2006

MRF 15

Registration number: 37/20.1.1/0624

Name of medicine: BMS-CEFEPIME 500 mg

Dosage form: INJECTION

Active ingredients: EACH VIAL CONTAINS:
CEFEPIME HYDROCHLORIDE EQUIVALENT TO
CEFEPIME 500,0 mg

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

Applicant: BRISTOL-MYERS SQUIBB (PTY) LTD

Manufacturer: BRISTOL-MYERS SQUIBB S.p.A., SERMONETA,
LATINA, ITALY

Packer: BRISTOL-MYERS SQUIBB S.p.A., SERMONETA,
LATINA, ITALY

Laboratory:FPRC: BRISTOL-MYERS SQUIBB S.p.A., SERMONETA,
LATINA, ITALY
MERCK PHARMACEUTICAL MANUFACTURING,
WADEVILLE, GERMISTON, RSA
CONSULTING CHEMICAL LABORATORIES,
STAR STREET, BOKSBURG, RSA
FPRR: BRISTOL-MYERS SQUIBB, BEDFORDVIEW, RSA

Shelf-life: 24 months

Date of registration: 7 JULY 2006

MRF 15

Registration number: 37/20.1.1/0625

Name of medicine: BMS-CEFEPIME 1 g

Dosage form: INJECTION

Active ingredients: EACH VIAL CONTAINS:
CEFEPIME HYDROCHLORIDE EQUIVALENT TO
CEFEPIME 1,0 g

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

Applicant: BRISTOL-MYERS SQUIBB (PTY) LTD

Manufacturer: BRISTOL-MYERS SQUIBB S.p.A., SERMONETA,
LATINA, ITALY

Packer: BRISTOL-MYERS SQUIBB S.p.A., SERMONETA,
LATINA, ITALY

Laboratory:FPRC: BRISTOL-MYERS SQUIBB S.p.A., SERMONETA,
LATINA, ITALY
MERCK PHARMACEUTICAL MANUFACTURING,
WADEVILLE, GERMISTON, RSA
CONSULTING CHEMICAL LABORATORIES,
STAR STREET, BOKSBURG, RSA

FPRR: BRISTOL-MYERS SQUIBB, BEDFORDVIEW, RSA

Shelf-life: 24 months

Date of registration: 7 JULY 2006

MRF 15

Registration number: 37/20.1.1/0626

Name of medicine: BMS-CEFEPIME 2 g

Dosage form: INJECTION

Active ingredients: EACH VIAL CONTAINS:
CEFEPIME HYDROCHLORIDE EQUIVALENT TO
CEFEPIME 2,0 g

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

Applicant: BRISTOL-MYERS SQUIBB (PTY) LTD

Manufacturer: BRISTOL-MYERS SQUIBB S.p.A., SERMONETA,
LATINA, ITALY

Packer: BRISTOL-MYERS SQUIBB S.p.A., SERMONETA,
LATINA, ITALY

Laboratory:FPRC: BRISTOL-MYERS SQUIBB S.p.A., SERMONETA,
LATINA, ITALY
MERCK PHARMACEUTICAL MANUFACTURING,
WADEVILLE, GERMISTON, RSA
CONSULTING CHEMICAL LABORATORIES,
STAR STREET, BOKSBURG, RSA

FPRR: BRISTOL-MYERS SQUIBB, BEDFORDVIEW, RSA

Shelf-life: 24 months

Date of registration: 7 JULY 2006

MRF 15

Registration number: 37/34/0643

Name of medicine: NICORETTE MICROTAB 2 mg

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
NICOTINE β -CYCLODEXTRIN EQUIVALENT TO
NICOTINE 2,0 mg

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

Applicant: WARNER-LAMBERT SOUTH AFRICA (PTY) LTD

Manufacturer: PFIZER HEALTH AB, HELSINGBORG, SWEDEN

Packer: PFIZER HEALTH AB, HELSINGBORG, SWEDEN

Laboratory:FPRC: PFIZER HEALTH AB, HELSINGBORG, SWEDEN
KHULULEKANI LABORATORY SERVICES,
MIDRAND, RSA
FPRR: SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA
WARNER-LAMBERT S.A., TOKAI, CAPE TOWN, RSA

Shelf-life: 24 months

Date of registration: 7 JULY 2006

MRF 15

Registration number: 37/20.1.2/0674

Name of medicine: CLAVICIN

Dosage form: INJECTION

Active ingredients: EACH VIAL CONTAINS:
AMOXYCILLIN SODIUM EQUIVALENT TO
AMOXYCILLIN 1000,0 mg
POTASSIUM CLAVULANATE EQUIVALENT TO
CLAVULANIC ACID 200,0 mg

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

Applicant: STRIDES SA PHARMACEUTICALS (PTY) LTD

Manufacturer: STRIDES ARCOLAB LTD, BANGALORE, INDIA

Packer: STRIDES ARCOLAB LTD, BANGALORE, INDIA

Laboratory:FPRC: STRIDES ARCOLAB LTD, BANGALORE, INDIA
INSTITUTE FOR PHARMACEUTICAL SERVICES,
BARDENE, BOKSBURG, RSA
NOVARTIS, SPARTAN, KEMPTON PARK, RSA
FPRR: STRIDES S.A., ARCADIA, PRETORIA, RSA

Shelf-life: 24 months

Date of registration: 7 JULY 2006

MRF 15

Registration number:	38/34/0085
Name of medicine:	MAXIDRONATE 90 mg/10 ml
Dosage form:	INFUSION
Active ingredients:	EACH 10,0 ml SOLUTION CONTAINS: MONOSODIUM PAMIDRONATE MONOHYDRATE EQUIVALENT TO DISODIUM PAMIDRONATE ANHYDRATE 90,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	HEXAL PHARMA (S.A.) (PTY) LTD
Manufacturer:	PHARMA-SKAN, SKANDERBORG, DENMARK
Packer:	PHARMA-SKAN, SKANDERBORG, DENMARK GEA FARMACEUTISK FABRIK, HVIDOVRE, DENMARK SALUTAS PHARMA GmbH, BARLEBEN, GERMANY DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG, RSA
Laboratory:FPRC:	PHARMA-SKAN, SKANDERBORG, DENMARK GEA FARMACEUTISK FABRIK, HVIDOVRE, DENMARK SALUTAS PHARMA GmbH, BARLEBEN, GERMANY CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA ANALYTICON, TERENCE, KEMPTON PARK
FPRR:	HEXAL PHARMA, WESTMEAD, KZN
Shelf-life:	24 months
Date of registration:	7 JULY 2006

MRF 15

Registration number: 38/20.1.1/0 149

Name of medicine: CEFIXAL 100 mg/5 ml

Dosage form: POWDER

Active ingredients: EACH 5,0 ml SUSPENSION CONTAINS:
CEFIXIME TRIHYDRATE EQUIVALENT TO
CEFIXIME 100,0 mg

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

Applicant: HEXAL PHARMA (S.A.) (PTY) LTD

Manufacturer: CIMEX AG, LIESBERG, SWITZERLAND

Packer: CIMEX AG, LIESBERG, SWITZERLAND
DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, JOHANNESBURG, RSA

Laboratory:FPRC: CIMEX AG, LIESBERG, SWITZERLAND
SALUTAS PHARMA GmbH, BARLEBEN, GERMANY
CONSULTING CHEMICAL LABORATORIES,
STAR STREET, BOKSBURG, RSA
ANALYTICON, TERENURE, KEMPTON PARK, RSA
FPRR: HEXAL PHARMA, WESTMEAD, RSA

Shelf-life: 24 months

Date of registration: 7 JULY 2006

MRF 15

Registration number: 38/20.1.1/0150

Name of medicine: CEFIXAL 200 mg

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
CEFIXIME TRIHYDRATE EQUIVALENT TO
CEFIXIME 200,0 mg

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

Applicant: HEXAL PHARMA (S.A.) (PTY) LTD

Manufacturer: CIMEX AG, LIESBERG, SWITZERLAND

Packer: CIMEX AG, LIESBERG, SWITZERLAND
DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, JOHANNESBURG, RSA

Laboratory:FPRC: CIMEX AG, LIESBERG, SWITZERLAND
SALUTAS PHARMA GmbH, BARLEBEN, GERMANY
CONSULTING CHEMICAL LABORATORIES,
STAR STREET, BOKSBURG, RSA
FPRR: ANALYTICON, TERENURE, KEMPTON PARK, RSA
HEXAL PHARMA, WESTMEAD, RSA

Shelf-life: 24 months

Date of registration: 7 JULY 2006

MRF 15

Registration number:	38/34/0158
Name of medicine:	MAXIDRONATE 15 mg/5 ml
Dosage form:	INFUSION
Active ingredients:	EACH 5,0 ml SOLUTION CONTAINS: MONOSODIUM PAMIDRONATE MONOHYDRATE EQUIVALENT TO DISODIUM PAMIDRONATE ANHYDRATE 15,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	HEXAL PHARMA (S.A.) (PTY) LTD
Manufacturer:	PHARMA-SKAN, SKANDERBORG, DENMARK
Packer:	PHARMA-SKAN, SKANDERBORG, DENMARK GEA FARMACEUTISK FABRIK, HVIDOVRE, DENMARK SALUTAS PHARMA GmbH, BARLEBEN, GERMANY DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG, RSA
Laboratory:FPRC:	PHARMA-SKAN, SKANDERBORG, DENMARK GEA FARMACEUTISK FABRIK, HVIDOVRE, DENMARK SALUTAS PHARMA GmbH, BARLEBEN, GERMANY CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA ANALYTICON, TERENCE, KEMPTON PARK
FPRR:	HEXAL PHARMA, WESTMEAD, KZN
Shelf-life:	24 months
Date of registration:	7 JULY 2006

MRF 15

Registration number: 38/34/0159

Name of medicine: MAXIDRONATE 60 mg/10 ml

Dosage form: INFUSION

Active ingredients: EACH 10,0 ml SOLUTION CONTAINS:
MONOSODIUM PAMIDRONATE MONOHYDRATE
EQUIVALENT TO DISODIUM PAMIDRONATE
ANHYDRATE 60,0 mg

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

Applicant: HEXAL PHARMA (S.A.) (PTY) LTD

Manufacturer: PHARMA-SKAN, SKANDERBORG, DENMARK

Packer: PHARMA-SKAN, SKANDERBORG, DENMARK
GEA FARMACEUTISK FABRIK, HVIDOVRE,
DENMARK
SALUTAS PHARMA GmbH, BARLEBEN, GERMANY
DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, JOHANNESBURG, RSA

Laboratory:FPRC: PHARMA-SKAN, SKANDERBORG, DENMARK
GEA FARMACEUTISK FABRIK, HVIDOVRE,
DENMARK
SALUTAS PHARMA GmbH, BARLEBEN, GERMANY
CONSULTING CHEMICAL LABORATORIES, STAR
STREET, BOKSBURG, RSA
ANALYTICON, TERENCE, KEMPTON PARK
FPRR: HEXAL PHARMA, WESTMEAD, KZN

Shelf-life: 24 months

Date of registration: 7 JULY 2006

MRF 15

Registration number: 38/20.1.1/0163

Name of medicine: RAN-CLARITHROMYCIN SUSPENSION 250 mg/5 ml

Dosage form: SUSPENSION

Active ingredients: EACH 5,0 ml SUSPENSION CONTAINS:
CLARITHROMYCIN 250,0 mg

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

Applicant: RANBAXY (S.A.) (PTY) LTD

Manufacturer: RANBAXY LABORATORIES LTD, DEWAS, INDIA

Packer: RANBAXY LABORATORIES LTD, DEWAS, INDIA

Laboratory:FPRC: RANBAXY LABORATORIES LTD, DEWAS, INDIA
CENTRE FOR QUALITY ASSURANCE OF
MEDICINES, UNIVERSITY, POTCHEFSTROOM
KHULULEKANI LABORATORY SERVICES,
MIDRAND, RSA
FPRR: RANBAXY (S.A.), CENTURION, PRETORIA

Shelf-life: 24 months

Date of registration: 7 JULY 2006

MRF 15

Registration number: 38/20.1.1/0176

Name of medicine: RAN-CLARITHROMYCIN SUSPENSION 125 mg/5 ml

Dosage form: SUSPENSION

Active ingredients: EACH 5,0 ml SUSPENSION CONTAINS:
CLARITHROMYCIN 125,0 mg

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

Applicant: RANBAXY (S.A.) (PTY) LTD

Manufacturer: RANBAXY LABORATORIES LTD, DEWAS, INDIA

Packer: RANBAXY LABORATORIES LTD, DEWAS, INDIA

Laboratory:FPRC: RANBAXY LABORATORIES LTD, DEWAS, INDIA
CENTRE FOR QUALITY ASSURANCE OF
MEDICINES, UNIVERSITY, POTCHEFSTROOM
KHULULEKANI LABORATORY SERVICES,
MIDRAND, RSA

FPRR: RANBAXY (S.A.), CENTURION, PRETORIA

Shelf-life: 24 months

Date of registration: 7 JULY 2006

MRF 15

Registration number: 38/15.2/0203

Name of medicine: ALREX

Dosage form: SUSPENSION

Active ingredients: EACH 1,0 ml SUSPENSION CONTAINS:
LOTEPREDNOL ETABONATE 2,0 mg

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

Applicant: SOFLENS (PTY) LTD

Manufacturer: BAUSCH & LOMB INC, TAMPA, FLORIDA, USA

Packer: BAUSCH & LOMB INC, TAMPA, FLORIDA, USA
COLUMBIA PHARMACEUTICALS, BARDENE,
BOKSBURG

Laboratory:FPRC: BAUSCH & LOMB INC, TAMPA, FLORIDA, USA
CONSULTING CHEMICAL LABORATORIES,
STAR STREET, BOKSBURG, RSA

FPRR: SOFLENS, RIVONIA, SANDTON, RSA

Shelf-life: 36 months

Date of registration: 7 JULY 2006

MRF 15

Registration number: 38/21.2/0224

Name of medicine: GLUCTAM MR 30 mg

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
GLICLAZIDE 30,0 mg

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

Applicant: EGIS PHARMACEUTICALS S.A. (PTY) LTD

Manufacturer: LES LABORATOIRES SERVIER INDUSTRIE,
GIDY, FRANCE
SERVIER (IRELAND) INDUSTRIES, WICKLOW,
IRELAND

Packer: LES LABORATOIRES SERVIER INDUSTRIE,
GIDY, FRANCE
SERVIER (IRELAND) INDUSTRIES, WICKLOW,
IRELAND
TECHNIKON LABORATORIES, ROBERTVILLE,
FLORIDA, RSA

Laboratory:FPRC: LES LABORATOIRES SERVIER INDUSTRIE,
GIDY, FRANCE
SERVIER (IRELAND) INDUSTRIES, WICKLOW,
IRELAND
INSPECTORATE M&L, ORMONDE,
JOHANNESBURG, RSA

FPRR: EGIS PHARMACEUTICALS, RIVONIA, RSA

Shelf-life: 24 months

Date of registration: 7 JULY 2006

MRF 15

Registration number: 38/5.1/0278

Name of medicine: EIPEN JUNIOR AUTO-INJECTOR

Dosage form: AUTO-INJECTOR

Active ingredients: EACH 0,3 ml SOLUTION CONTAINS:
ADRENALINE 0,15 mg

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

Applicant: MERCK (PTY) LTD

Manufacturer: MERIDIAN MEDICAL TECHNOLOGIES,
ST LOUIS, MO, USA

Packer: MERIDIAN MEDICAL TECHNOLOGIES,
ST LOUIS, MO, USA
DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, JOHANNESBURG
MERCK PHARMACEUTICALS
MANUFACTURING, WADEVILLE, GERMISTON

Laboratory:FPRC: MERIDIAN MEDICAL TECHNOLOGIES,
ST LOUIS, MO, USA
SCIENTIFIC ASSOCIATES, ST LOUIS, MISSOURI,
USA
SKYLAND SCIENTIFIC SERVICES, BELGRADE,
MONTANA, USA
O'NEAL SCIENTIFIC SERVICES, ST LOUIS,
MISSOURI, USA
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
MERCK PHARMACEUTICALS
MANUFACTURING, WADEVILLE, GERMISTON

FPRR: MERCK, MODDERFONTEIN, RSA

Shelf-life: 20 months

Date of registration: 7 JULY 2006

MRF 15

Registration number: 38/20.2.2/0304

Name of medicine: CLODERMA TOPICAL CREAM

Dosage form: CREAM

Active ingredients: EACH 1,0 g CREAM CONTAINS:
CLOTRIMAZOLE 10,0 mg

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

Applicant: MDI CC

Manufacturer: PHARMANOVA (PVT) LTD, HARARE, ZIMBABWE

Packer: PHARMANOVA (PVT) LTD, HARARE, ZIMBABWE

Laboratory:FPRC: PHARMANOVA (PVT) LTD, HARARE, ZIMBABWE
FPRR: MDI CC, MENLO PARK, PRETORIA, RSA

Shelf-life: 24 months

Date of registration: 7 JULY 2006

MRF 15

Registration number: 38/20.2.2/0305

Name of medicine: CLOFEM VAGINAL CREAM

Dosage form: CREAM

Active ingredients: EACH 1,0 g CREAM CONTAINS:
CLOTRIMAZOLE 10,0 mg

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

Applicant: MDI CC

Manufacturer: PHARMANOVA (PVT) LTD, HARARE, ZIMBABWE

Packer: PHARMANOVA (PVT) LTD, HARARE, ZIMBABWE

Laboratory:FPRC: PHARMANOVA (PVT) LTD, HARARE, ZIMBABWE
FPRR: MDI CC, MENLO PARK, PRETORIA, RSA

Shelf-life: 24 months

Date of registration: 7 JULY 2006

MRF 15

Registration number:	A38/10.1/0358
Name of medicine:	FLUTEX COUGH MIXTURE HONEY
Dosage form:	SYRUP
Active ingredients:	EACH 5,0 ml SYRUP CONTAINS: GUAIPHENESIN 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMACARE LIMITED
Manufacturer:	PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH
Packer:	PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH
Laboratory:FPRC:	SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY, POTCHEFSTROOM
FPRC/FPRR:	PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH
Shelf-life:	24 months
Date of registration:	7 JULY 2006

MRF 15

Registration number: A38/10.1/0359

Name of medicine: FLUTEX COUGH MIXTURE ORANGE

Dosage form: SYRUP

Active ingredients: EACH 5,0 ml SYRUP CONTAINS:
GUAIPHENESIN 100,0 mg

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

Applicant: PHARMACARE LIMITED

Manufacturer: PHARMACARE LIMITED, KORSTEN,
PORT ELIZABETH

Packer: PHARMACARE LIMITED, KORSTEN,
PORT ELIZABETH

Laboratory:FPRC: SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
FPRC/FPRR: RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, UNIVERSITY, POTCHEFSTROOM
PHARMACARE LIMITED, KORSTEN,
PORT ELIZABETH

Shelf-life: 24 months

Date of registration: 7 JULY 2006

MRF 15

Registration number: A38/10.1/0360

Name of medicine: FLUTEX COUGH MIXTURE BLACKCURRANT

Dosage form: SYRUP

Active ingredients: EACH 5,0 ml SYRUP CONTAINS:
GUAIPHENESIN 100,0 mg

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

Applicant: PHARMACARE LIMITED

Manufacturer: PHARMACARE LIMITED, KORSTEN,
PORT ELIZABETH

Packer: PHARMACARE LIMITED, KORSTEN,
PORT ELIZABETH

Laboratory:FPRC: SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
FPRC/FPRR: RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, UNIVERSITY, POTCHEFSTROOM
PHARMACARE LIMITED, KORSTEN,
PORT ELIZABETH

Shelf-life: 24 months

Date of registration: 7 JULY 2006

MRF 15

Registration number: A38/10.1/0361

Name of medicine: LENNON COUGH MIXTURE HONEY

Dosage form: SYRUP

Active ingredients: EACH 5,0 ml SYRUP CONTAINS:
GUAIPHENESIN 100,0 mg

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

Applicant: PHARMACARE LIMITED

Manufacturer: PHARMACARE LIMITED, KORSTEN,
PORT ELIZABETH

Packer: PHARMACARE LIMITED, KORSTEN,
PORT ELIZABETH

Laboratory:FPRC: SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, UNIVERSITY, POTCHEFSTROOM

FPRC/FPRR: PHARMACARE LIMITED, KORSTEN,
PORT ELIZABETH

Shelf-life: 24 months

Date of registration: 7 JULY 2006

MRF 15

Registration number: A38/10.1/0362

Name of medicine: LENNON COUGH MIXTURE ORANGE

Dosage form: SYRUP

Active ingredients: EACH 5,0 ml SYRUP CONTAINS:
GUAIPHENESIN 100,0 mg

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

Applicant: PHARMACARE LIMITED

Manufacturer: PHARMACARE LIMITED, KORSTEN,
PORT ELIZABETH

Packer: PHARMACARE LIMITED, KORSTEN,
PORT ELIZABETH

Laboratory:FPRC: SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, UNIVERSITY, POTCHEFSTROOM

FPRC/FPRR: PHARMACARE LIMITED, KORSTEN,
PORT ELIZABETH

Shelf-life: 24 months

Date of registration: 7 JULY 2006

MRF 15

Registration number:	A38/10.1/0363
Name of medicine:	LENNON COUGH MIXTURE BLACKCURRANT
Dosage form:	SYRUP
Active ingredients:	EACH 5,0 ml SYRUP CONTAINS: GUAIPHENESIN 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMACARE LIMITED
Manufacturer:	PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH
Packer:	PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH
Laboratory:FPRC:	SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY, POTCHEFSTROOM
FPRC/FPRR:	PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH
Shelf-life:	24 months
Date of registration:	7 JULY 2006

MRF 15

Registration number:	A38/10.1/0364
Name of medicine:	MUCOSPECT EXPECTORANT HONEY
Dosage form:	SYRUP
Active ingredients:	EACH 5,0 ml SYRUP CONTAINS: GUAIPHENESIN 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMACARE LIMITED
Manufacturer:	PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH
Packer:	PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH
Laboratory:FPRC:	SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY, POTCHEFSTROOM
FPRC/FPRR:	PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH
Shelf-life:	24 months
Date of registration:	7 JULY 2006

MRF 15

Registration number: A38/10.1/0365

Name of medicine: MUCOSPECT EXPECTORANT ORANGE

Dosage form: SYRUP

Active ingredients: EACH 5,0 ml SYRUP CONTAINS:
GUAIPHENESIN 100,0 mg

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

Applicant: PHARMACARE LIMITED

Manufacturer: PHARMACARE LIMITED, KORSTEN,
PORT ELIZABETH

Packer: PHARMACARE LIMITED, KORSTEN,
PORT ELIZABETH

Laboratory:FPRC: SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, UNIVERSITY, POTCHEFSTROOM

FPRC/FPRR: PHARMACARE LIMITED, KORSTEN,
PORT ELIZABETH

Shelf-life: 24 months

Date of registration: 7 JULY 2006

MRF 15

Registration number: A38/10.1/0366

Name of medicine: MUCOSPECT EXPECTORANT BLACKCURRANT

Dosage form: SYRUP

Active ingredients: EACH 5,0 ml SYRUP CONTAINS:
GUAIPHENESIN 100,0 mg

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

Applicant: PHARMACARE LIMITED

Manufacturer: PHARMACARE LIMITED, KORSTEN,
PORT ELIZABETH

Packer: PHARMACARE LIMITED, KORSTEN,
PORT ELIZABETH

Laboratory:FPRC: SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, UNIVERSITY, POTCHEFSTROOM
FPRC/FPRR: PHARMACARE LIMITED, KORSTEN,
PORT ELIZABETH

Shelf-life: 24 months

Date of registration: 7 JULY 2006

MRF 15

Registration number: A38/10.1/0367

Name of medicine: WOODWARDS COUGH MIXTURE HONEY

Dosage form: SYRUP

Active ingredients: EACH 5,0 ml SYRUP CONTAINS:
GUAIPHENESIN 100,0 mg

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

Applicant: PHARMACARE LIMITED

Manufacturer: PHARMACARE LIMITED, KORSTEN,
PORT ELIZABETH

Packer: PHARMACARE LIMITED, KORSTEN,
PORT ELIZABETH

Laboratory:FPRC: SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, UNIVERSITY, POTCHEFSTROOM
FPRC/FPRR: PHARMACARE LIMITED, KORSTEN,
PORT ELIZABETH

Shelf-life: 24 months provisional

Date of registration: 7 JULY 2006

MRF 15

Registration number: A38/10.1/0368

Name of medicine: WOODWARDS COUGH MIXTURE ORANGE

Dosage form: SYRUP

Active ingredients: EACH 5,0 ml SYRUP CONTAINS:
GUAIPHENESIN 100,0 mg

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

Applicant: PHARMACARE LIMITED

Manufacturer: PHARMACARE LIMITED, KORSTEN,
PORT ELIZABETH

Packer: PHARMACARE LIMITED, KORSTEN,
PORT ELIZABETH

Laboratory:FPRC: SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
FPRC/FPRR: RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, UNIVERSITY, POTCHEFSTROOM
PHARMACARE LIMITED, KORSTEN,
PORT ELIZABETH

Shelf-life: 24 months provisional

Date of registration: 7 JULY 2006

MRF 15

Registration number: A38/10.1/0369

Name of medicine: WOODWARDS COUGH MIXTURE BLACKCURRANT

Dosage form: SYRUP

Active ingredients: EACH 5,0 ml SYRUP CONTAINS:
GUAIPHENESIN 100,0 mg

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

Applicant: PHARMACARE LIMITED

Manufacturer: PHARMACARE LIMITED, KORSTEN,
PORT ELIZABETH

Packer: PHARMACARE LIMITED, KORSTEN,
PORT ELIZABETH

Laboratory:FPRC: SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, UNIVERSITY, POTCHEFSTROOM

FPRC/FPRR: PHARMACARE LIMITED, KORSTEN,
PORT ELIZABETH

Shelf-life: 24 months provisional

Date of registration: 7 JULY 2006

MRF 15

Registration number:	A38/20.1.2/0385
Name of medicine:	AMPOXIN 250
Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: AMPICILLIN SODIUM EQUIVALENT TO AMPICILLIN 125,0 mg CLOXACILLIN SODIUM EQUIVALENT TO CLOXACILLIN 125,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	UNICHEM SA (PTY) LTD
Manufacturer:	UNICHEM LABORATORIES LTD, SOLAN, INDIA
Packer:	UNICHEM LABORATORIES LTD, SOLAN, INDIA
Laboratory:FPRC:	UNICHEM LABORATORIES LTD, SOLAN, INDIA INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY, POTCHEFSTROOM CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES, BARDENE, BOKSBURG
FPRR:	UNICHEM, NOORDBRUG, POTCHEFSTROOM, RSA
Shelf-life:	24 months
Date of registration:	7 JULY 2006

MRF 15

Registration number:	A38/20.1.2/0386
Name of medicine:	AMPOXIN 500
Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: AMPICILLIN SODIUM EQUIVALENT TO AMPICILLIN 250,0 mg CLOXACILLIN SODIUM EQUIVALENT TO CLOXACILLIN 250,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	UNICHEM SA (PTY) LTD
Manufacturer:	UNICHEM LABORATORIES LTD, SOLAN, INDIA
Packer:	UNICHEM LABORATORIES LTD, SOLAN, INDIA
Laboratory:FPRC:	UNICHEM LABORATORIES LTD, SOLAN, INDIA INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY, POTCHEFSTROOM CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES, BARDENE, BOKSBURG
FPRR:	UNICHEM, NOORDBRUG, POTCHEFSTROOM, RSA
Shelf-life:	24 months
Date of registration:	7 JULY 2006

MRF 15

Registration number: A38/20.1.2/0388

Name of medicine: AMPOXIN 1000

Dosage form: INJECTION

Active ingredients: EACH VIAL CONTAINS:
AMPICILLIN SODIUM EQUIVALENT TO
AMPICILLIN 500,0 mg
CLOXACILLIN SODIUM EQUIVALENT TO
CLOXACILLIN 500,0 mg

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

Applicant: UNICHEM SA (PTY) LTD

Manufacturer: UNICHEM LABORATORIES LTD, SOLAN, INDIA

Packer: UNICHEM LABORATORIES LTD, SOLAN, INDIA

Laboratory:FPRC: UNICHEM LABORATORIES LTD, SOLAN, INDIA
INSTITUTE FOR INDUSTRIAL PHARMACY,
UNIVERSITY, POTCHEFSTROOM
CONSULTING CHEMICAL LABORATORIES, STAR
STREET, BOKSBURG, RSA
INSTITUTE FOR PHARMACEUTICAL SERVICES,
BARDENE, BOKSBURG

FPRR: UNICHEM, NOORDBRUG, POTCHEFSTROOM, RSA

Shelf-life: 24 months

Date of registration: 7 JULY 2006

MRF 15

Registration number: A38/11.5/0389

Name of medicine: PICOPREP

Dosage form: POWDER

Active ingredients: EACH SACHET CONTAINS:
SODIUM PICOSULPHATE 10,0 mg
MAGNESIUM OXIDE 3,0 g
CITRIC ACID 12,0 g

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

Applicant: BETA PHARMACEUTICALS cc

Manufacturer: DFC THOMPSON AUSTRALIA THORNLEIGH,
NEW SOUTH WALES, AUSTRALIA

Packer: A.C.E. PACKWELL, BELROSE, NEW SOUTH WALES,
AUSTRALIA
BETA PHARMACEUTICALS, KINI BAY,
PORT ELIZABETH

Laboratory:FPRC: AMDEL LABORATORIES, ASQUITH, SYDNEY,
AUSTRALIA
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, UNIVERSITY, POTCHEFSTROOM
CONSULTING CHEMICAL LABORATORIES, STAR
STREET, BOKSBURG

FPRR: BETA PHARMACEUTICALS, KINI BAY,
PORT ELIZABETH

Shelf-life: 24 months provisional

Date of registration: 7 JULY 2006

MRF 15

Registration number: A38/5.7.1/0400

Name of medicine: FEXADIN 120

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
FEXOFENADINE HYDROCHLORIDE 120,0 mg

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

Applicant: RANBAXY (S.A.) (PTY) LTD

Manufacturer: RANBAXY LABORATORIES LTD, DEWAS, INDIA

Packer: RANBAXY LABORATORIES LTD, DEWAS, INDIA

Laboratory:FPRC: RANBAXY LABORATORIES LTD, DEWAS, INDIA
KHULULEKANI LABORATORY SERVICES,
MIDRAND, RSA
CENTRE FOR QAULITY ASSURANCE OF
MEDICINES, UNIVERSITY, POTCHEFSTROOM
FPRR: RANBAXY, CENTURION, RSA

Shelf-life: 24 months

Date of registration: 7 JULY 2006

MRF 15

Registration number: A38/5.7.1/0401

Name of medicine: FEXADIN 180

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
FEXOFENADINE HYDROCHLORIDE 180,0 mg

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

Applicant: RANBAXY (S.A.) (PTY) LTD

Manufacturer: RANBAXY LABORATORIES LTD, DEWAS, INDIA

Packer: RANBAXY LABORATORIES LTD, DEWAS, INDIA

Laboratory:FPRC: RANBAXY LABORATORIES LTD, DEWAS, INDIA
KHULULEKANI LABORATORY SERVICES,
MIDRAND, RSA
FPRR: CENTRE FOR QAULITY ASSURANCE OF
MEDICINES, UNIVERSITY, POTCHEFSTROOM
RANBAXY, CENTURION, RSA

Shelf-life: 24 months

Date of registration: 7 JULY 2006

MRF 15

Registration number: A38/5.7.1/0407

Name of medicine: FENOFEX 120

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
FEXOFENADINE HYDROCHLORIDE 120,0 mg

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

Applicant: RANBAXY (S.A.) (PTY) LTD

Manufacturer: RANBAXY LABORATORIES LTD, DEWAS, INDIA

Packer: RANBAXY LABORATORIES LTD, DEWAS, INDIA

Laboratory:FPRC: RANBAXY LABORATORIES LTD, DEWAS, INDIA
KHULULEKANI LABORATORY SERVICES,
MIDRAND, RSA
FPRR: CENTRE FOR QAULITY ASSURANCE OF
MEDICINES, UNIVERSITY, POTCHEFSTROOM
RANBAXY, CENTURION, RSA

Shelf-life: 24 months

Date of registration: 7 JULY 2006

MRF 15

Registration number: A38/5.7.1/0408

Name of medicine: FENOFEX 180

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
FEXOFENADINE HYDROCHLORIDE 180,0 mg

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

Applicant: RANBAXY (S.A.) (PTY) LTD

Manufacturer: RANBAXY LABORATORIES LTD, DEWAS, INDIA

Packer: RANBAXY LABORATORIES LTD, DEWAS, INDIA

Laboratory:FPRC: RANBAXY LABORATORIES LTD, DEWAS, INDIA
KHULULEKANI LABORATORY SERVICES,
MIDRAND, RSA
CENTRE FOR QAULITY ASSURANCE OF
MEDICINES, UNIVERSITY, POTCHEFSTROOM
FPRR: RANBAXY, CENTURION, RSA

Shelf-life: 24 months

Date of registration: 7 JULY 2006

MRF 15

Registration number:	A38/12/0425
Name of medicine:	NUBEND-400
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ALBENDAZOLE 400,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	BE-TABS PHARMACEUTICALS (PTY) LTD
Manufacturer:	KOPRAN LTD, KHALAPUR, RAIGAD, INDIA
Packer:	KOPRAN LTD, KHALAPUR, RAIGAD, INDIA
Laboratory:FPRC: FPRC/FPRR:	KOPRAN LTD, KHALAPUR, RAIGAD, INDIA BE-TABS PHARMACEUTICALS, ROODEPOORT, RSA
Shelf-life:	24 months
Date of registration:	7 JULY 2006

MRF 15

Registration number: A38/12/0426

Name of medicine: WORMADOLE

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
ALBENDAZOLE 400,0 mg

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

Applicant: BE-TABS PHARMACEUTICALS (PTY) LTD

Manufacturer: KOPRAN LTD, KHALAPUR, RAIGAD, INDIA

Packer: KOPRAN LTD, KHALAPUR, RAIGAD, INDIA

Laboratory:FPRC: KOPRAN LTD, KHALAPUR, RAIGAD, INDIA
FPRC/FPRR: BE-TABS PHARMACEUTICALS, ROODEPOORT, RSA

Shelf-life: 24 months

Date of registration: 7 JULY 2006

MRF 15

Registration number:	A38/8.4/0439
Name of medicine:	GELPLEX
Dosage form:	INFUSION
Active ingredients:	EACH 100,0 ml SOLUTION CONTAINS: SUCCINYLATED GELATIN 4,0 g
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM CRITICAL CARE (PTY) LTD
Manufacturer:	IVEX PHARMACEUTICALS LTD, LARNE, NORTHERN IRELAND
Packer:	IVEX PHARMACEUTICALS LTD, LARNE, NORTHERN IRELAND
Laboratory:FPRC:	IVEX PHARMACEUTICALS LTD, LARNE, NORTHERN IRELAND BODYCOTE MATERIALS TESTING LTD, MIDLOTHIAN, SCOTLAND BIOLOGICAL LABORATORIES LTD, COUNTY MAYO, IRELAND
FPRR:	ADCOCK INGRAM CRITICAL CARE, AEROTON, JOHANNESBURG
Shelf-life:	24 months
Date of registration:	7 JULY 2006

MRF 15

Registration number: A38/7.3/0507

Name of medicine: MIGREX 50 TABLETS

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

Applicant: HEXAL PHARMA (S.A.) (PTY) LTD

Manufacturer: SALUTAS PHARMA GmbH, BARLEBEN, GERMANY
HEXAL AG, HOLZKIRCHEN, GERMANY

Packer: SALUTAS PHARMA GmbH, BARLEBEN, GERMANY
HEXAL AG, HOLZKIRCHEN, GERMANY
DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, JOHANNESBURG, RSA

Laboratory:FPRC: SALUTAS PHARMA GmbH, BARLEBEN, GERMANY
HEXAL AG, HOLZKIRCHEN, GERMANY
CONSULTING CHEMICAL LABORATORIES, STAR
STREET, BOKSBURG, RSA
FPRR: ANALYTICON, TERENURE, KEMPTON PARK
HEXAL PHARMA, WESTMEAD, KZN

Shelf-life: 36 months

Date of registration: 7 JULY 2006

MRF 15

Registration number: A38/7.3/0508

Name of medicine: MIGREX 100 TABLETS

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

Applicant: HEXAL PHARMA (S.A.) (PTY) LTD

Manufacturer: SALUTAS PHARMA GmbH, BARLEBEN, GERMANY
HEXAL AG, HOLZKIRCHEN, GERMANY

Packer: SALUTAS PHARMA GmbH, BARLEBEN, GERMANY
HEXAL AG, HOLZKIRCHEN, GERMANY
DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, JOHANNESBURG, RSA

Laboratory:FPRC: SALUTAS PHARMA GmbH, BARLEBEN, GERMANY
HEXAL AG, HOLZKIRCHEN, GERMANY
CONSULTING CHEMICAL LABORATORIES, STAR
STREET, BOKSBURG, RSA
FPRR: ANALYTICON, TERENURE, KEMPTON PARK
HEXAL PHARMA, WESTMEAD, KZN

Shelf-life: 36 months

Date of registration: 7 JULY 2006

MRF 15

Registration number: A38/3.2/0562

Name of medicine: BONDRONAT 50

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
IBANDRONIC ACID 50,0 mg

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

Applicant: ROCHE PRODUCTS (PTY) LTD

Manufacturer: F. HOFFMANN-LA ROCHE LTD, BASEL,
SWITZERLAND

Packer: F. HOFFMANN-LA ROCHE LTD, BASEL,
SWITZERLAND
F. HOFFMANN-LA ROCHE LTD, KAISERAUGST,
SWITZERLAND
ROCHE PRODUCTS, ISANDO, RSA

Laboratory:FPRC: F. HOFFMANN-LA ROCHE LTD, BASEL,
SWITZERLAND
FPRC/FPRR: ROCHE PRODUCTS, ISANDO, RSA

Shelf-life: 24 months

Date of registration: 7 JULY 2006

MRF 15

Registration number: A38/1.2/0616

Name of medicine: APEX-SERTRALINE 50 mg

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: CAMOX PHARMACEUTICALS (PTY) LTD

Manufacturer: INTAS PHARMACEUTICALS LTD, AHMEDABAD,
GUJARAT, INDIA

Packer: INTAS PHARMACEUTICALS LTD, AHMEDABAD,
GUJARAT, INDIA

Laboratory:FPRC: INTAS PHARMACEUTICALS LTD, AHMEDABAD,
GUJARAT, INDIA
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
INSTITUTE FOR PHARMACEUTICAL
SERVICES, BARDENE, BOKSBURG, RSA
INSPECTORATE M&L, ORMONDE, JOHANNESBURG
FPRR: CAMOX PHARMACEUTICALS, AMALGAM,
JOHANNESBURG, RSA

Shelf-life: 24 months provisional

Date of registration: 7 JULY 2006

MRF 15

Registration number: A38/1.2/0617

Name of medicine: APEX-SERTRALINE 100 mg

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: CAMOX PHARMACEUTICALS (PTY) LTD

Manufacturer: INTAS PHARMACEUTICALS LTD, AHMEDABAD,
GUJARAT, INDIA

Packer: INTAS PHARMACEUTICALS LTD, AHMEDABAD,
GUJARAT, INDIA

Laboratory:FPRC: INTAS PHARMACEUTICALS LTD, AHMEDABAD,
GUJARAT, INDIA
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
INSTITUTE FOR PHARMACEUTICAL
SERVICES, BARDENE, BOKSBURG, RSA
INSPECTORATE M&L, ORMONDE, JOHANNESBURG
FPRR: CAMOX PHARMACEUTICALS, AMALGAM,
JOHANNESBURG, RSA

Shelf-life: 24 months provisional

Date of registration: 7 JULY 2006

MRF 15

Registration number: A38/5.7.2/0620

Name of medicine: APEX-DOMPERIDONE 10 mg TABLETS

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
DOMPERIDONE MALEATE EQUIVALENT TO
DOMPERIDONE 10,0 mg

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

Applicant: CAMOX PHARMACEUTICALS (PTY) LTD

Manufacturer: MEDREICH STERILAB LTD, VIRGONAGAR,
BANGALORE, INDIA

Packer: MEDREICH STERILAB LTD, VIRGONAGAR,
BANGALORE, INDIA

Laboratory:FPRC: MEDREICH STERILAB LTD, VIRGONAGAR,
BANGALORE, INDIA
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
INSTITUTE FOR PHARMACEUTICAL SERVICES,
BARDENE, BOKSBURG, RSA
INSPECTORATE M&L, ORMONDE, JOHANNESBURG
FPRR: CAMOX PHARMACEUTICALS, AMALGAM,
JOHANNESBURG

Shelf-life: 24 months

Date of registration: 7 JULY 2006

MRF 15

Registration number: A38/5.7.2/0636

Name of medicine: VOMI-GUARD 10 mg TABLETS

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
DOMPERIDONE MALEATE EQUIVALENT TO
DOMPERIDONE 10,0 mg

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

Applicant: CAMOX PHARMACEUTICALS (PTY) LTD

Manufacturer: MEDREICH STERILAB LTD, VIRGONAGAR,
BANGALORE, INDIA

Packer: MEDREICH STERILAB LTD, VIRGONAGAR,
BANGALORE, INDIA

Laboratory:FPRC: MEDREICH STERILAB LTD, VIRGONAGAR,
BANGALORE, INDIA
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
INSTITUTE FOR PHARMACEUTICAL SERVICES,
BARDENE, BOKSBURG, RSA
INSPECTORATE M&L, ORMONDE, JOHANNESBURG
FPRR: CAMOX PHARMACEUTICALS, AMALGAM,
JOHANNESBURG

Shelf-life: 24 months

Date of registration: 7 JULY 2006

MRF 15

Registration number: A39/21.8.1/0035

Name of medicine: MENOSTAR

Dosage form: TRANSDERMAL DELIVERY SYSTEM

Active ingredients: EACH CM₂ CONTAINS:
ESTRADIOL HEMIHYDRATE 0,30 mg

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

Applicant: SCHERING (PTY) LTD

Manufacturer: 3M PHARMACEUTICALS, NORTHRIDGE,
CALIFORNIA, USA

Packer: 3M PHARMACEUTICALS, NORTHRIDGE,
CALIFORNIA, USA
SCHERING GmbH & CO, WEIMAR, GERMANY

Laboratory:FPRC: 3M SANTE, CEDEX, FRANCE
SCHERING GmbH & CO, WEIMAR, GERMANY
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
FPRR: SCHERING, MIDRAND, RSA

Shelf-life: 36 months

Date of registration: 7 JULY 2006

MRF 15

Registration number: A39/2.6/0072

Name of medicine: STRESAM

Dosage form: CAPSULE

Active ingredients: EACH CAPSULE CONTAINS:
ETIFOXINE HYDROCHLORIDE 50,0 mg

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

Applicant: ADCOCK INGRAM LIMITED

Manufacturer: LABORATOIRES BIOCOCODEX, BEAUVAIS, FRANCE

Packer: LABORATOIRES BIOCOCODEX, BEAUVAIS, FRANCE

Laboratory:FPRC: LABORATOIRES BIOCOCODEX, BEAUVAIS, FRANCE
FPRC/FPRR: ADCOCK INGRAM HEALTHCARE, CLAYVILLE,
OLIFANTSFONTEIN, RSA
ADCOCK INGRAM HEALTHCARE, WADEVILLE,
GERMISTON, RSA

Shelf-life: 24 months

Date of registration: 7 JULY 2006

MRF 15 (MBR 15)

Registration number: A39/5.7.1/0103

Name of medicine: CETIRIZINE-HEXAL 1,0 mg/ml ORAL SOLUTION

Dosage form: SOLUTION

Active ingredients: EACH 1,0 ml SOLUTION CONTAINS:
CETIRIZINE DIHYDROCHLORIDE 1,0 mg

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

Applicant: HEXAL PHARMA (SA) (PTY) LTD

Manufacturer: SALUTAS PHARMA, BARLEBEN, GERMANY

Packer: SALUTAS PHARMA, BARLEBEN, GERMANY
DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, RSA

Laboratory:FPRC: SALUTAS PHARMA, BARLEBEN, GERMANY
CONSULTING CHEMICAL LABORATORIES,
STAR STREET, BOKSBURG, RSA
ANALYTICON, KEMPTON PARK, RSA
FPRR: HEXAL PHARMA, PINETOWN, RSA

Shelf-life: 24 months

Date of registration: 7 JULY 2006

MRF 15

Registration number: A39/11.4.3/0116

Name of medicine: ADCO-ROZNAL 15

Dosage form: CAPSULE

Active ingredients: EACH CAPSULE CONTAINS:
LANSOPRAZOLE 15,0 mg

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

Applicant: ADCOCK INGRAM LIMITED

Manufacturer: LICONSA S.A., GUADALAJARA, SPAIN

Packer: LICONSA S.A., GUADALAJARA, SPAIN

Laboratory:FPRC: LICONSA S.A., GUADALAJARA, SPAIN
FPRC/FPRR: ADCOCK INGRAM HEALTHCARE, CLAYVILLE,
OLIFANTSFONTEIN
ADCOCK INGRAM HEALTHCARE, WADEVILLE,
GERMISTON

Shelf-life: 24 months provisional

Date of registration: 7 JULY 2006

MRF 15

Registration number: A39/20.1.1/0149

Name of medicine: APEX-OFLOXACIN 200 mg

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
OFLOXACIN 200,0 mg

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

Applicant: CAMOX PHARMACEUTICALS (PTY) LTD

Manufacturer: INTAS PHARMACEUTICALS LTD, MATODA,
GUJARAT, INDIA

Packer: INTAS PHARMACEUTICALS LTD, MATODA,
GUJARAT, INDIA

Laboratory:FPRC: INTAS PHARMACEUTICALS LTD, MATODA,
GUJARAT, INDIA
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
INSTITUTE FOR PHARMACEUTICAL SERVICES,
SILVERTONDALE, RSA
INSPECTORATE M&L, ORMONDE, JOHANNESBURG
FPRR: CAMOX PHARMACEUTICALS, AMALGAM,
JOHANNESBURG, RSA

Shelf-life: 24 months provisional

Date of registration: 7 JULY 2006

MRF 15

Registration number:	A39/20.1.1/0150
Name of medicine:	APEX-OFLOXACIN 400 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: OFLOXACIN 400,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CAMOX PHARMACEUTICALS (PTY) LTD
Manufacturer:	INTAS PHARMACEUTICALS LTD, MATODA, GUJARAT, INDIA
Packer:	INTAS PHARMACEUTICALS LTD, MATODA, GUJARAT, INDIA
Laboratory:FPRC:	INTAS PHARMACEUTICALS LTD, MATODA, GUJARAT, INDIA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, RSA INSPECTORATE M&L, ORMONDE, JOHANNESBURG
FPRR:	CAMOX PHARMACEUTICALS, AMALGAM, JOHANNESBURG, RSA
Shelf-life:	24 months provisional
Date of registration:	7 JULY 2006

MRF 15

Registration number: A39/6.2/0155

Name of medicine: HEXARONE 150 mg/3 ml

Dosage form: INJECTION

Active ingredients: EACH 3,0 ml SOLUTION CONTAINS:
AMIODARONE 150,0 mg

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

Applicant: HEXAL PHARMA (S.A.) (PTY) LTD

Manufacturer: EBEWE ARZNEIMITTEL, UNTERACH, AUSTRIA

Packer: EBEWE ARZNEIMITTEL, UNTERACH, AUSTRIA
DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, JOHANNESBURG, RSA

Laboratory:FPRC: EBEWE ARZNEIMITTEL, UNTERACH, AUSTRIA
SALUTAS PHARMA GmbH, BARLEBEN, GERMANY
CONSULTING CHEMICAL LABORATORIES, STAR
STREET, BOKSBURG, RSA
FPRR: ANALYTICON, TERENURE, KEMPTON PARK
HEXAL PHARMA, WESTMEAD, KZN

Shelf-life: 24 months

Date of registration: 7 JULY 2006

MRF 15

Registration number: A39/6.2/0156

Name of medicine: AMIODARONE HCL – HEXAL 150 mg/3 ml

Dosage form: INJECTION

Active ingredients: EACH 3,0 ml SOLUTION CONTAINS:
AMIODARONE 150,0 mg

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

Applicant: HEXAL PHARMA (S.A.) (PTY) LTD

Manufacturer: EBEWE ARZNEIMITTEL, UNTERACH, AUSTRIA

Packer: EBEWE ARZNEIMITTEL, UNTERACH, AUSTRIA
DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, JOHANNESBURG, RSA

Laboratory:FPRC: EBEWE ARZNEIMITTEL, UNTERACH, AUSTRIA
SALUTAS PHARMA GmbH, BARLEBEN, GERMANY
CONSULTING CHEMICAL LABORATORIES, STAR
STREET, BOKSBURG, RSA
FPRR: ANALYTICON, TERENURE, KEMPTON PARK
HEXAL PHARMA, WESTMEAD, KZN

Shelf-life: 24 months

Date of registration: 7 JULY 2006

MRF 15

Registration number: A39/26/0170

Name of medicine: CARBOSIN 600

Dosage form: INJECTION

Active ingredients: EACH 1,0 ml SOLUTION CONTAINS:
CARBOPLATIN 10,0 mg

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

Applicant: PHARMACHEMIE (PTY) LTD

Manufacturer: PHARMACHEMIE BV, HAARLEM,
THE NETHERLANDS

Packer: PHARMACHEMIE BV, HAARLEM,
THE NETHERLANDS
DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, JOHANNESBURG

Laboratory:FPRC: PHARMACHEMIE BV, HAARLEM,
THE NETHERLANDS
CONSULTING CHEMICAL LABORATORIES,
STAR STREET, BOKSBURG, RSA
FPRR: PHARMACHEMIE, CENTURION, RSA

Shelf-life: 24 months provisional

Date of registration: 7 JULY 2006

MRF 15

Registration number: A39/18.1/0189

Name of medicine: TORAHEXAL 2,5 mg

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
TORASEMIDE 2,5 mg

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

Applicant: HEXAL PHARMA (S.A.) (PTY) LTD

Manufacturer: SALUTAS PHARMA GmbH, BARLEBEN, GERMANY

Packer: SALUTAS PHARMA GmbH, BARLEBEN, GERMANY
DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, RSA

Laboratory:FPRC: SALUTAS PHARMA GmbH, BARLEBEN, GERMANY
CONSULTING CHEMICAL LABORATORIES, STAR
STREET, BOKSBURG, RSA
FPRR: ANALYTICON, TERENURE, KEMPTON PARK, RSA
HEXAL PHARMA, WESTMEAD, KZN

Shelf-life: 24 months

Date of registration: 7 JULY 2006

MRF 15

Registration number: A39/18.1/0190

Name of medicine: TORAHEXAL 5 mg

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
TORASEMIDE 5,0 mg

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

Applicant: HEXAL PHARMA (S.A.) (PTY) LTD

Manufacturer: SALUTAS PHARMA GmbH, BARLEBEN, GERMANY

Packer: SALUTAS PHARMA GmbH, BARLEBEN, GERMANY
DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, RSA

Laboratory:FPRC: SALUTAS PHARMA GmbH, BARLEBEN, GERMANY
CONSULTING CHEMICAL LABORATORIES, STAR
STREET, BOKSBURG, RSA
FPRR: ANALYTICON, TERENURE, KEMPTON PARK, RSA
HEXAL PHARMA, WESTMEAD, KZN

Shelf-life: 24 months

Date of registration: 7 JULY 2006

MRF 15

Registration number: A39/18.1/0191

Name of medicine: TORAHEXAL 10 mg

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
TORASEMIDE 10,0 mg

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

Applicant: HEXAL PHARMA (S.A.) (PTY) LTD

Manufacturer: SALUTAS PHARMA GmbH, BARLEBEN, GERMANY

Packer: SALUTAS PHARMA GmbH, BARLEBEN, GERMANY
DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, RSA

Laboratory:FPRC: SALUTAS PHARMA GmbH, BARLEBEN, GERMANY
CONSULTING CHEMICAL LABORATORIES, STAR
STREET, BOKSBURG, RSA
FPRR: ANALYTICON, TERENURE, KEMPTON PARK, RSA
HEXAL PHARMA, WESTMEAD, KZN

Shelf-life: 24 months

Date of registration: 7 JULY 2006

MRF 15

Registration number:	A39/18.1/0192
Name of medicine:	TORASEMIDE-HEXAL 2,5 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: TORASEMIDE 2,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	HEXAL PHARMA (S.A.) (PTY) LTD
Manufacturer:	SALUTAS PHARMA GmbH, BARLEBEN, GERMANY
Packer:	SALUTAS PHARMA GmbH, BARLEBEN, GERMANY DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, RSA
Laboratory:FPRC:	SALUTAS PHARMA GmbH, BARLEBEN, GERMANY CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA
FPRR:	ANALYTICON, TERENURE, KEMPTON PARK, RSA HEXAL PHARMA, WESTMEAD, KZN
Shelf-life:	24 months
Date of registration:	7 JULY 2006

MRF 15

Registration number: A39/18.1/0193

Name of medicine: TORASEMIDE-HEXAL 5 mg

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
TORASEMIDE 5,0 mg

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

Applicant: HEXAL PHARMA (S.A.) (PTY) LTD

Manufacturer: SALUTAS PHARMA GmbH, BARLEBEN, GERMANY

Packer: SALUTAS PHARMA GmbH, BARLEBEN, GERMANY
DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, RSA

Laboratory:FPRC: SALUTAS PHARMA GmbH, BARLEBEN, GERMANY
CONSULTING CHEMICAL LABORATORIES, STAR
STREET, BOKSBURG, RSA
FPRR: ANALYTICON, TERENURE, KEMPTON PARK, RSA
HEXAL PHARMA, WESTMEAD, KZN

Shelf-life: 24 months

Date of registration: 7 JULY 2006

MRF 15

Registration number: A39/18.1/0194

Name of medicine: TORASEMIDE-HEXAL 10 mg

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
TORASEMIDE 10,0 mg

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

Applicant: HEXAL PHARMA (S.A.) (PTY) LTD

Manufacturer: SALUTAS PHARMA GmbH, BARLEBEN, GERMANY

Packer: SALUTAS PHARMA GmbH, BARLEBEN, GERMANY
DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, RSA

Laboratory:FPRC: SALUTAS PHARMA GmbH, BARLEBEN, GERMANY
CONSULTING CHEMICAL LABORATORIES, STAR
STREET, BOKSBURG, RSA
ANALYTICON, TERENURE, KEMPTON PARK, RSA
FPRR: HEXAL PHARMA, WESTMEAD, KZN

Shelf-life: 24 months

Date of registration: 7 JULY 2006

MRF 15

Registration number: A39/16.1/0198

Name of medicine: SINUSTOP PAEDIATRIC NASAL DROPS

Dosage form: DROPS

Active ingredients: EACH 1,0 ml SOLUTION CONTAINS:
OXYMETAZOLINE HYDROCHLORIDE 0,250 mg

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

Applicant: ADCOCK INGRAM LIMITED

Manufacturer: ADCOCK INGRAM HEALTHCARE, WADEVILLE,
GERMISTON, RSA

Packer: ADCOCK INGRAM HEALTHCARE, WADEVILLE,
GERMISTON, RSA

Laboratory:FPRC/FPRR: ADCOCK INGRAM HEALTHCARE, WADEVILLE,
GERMISTON, RSA

Shelf-life: 24 months provisional

Date of registration: 7 JULY 2006

MRF 15

Registration number: A39/16.1/0200

Name of medicine: NAZENE PAEDIATRIC NASAL METERED SPRAY

Dosage form: SPRAY

Active ingredients: EACH 1,0 ml SOLUTION CONTAINS:
OXYMETAZOLINE HYDROCHLORIDE 0,250 mg

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

Applicant: ADCOCK INGRAM LIMITED

Manufacturer: ADCOCK INGRAM HEALTHCARE, WADEVILLE,
GERMISTON, RSA

Packer: ADCOCK INGRAM HEALTHCARE, WADEVILLE,
GERMISTON, RSA

Laboratory:FPRC/FPRR: ADCOCK INGRAM HEALTHCARE, WADEVILLE,
GERMISTON, RSA

Shelf-life: 24 months

Date of registration: 7 JULY 2006

MRF 15

Registration number: A39/16.1/0201

Name of medicine: NAZENE PAEDIATRIC NASAL DROPS

Dosage form: DROPS

Active ingredients: EACH 1,0 ml SOLUTION CONTAINS:
OXYMETAZOLINE HYDROCHLORIDE 0,250 mg

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

Applicant: ADCOCK INGRAM LIMITED

Manufacturer: ADCOCK INGRAM HEALTHCARE, WADEVILLE,
GERMISTON, RSA

Packer: ADCOCK INGRAM HEALTHCARE, WADEVILLE,
GERMISTON, RSA

Laboratory:FPRC/FPRR: ADCOCK INGRAM HEALTHCARE, WADEVILLE,
GERMISTON, RSA

Shelf-life: 24 months

Date of registration: 7 JULY 2006

MRF 15

Registration number: A39/2.1/0210

Name of medicine: ABBOTT-SEVOFLURANE

Dosage form: LIQUID

Active ingredients: EACH BOTTLE CONTAINS:
SEVOFLURANE

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

Applicant: ABBOTT-LABORATORIES S.A. (PTY) LTD

Manufacturer: CENTRAL GLASS CO. LTD, YAMAMGUCHI
PREFECTURE, JAPAN
ABBOTT S.p.A., LATINA, ITALY

Packer: ABBOTT LABORATORIES LTD, QUEENSBOROUGH,
KENT, UK
ABBOTT S.p.A., LATINA, ITALY

Laboratory:FPRC: ABBOTT LABORATORIES LTD, QUEENSBOROUGH,
KENT, UK
ABBOTT S.p.A., LATINA, ITALY
FPRC/FPRR: ABBOTT LABORATORIES S.A., CONSTANTIA
KLOOF, JOHANNESBURG, RSA

Shelf-life: 24 months provisional

Date of registration: 7 JULY 2006

MRF 15

Registration number: A39/20.1.2/0213

Name of medicine: MERCK-CO-AMOXYCLAV 1000 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

Applicant: MERCK GENERICS RSA (PTY) LTD

Manufacturer: SANDOZ GmbH, KUNDL, AUSTRIA

Packer: SANDOZ GmbH, KUNDL, AUSTRIA

Laboratory:FPRC: SANDOZ GmbH, KUNDL, AUSTRIA
GERARD LABORATORIES, DUBLIN, IRELAND
GENERICS LTD, STATION CLOSE,
HERTFORDSHIRE, U.K.
GENERICS LTD, LETCHWORTH, HERTFORDSHIRE,
U.K.
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, UNIVERSITY, POTCHEFSTROOM
MERCK PHARMACEUTICAL MANUFACTURING,
WADEVILLE, RSA

FPRR: MERCK GENERICS RSA, MODDERFONTEIN, RSA

Shelf-life: 24 months

Date of registration: 7 JULY 2006

MRF 15

Registration number: A39/1.2/0217

Name of medicine: ADCO-MIRTERON 15

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
MIRTAZEPINE 15,0 mg

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

Applicant: ADCOCK INGRAM LIMITED

Manufacturer: DELTA LTD, HAFNARJORDUR, ICELAND

Packer: DELTA LTD, HAFNARJORDUR, ICELAND

Laboratory:FPRC: DELTA LTD, HAFNARJORDUR, ICELAND
FPRC/FPRR: ADCOCK INGRAM HEALTHCARE, CLAYVILLE,
OLIFANTSFONTEIN, RSA
ADCOCK INGRAM HEALTHCARE, WADEVILLE,
GERMISTON, RSA

Shelf-life: 24 months provisional

Date of registration: 7 JULY 2006

MRF 15

Registration number: A39/1.2/0218

Name of medicine: ADCO-MIRTERON 30

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
MIRTAZEPINE 30,0 mg

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

Applicant: ADCOCK INGRAM LIMITED

Manufacturer: DELTA LTD, HAFNARFJORDUR, ICELAND

Packer: DELTA LTD, HAFNARFJORDUR, ICELAND

Laboratory:FPRC: DELTA LTD, HAFNARFJORDUR, ICELAND
FPRC/FPRR: ADCOCK INGRAM HEALTHCARE, CLAYVILLE,
OLIFANTSFONTEIN, RSA
ADCOCK INGRAM HEALTHCARE, WADEVILLE,
GERMISTON, RSA

Shelf-life: 24 months provisional

Date of registration: 7 JULY 2006

MRF 15

Registration number: A39/1.2/0219

Name of medicine: ADCO-MIRTERON 45

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
MIRTAZEPINE 45,0 mg

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

Applicant: ADCOCK INGRAM LIMITED

Manufacturer: DELTA LTD, HAFNARFJORDUR, ICELAND

Packer: DELTA LTD, HAFNARFJORDUR, ICELAND

Laboratory:FPRC: DELTA LTD, HAFNARFJORDUR, ICELAND
FPRC/FPRR: ADCOCK INGRAM HEALTHCARE, CLAYVILLE,
OLIFANTSFONTEIN, RSA
ADCOCK INGRAM HEALTHCARE, WADEVILLE,
GERMISTON, RSA

Shelf-life: 24 months provisional

Date of registration: 7 JULY 2006

MRF 15

Registration number: A39/16.1/0225

Name of medicine: NAZENE ADULT NASAL DROPS

Dosage form: DROPS

Active ingredients: EACH 1,0 ml SOLUTION CONTAINS:
OXYMETAZOLINE HYDROCHLORIDE 0,50 mg

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

Applicant: ADCOCK INGRAM LIMITED

Manufacturer: ADCOCK INGRAM HEALTHCARE, WADEVILLE,
GERMISTON, RSA

Packer: ADCOCK INGRAM HEALTHCARE, WADEVILLE,
GERMISTON, RSA

Laboratory:FPRC/FPRR: ADCOCK INGRAM HEALTHCARE, WADEVILLE,
GERMISTON, RSA

Shelf-life: 24 months

Date of registration: 7 JULY 2006

MRF 15

Registration number: A39/34/0230

Name of medicine: CELLCEPT 500 mg

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
MYCOPHENOLATE MOFETIL 500,0 mg

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

Applicant: ROCHE PRODUCTS (PTY) LTD

Manufacturer: ROCHE S.p.A., SEGRATE, ITALY

Packer: ROCHE S.p.A., SEGRATE, ITALY
F. HOFFMANN-LA ROCHE, KAISERAUGST,
SWITZERLAND
ROCHE PRODUCTS, ISANDO, RSA

Laboratory:FPRC: ROCHE S.p.A., SEGRATE, ITALY
F. HOFFMAN-LA ROCHE, BASEL, SWITZERLAND
FPRC/FPRR: ROCHE PRODUCTS, ISANDO, RSA

Shelf-life: 24 months

Date of registration: 7 JULY 2006

MRF 15

Registration number:	A39/11.5/0285
Name of medicine:	LENNON SENNA 7,5 mg TABLETS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CALCIUM SENNOSIDES EQUIVALENT TO SENNOSIDES 7,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMACARE LIMITED
Manufacturer:	PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE, WILSONIA, EAST LONDON
Packer:	PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE, WILSONIA, EAST LONDON
Laboratory:FPRC:	SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY, POTCHEFTSROOM
FPRC/FPRR:	PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE, WILSONIA, EAST LONDON
Shelf-life:	24 months
Date of registration:	7 JULY 2006

MRF 15

Registration number: A39/2.9/0318

Name of medicine: TRAMAZAC INJECTION

Dosage form: INJECTION

Active ingredients: EACH 2,0 ml AMPOULE CONTAINS:
TRAMADOL HYDROCHLORIDE 100,0 mg

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

Applicant: ZYDUS HEALTHCARE S.A. (PTY) LTD

Manufacturer: ZYDUS CADILA HEALTHCARE LTD, AHMEDABAD,
INDIA

Packer: ZYDUS CADILA HEALTHCARE LTD, AHMEDABAD,
INDIA

Laboratory:FPRC: ZYDUS CADILA HEALTHCARE LTD, AHMEDABAD,
INDIA
INSTITUTE FOR PHARMACEUTICAL AND
CHEMICAL SERVICES, SILVERTONDALE, LTD
INSTITUTE FOR INDUSTRIAL PHARMACY,
UNIVERSITY, POTCHEFSTROOM

FPRR: ZYDUS HEALTHCARE, VAN DER HOFF PARK,
POTCHEFSTROOM, RSA

Shelf-life: 24 months provisional

Date of registration: 7 JULY 2006

MRF 15

Registration number:	A39/5.7.1/0384
Name of medicine:	BETEK
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CETIRIZINE HYDROCHLORIDE 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	BE-TABS PHARMACEUTICALS (PTY) LTD
Manufacturer:	CADILA PHARMACEUTICALS LTD, AHMEDABAD, GUJARAT, INDIA
Packer:	CADILA PHARMACEUTICALS LTD, AHMEDABAD, GUJARAT, INDIA
Laboratory:FPRC:	CADILA PHARMACEUTICALS LTD, AHMEDABAD, GUJARAT, INDIA
FPRC/FPRR:	BE-TABS PHARMACEUTICALS, ROODEPOORT, RSA
Shelf-life:	24 months provisional
Date of registration:	7 JULY 2006

MRF 15

Registration number: A39/11.4.3/0468

Name of medicine: ACIPHEX 10

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
RABEPRAZOLE SODIUM 10,0 mg

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

Applicant: JANSSEN PHARMACEUTICA (PTY) LTD

Manufacturer: EISAI CO LTD, KODAMA-GUN, SAITAMA-KEN,
JAPAN

Packer: UNIPACK LTD, SHOTGATE, ESSEX, UK
CILAG AG, SCHAFFHAUSEN, SWITZERLAND
JANSSEN PHARMACEUTICA, HALFWAY HOUSE,
RSA

Laboratory:FPRC: EISAI CO LTD, KODAMA-GUN, SAITAMA-KEN,
JAPAN
CILAG AG, SCHAFFHAUSEN, SWITZERLAND
THE BOOTS CO PLC. NOTTINGHAM UK
FPRC/FPRR: JANSSEN PHARMACEUTICA, HALFWAY HOUSE,
RSA

Shelf-life: 36 months provisional packed in PVC/PVdC/PE
Laminate/Al Blisters
24 months packed in Al/Al foil Blisters

Date of registration: 7 JULY 2006

MRF 15

Registration number: A39/11.4.3/0469

Name of medicine: ACIPHEX 20

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
RABEPRAZOLE SODIUM 20,0 mg

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

Applicant: JANSSEN PHARMACEUTICA (PTY) LTD

Manufacturer: EISAI CO LTD, KODAMA-GUN, SAITAMA-KEN,
JAPAN

Packer: UNIPACK LTD, SHOTGATE, ESSEX, UK
CILAG AG, SCHAFFHAUSEN, SWITZERLAND
JANSSEN PHARMACEUTICA, HALFWAY HOUSE,
RSA

Laboratory:FPRC: EISAI CO LTD, KODAMA-GUN, SAITAMA-KEN,
JAPAN
CILAG AG, SCHAFFHAUSEN, SWITZERLAND
THE BOOTS CO PLC. NOTTINGHAM UK
FPRC/FPRR: JANSSEN PHARMACEUTICA, HALFWAY HOUSE,
RSA

Shelf-life: 36 months provisional packed in PVC/PVdC/PE
Laminate/AlBlisters
24 months packed in Al/Al foil Blisters

Date of registration: 7 JULY 2006

MRF 15

Registration number: A39/7.1/0532

Name of medicine: AMLODAC 5 TABLETS

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

Applicant: ZYDUS HEALTHCARE S.A. (PTY) LTD

Manufacturer: ZYDUS CADILA HEALTHCARE LTD, AHMEDABAD,
INDIA

Packer: ZYDUS CADILA HEALTHCARE LTD, AHMEDABAD,
INDIA

Laboratory:FPRC: ZYDUS CADILA HEALTHCARE LTD, AHMEDABAD,
INDIA
INSTITUTE FOR PHARMACEUTICAL & CHEMICAL
SERVICES, SILVERTONDALE, RSA
INSTITUTE FOR INDUSTRIAL PHARMACY,
UNIVERSITY, POTCHEFSTROOM, RSA
FPRR: ZYDUS HEALTHCARE, VAN DER HOFF PARK,
POTCHEFSTROOM, RSA

Shelf-life: 24 months provisional

Date of registration: 7 JULY 2006

MRF 15

Registration number: A39/7.1/0533

Name of medicine: AMLODAC 10 TABLETS

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

Applicant: ZYDUS HEALTHCARE S.A. (PTY) LTD

Manufacturer: ZYDUS CADILA HEALTHCARE LTD, AHMEDABAD,
INDIA

Packer: ZYDUS CADILA HEALTHCARE LTD, AHMEDABAD,
INDIA

Laboratory:FPRC: ZYDUS CADILA HEALTHCARE LTD, AHMEDABAD,
INDIA
INSTITUTE FOR PHARMACEUTICAL & CHEMICAL
SERVICES, SILVERTONDALE, RSA
INSTITUTE FOR INDUSTRIAL PHARMACY,
UNIVERSITY, POTCHEFSTROOM, RSA
FPRR: ZYDUS HEALTHCARE, VAN DER HOFF PARK,
POTCHEFSTROOM, RSA

Shelf-life: 24 months provisional

MRF 15

Registration number: A39/5.10/0557

Name of medicine: ONDANTOR 4

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
ONDANSETRON HYDROCHLORIDE DIHYDRATE
EQUIVALENT TO ONDANSETRON 4,0 mg

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

Applicant: SANDOZ (PTY) LTD

Manufacturer: NOVARTIS BANGLADESH, GAZIPUR,
BANGLADESH

Packer: NOVARTIS BANGLADESH, GAZIPUR,
BANGLADESH
NOVARTIS S.A., SPARTAN, KEMPTON PARK

Laboratory:FPRC: NOVARTIS BANGLADESH, GAZIPUR,
BANGLADESH
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA
ANALYTICON, TERENURE, KEMPTON PARK
FPRC/FPRR: NOVARTIS S.A., SPARTAN, KEMPTON PARK

Shelf-life: 24 months

Date of registration: 7 JULY 2006

MRF 15

Registration number: A39/5.10/0558

Name of medicine: ONDANTOR 8

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
ONDANSETRON HYDROCHLORIDE DIHYDRATE
EQUIVALENT TO ONDANSETRON 8,0 mg

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

Applicant: SANDOZ (PTY) LTD

Manufacturer: NOVARTIS BANGLADESH, GAZIPUR,
BANGLADESH

Packer: NOVARTIS BANGLADESH, GAZIPUR,
BANGLADESH
NOVARTIS S.A., SPARTAN, KEMPTON PARK

Laboratory:FPRC: NOVARTIS BANGLADESH, GAZIPUR,
BANGLADESH
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA
ANALYTICON, TERENURE, KEMPTON PARK
FPRC/FPRR: NOVARTIS S.A., SPARTAN, KEMPTON PARK

Shelf-life: 24 months

Date of registration: 7 JULY 2006

MRF 15

Registration number:	A39/5.10/0568
Name of medicine:	MERCK-ONDANSETRON 4 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ONDANSETRON HYDROCHLORIDE DIHYDRATE EQUIVALENT TO ONDANSETRON 4,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	MERCK GENERICS RSA (PTY) LTD
Manufacturer:	PHARMATHEN PHARMACEUTICAL INDUSTRY, ATHENS, GREECE
Packer:	PHARMATHEN PHARMACEUTICAL INDUSTRY, ATHENS, GREECE GERARD LABORATORIES, DUBLIN, IRELAND GENERICS (U.K.) LTD, STATION CLOSE, HERTFORDSHIRE, U.K. MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON, RSA
Laboratory:FPRC:	PHARMATHEN PHARMACEUTICAL INDUSTRY, ATHENS, GREECE GERARD LABORATORIES, DUBLIN, IRELAND GENERICS (U.K.) LTD, STATION CLOSE, HERTFORDSHIRE, U.K. MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY, POTCHEFSTROOM SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA, RSA
FPRR:	MERCK GENERICS RSA, MODDERFONTEIN, RSA
Shelf-life:	36 months
Date of registration:	7 JULY 2006

MRF 15

Registration number: A39/5.10/0569

Name of medicine: MERCK-ONDANSETRON 8 mg

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
ONDANSETRON HYDROCHLORIDE DIHYDRATE
EQUIVALENT TO ONDANSETRON 8,0 mg

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

Applicant: MERCK GENERICS RSA (PTY) LTD

Manufacturer: PHARMATHEN PHARMACEUTICAL INDUSTRY,
ATHENS, GREECE

Packer: PHARMATHEN PHARMACEUTICAL INDUSTRY,
ATHENS, GREECE
GERARD LABORATORIES, DUBLIN, IRELAND
GENERICS (U.K.) LTD, STATION CLOSE,
HERTFORDSHIRE, U.K.
MERCK PHARMACEUTICAL MANUFACTURING,
WADEVILLE, GERMISTON, RSA

Laboratory:FPRC: PHARMATHEN PHARMACEUTICAL INDUSTRY,
ATHENS, GREECE
GERARD LABORATORIES, DUBLIN, IRELAND
GENERICS (U.K.) LTD, STATION CLOSE,
HERTFORDSHIRE, U.K.
MERCK PHARMACEUTICAL MANUFACTURING,
WADEVILLE, GERMISTON, RSA
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, UNIVERSITY, POTCHEFSTROOM
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA

FPRR: MERCK GENERICS RSA, MODDERFONTEIN, RSA

Shelf-life: 36 months

Date of registration: 7 JULY 2006

MRF 15

Registration number: A39/5.10/0570

Name of medicine: MERGENSIC 4 mg

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
ONDANSETRON HYDROCHLORIDE DIHYDRATE
EQUIVALENT TO ONDANSETRON 4,0 mg

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

Applicant: MERCK GENERICS RSA (PTY) LTD

Manufacturer: PHARMATHEN PHARMACEUTICAL INDUSTRY,
ATHENS, GREECE

Packer: PHARMATHEN PHARMACEUTICAL INDUSTRY,
ATHENS, GREECE
GERARD LABORATORIES, DUBLIN, IRELAND
GENERICS (U.K.) LTD, STATION CLOSE,
HERTFORDSHIRE, U.K.
MERCK PHARMACEUTICAL MANUFACTURING,
WADEVILLE, GERMISTON, RSA

Laboratory:FPRC: PHARMATHEN PHARMACEUTICAL INDUSTRY,
ATHENS, GREECE
GERARD LABORATORIES, DUBLIN, IRELAND
GENERICS (U.K.) LTD, STATION CLOSE,
HERTFORDSHIRE, U.K.
MERCK PHARMACEUTICAL MANUFACTURING,
WADEVILLE, GERMISTON, RSA
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, UNIVERSITY, POTCHEFSTROOM
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA

FPRR: MERCK GENERICS RSA, MODDERFONTEIN, RSA

Shelf-life: 36 months

Date of registration: 7 JULY 2006

MRF 15

Registration number:	A39/5.10/0571
Name of medicine:	MERGENSIC 8 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ONDANSETRON HYDROCHLORIDE DIHYDRATE EQUIVALENT TO ONDANSETRON 8,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	MERCK GENERICS RSA (PTY) LTD
Manufacturer:	PHARMATHEN PHARMACEUTICAL INDUSTRY, ATHENS, GREECE
Packer:	PHARMATHEN PHARMACEUTICAL INDUSTRY, ATHENS, GREECE GERARD LABORATORIES, DUBLIN, IRELAND GENERICS (U.K.) LTD, STATION CLOSE, HERTFORDSHIRE, U.K. MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON, RSA
Laboratory:FPRC:	PHARMATHEN PHARMACEUTICAL INDUSTRY, ATHENS, GREECE GERARD LABORATORIES, DUBLIN, IRELAND GENERICS (U.K.) LTD, STATION CLOSE, HERTFORDSHIRE, U.K. MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY, POTCHEFSTROOM SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA, RSA
FPRR:	MERCK GENERICS RSA, MODDERFONTEIN, RSA
Shelf-life:	36 months
Date of registration:	7 JULY 2006

MRF 15

Registration number: A39/30.1/0585

Name of medicine: ROTARIX

Dosage form: POWDER

Active ingredients: EACH 1,0 ml DOSE CONTAINS:
LIVE ATTENUATED HUMAN ROTAVIRUS,
RIX4414 STRAIN not less than 10^6 CCID₅₀

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

Applicant: GLAXOSMITHKLINE SOUTH AFRICA (PTY) LTD

Manufacturer: GLAXOSMITHKLINE BIOLOGICALS S.A.,
RIXENSART, BELGIUM
PARC DE LA NOIRE EPINE, WAVRE, BELGIUM

Packer: GLAXOSMITHKLINE BIOLOGICALS S.A.,
RIXENSART, BELGIUM
CRNA, FLEURUS, BELGIUM
GLAXOSMITHKLINE, EPPING, CAPE TOWN

Laboratory:FPRC: GLAXOSMITHKLINE BIOLOGICALS S.A.,
RIXENSART, BELGIUM
FPRC/FPRR: GLAXOSMITHKLINE, EPPING, CAPE TOWN

Shelf-life: 24 months

Date of registration: 7 JULY 2006

MRF 15

Registration number: A39/21.12/0629

Name of medicine: ANDROFEM 100

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
CYPROTERONE ACETATE 100,0 mg

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

Applicant: CIPLA MEDPRO (PTY) LTD

Manufacturer: CIPLA LTD, PATALGANGA, MAHARASHTRA, INDIA

Packer: CIPLA LTD, PATALGANGA, MAHARASHTRA, INDIA

Laboratory:FPRC: CIPLA LTD, PATALGANGA, MAHARASHTRA, INDIA
FPRR: CIPLA MEDPRO, ROSENPARK, BELLVILLE

Shelf-life: 24 months

Date of registration: 7 JULY 2006

MRF 15

Registration number: A39/21.12/0630

Name of medicine: CIPLA-CYPROTERONE ACETATE 100

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
CYPROTERONE ACETATE 100,0 mg

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

Applicant: CIPLA LIFE SCIENCES (PTY) LTD

Manufacturer: CIPLA LTD, PATALGANGA, MAHARASHTRA, INDIA

Packer: CIPLA LTD, PATALGANGA, MAHARASHTRA, INDIA

Laboratory:FPRC: CIPLA LTD, PATALGANGA, MAHARASHTRA, INDIA
FPRR: CIPLA LIFE SCIENCES, ROSENPARK, BELLVILLE

Shelf-life: 24 months

Date of registration: 7 JULY 2006

MRF 15 (MBR 15)

Registration number: A39/21.10/0631

Name of medicine: GONAL-f PEN 300 I.U./0,5 ml
(22 MICROGRAMS/0,5 ml)

Dosage form: INJECTION

Active ingredients: EACH CARTRIDGE CONTAINS:
FOLLITROPIN ALFA 300,0 I.U.

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

Applicant: SERONO SOUTH AFRICA (PTY) LTD

Manufacturer: INDUSTRIA FARMACEUTICA SERONO, BARI,
ITALY

Packer: INDUSTRIA FARMACEUTICA SERONO, BARI,
ITALY
LABORATOIRES SERONO SA, COINSINS,
SWITZERLAND

Laboratory:FPRC: INDUSTRIA FARMACEUTICA SERONO, BARI,
ITALY
FPRR: SERONO SA, KINGFISHER, FOURWAYS, RSA

Shelf-life: 24 months

Date of registration: 7 JULY 2006

MRF 15 (MBR 15)

Registration number: A39/21.10/0632

Name of medicine: GONAL-f PEN 450 I.U./0,75 ml
(33 MICROGRAMS/0,75 ml)

Dosage form: INJECTION

Active ingredients: EACH CARTRIDGE CONTAINS:
FOLLITROPIN ALFA 450,0 I.U.

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

Applicant: SERONO SOUTH AFRICA (PTY) LTD

Manufacturer: INDUSTRIA FARMACEUTICA SERONO, BARI,
ITALY

Packer: INDUSTRIA FARMACEUTICA SERONO, BARI,
ITALY
LABORATOIRES SERONO SA, COINSINS,
SWITZERLAND

Laboratory:FPRC: INDUSTRIA FARMACEUTICA SERONO, BARI,
ITALY
FPRR: SERONO SA, KINGFISHER, FOURWAYS, RSA

Shelf-life: 24 months

Date of registration: 7 JULY 2006

MRF 15 (MBR 15)

Registration number: A39/21.10/0633

Name of medicine: GONAL-f PEN 900 I.U./1,5 ml
(66 MICROGRAMS/1,5 ml)

Dosage form: INJECTION

Active ingredients: EACH CARTRIDGE CONTAINS:
FOLLITROPIN ALFA 900,0 I.U.

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

Applicant: SERONO SOUTH AFRICA (PTY) LTD

Manufacturer: INDUSTRIA FARMACEUTICA SERONO, BARI,
ITALY

Packer: INDUSTRIA FARMACEUTICA SERONO, BARI,
ITALY
LABORATOIRES SERONO SA, COINSINS,
SWITZERLAND

Laboratory:FPRC: INDUSTRIA FARMACEUTICA SERONO, BARI,
ITALY
FPRR: SERONO SA, KINGFISHER, FOURWAYS, RSA

Shelf-life: 24 months

Date of registration: 7 JULY 2006

MRF 15

Registration number: A40/26/0005

Name of medicine: VELCADE

Dosage form: INJECTION

Active ingredients: EACH VIAL CONTAINS:
BORTEZOMIB 3,5 mg

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

Applicant: JANSSEN PHARMACEUTICA (PTY) LTD

Manufacturer: BEN VENUE LABORATORIES INC, BEDFORD, OHIO,
USA

Packer: BEN VENUE LABORATORIES INC, BEDFORD, OHIO,
USA
JANSSEN PHARMACEUTICA N.V, BEERSE,
BELGIUM
JANSSEN PHARMACEUTICA, HALFWAY HOUSE,
RSA

Laboratory:FPRC: JANSSEN PHARMACEUTICA N.V, BEERSE,
BELGIUM
FPRC/FPRR: JANSSEN PHARMACEUTICA, HALFWAY HOUSE,
RSA

Shelf-life: 24 months

Date of registration: 7 JULY 2006

MRF 15

Registration number: A40/11.5/0079

Name of medicine: ADCOSENNA TABLETS

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
SENNA DRY EXTRACT EQUIVALENT TO
SENNOSIDES A & B 13,5 mg

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

Applicant: ADCOCK INGRAM LIMITED

Manufacturer: ADCOCK INGRAM HEALTHCARE, CLAYVILLE,
OLIFANTSFONTEIN, RSA
ADCOCK INGRAM HEALTHCARE, WADEVILLE,
GERMISTON, RSA

Packer: ADCOCK INGRAM HEALTHCARE, CLAYVILLE,
OLIFANTSFONTEIN, RSA
ADCOCK INGRAM HEALTHCARE, WADEVILLE,
GERMISTON, RSA

Laboratory:FPRC/FPRR: ADCOCK INGRAM HEALTHCARE, CLAYVILLE,
OLIFANTSFONTEIN, RSA
ADCOCK INGRAM HEALTHCARE, WADEVILLE,
GERMISTON, RSA

Shelf-life: 24 months provisional

Date of registration: 7 JULY 2006

MRF 15

Registration number: A40/11.5/0080

Name of medicine: FRESHEN SENNA TABLETS

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
SENNA DRY EXTRACT EQUIVALENT TO
SENNOSIDES A & B 13,5 mg

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

Applicant: ADCOCK INGRAM LIMITED

Manufacturer: ADCOCK INGRAM HEALTHCARE, CLAYVILLE,
OLIFANTSFONTEIN, RSA
ADCOCK INGRAM HEALTHCARE, WADEVILLE,
GERMISTON, RSA

Packer: ADCOCK INGRAM HEALTHCARE, CLAYVILLE,
OLIFANTSFONTEIN, RSA
ADCOCK INGRAM HEALTHCARE, WADEVILLE,
GERMISTON, RSA

Laboratory:FPRC/FPRR: ADCOCK INGRAM HEALTHCARE, CLAYVILLE,
OLIFANTSFONTEIN, RSA
ADCOCK INGRAM HEALTHCARE, WADEVILLE,
GERMISTON, RSA

Shelf-life: 24 months provisional

Date of registration: 7 JULY 2006

MRF 15

Registration number: A40/11.5/0081

Name of medicine: PROPAN SENNA TABLETS

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
SENNA DRY EXTRACT EQUIVALENT TO
SENNOSIDES A & B 13,5 mg

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

Applicant: ADCOCK INGRAM LIMITED

Manufacturer: ADCOCK INGRAM HEALTHCARE, CLAYVILLE,
OLIFANTSFONTEIN, RSA
ADCOCK INGRAM HEALTHCARE, WADEVILLE,
GERMISTON, RSA

Packer: ADCOCK INGRAM HEALTHCARE, CLAYVILLE,
OLIFANTSFONTEIN, RSA
ADCOCK INGRAM HEALTHCARE, WADEVILLE,
GERMISTON, RSA

Laboratory:FPRC/FPRR: ADCOCK INGRAM HEALTHCARE, CLAYVILLE,
OLIFANTSFONTEIN, RSA
ADCOCK INGRAM HEALTHCARE, WADEVILLE,
GERMISTON, RSA

Shelf-life: 24 months provisional

MRF 15

Registration number: A40/11.5/0082

Name of medicine: PURITONE SENNA TABLETS

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
SENNA DRY EXTRACT EQUIVALENT TO
SENNOSIDES A & B 13,5 mg

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

Applicant: ADCOCK INGRAM LIMITED

Manufacturer: ADCOCK INGRAM HEALTHCARE, CLAYVILLE,
OLIFANTSFONTEIN, RSA
ADCOCK INGRAM HEALTHCARE, WADEVILLE,
GERMISTON, RSA

Packer: ADCOCK INGRAM HEALTHCARE, CLAYVILLE,
OLIFANTSFONTEIN, RSA
ADCOCK INGRAM HEALTHCARE, WADEVILLE,
GERMISTON, RSA

Laboratory:FPRC/FPRR: ADCOCK INGRAM HEALTHCARE, CLAYVILLE,
OLIFANTSFONTEIN, RSA
ADCOCK INGRAM HEALTHCARE, WADEVILLE,
GERMISTON, RSA

Shelf-life: 24 months provisional

Date of registration: 7 JULY 2006

MRF 15

Registration number: A40/2.7/0147

Name of medicine: BEDORAL 30

Dosage form: INJECTION

Active ingredients: EACH 1,0 ml AMPOULE CONTAINS:
KETOROLAC TROMETHAMINE 30,0 mg

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

Applicant: BE-TABS PHARMACEUTICALS (PTY) LTD

Manufacturer: CADILA PHARMACEUTICALS LTD, AHMEDABAD,
GUJARAT, INDIA

Packer: CADILA PHARMACEUTICALS LTD, AHMEDABAD,
GUJARAT, INDIA

Laboratory:FPRC: CADILA PHARMACEUTICALS LTD, AHMEDABAD,
GUJARAT, INDIA
FPRC/FPRR: BE-TABS PHARMACEUTICALS, ROODEPOORT, RSA

Shelf-life: 24 months

Date of registration: 7 JULY 2006
