Government Gazette

REPUBLIC OF SOUTH AFRICA

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AIDS HELPLINE: 0800-0123-22 Prevention is the cure

GENERAL NOTICE
ALGEMENE KENNISGEWING

NOTICE 1891 OF 2003

MEDICINES CONTROL COUNCIL

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

1. The applicant shall ensure that the medicine is manufactured and controlled in terms of 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 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.

Registration number/Registrasienommer: 34/6.2/0119

Name of medicine/Naam van medisyne: RIVODARONE

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
AMIODARONE HYDROCHLORIDE ... 200,0 mg

Conditions of registration/Voorwaardes vir registrasie:
1, 2, 3, 4, 5, 6, 7

Applicant/Applikant: AMAYEZA PHARMACEUTICALS (PTY) LTD

Manufacturer/Vervaardiger: RIVOPHARM S.A., MANNO,SWITZERLAND

Packer/Verpakker: RIVOPHARM S.A., MANNO,SWITZERLAND

Laboratory/Laboratorium: RIVOPHARM S.A., MANNO,SWITZERLAND
AMAYEZA PHARMACEUTICALS, CAPE TOWN RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 24 JANUARY 2003
Datum van registrasie 24 JANUARIE 2003

Registration number/Registrasienommer: 36/2.7/0029

Name of medicine/Naam van medisyne: NUROFEN MELTLETS

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
IBUPROFEN ... 200,0 mg

Conditions of registration/Voorwaardes vir registrasie:
1, 2, 3, 4, 5a, 6, 7

Applicant/Applikant: BOOTS HEALTHCARE (SOUTH AFRICA) (PTY) LTD

Manufacturer/Vervaardiger: PROGRAPHARM LABORATORIES, CHATEAUNEUF FRANCE

Packer/Verpakker: PROGRAPHARM LABORATORIES, CHATEAUNEUF FRANCE

Laboratory/Laboratorium: PROGRAPHARM LABORATORIES, CHATEAUNEUF FRANCE
PHARMACEUTICAL CONTRACTORS, ISANDO RSA
RECKITT BENCKISER PHARMACEUTICALS, MOBENI

Shelf-life/Rakleeftyd: 36 months/maande

Date of registration: 24 JANUARY 2003
Datum van registrasie 24 JANUARIE 2003

Registration number/Registrasienommer: 36/5.7.1/0003

Name of medicine/Naam van medisyne: ROHIST

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
LORATADINE ... 10,0 mg

Conditions of registration/Voorwaardes vir registrasie:
1, 2, 3, 4, 5a, 6, 7

Applicant/Applikant: ROLAB (PTY) LTD

Manufacturer/Vervaardiger: NOVARTIS, SPARTAN KEMPTON PARK RSA

Packer/Verpakker: NOVARTIS, SPARTAN KEMPTON PARK RSA

Laboratory/Laboratorium: NOVARTIS, SPARTAN KEMPTON PARK RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 24 JANUARY 2003
Datum van registrasie 24 JANUARIE 2003

Registration number/Registrasienommer: 36/5.7.1/0004

Name of medicine/Naam van medisyne: ROLAB-LORATADINE 10

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
LORATADINE ... 10,0 mg

Conditions of registration/Voorwaardes vir registrasie:
1, 2, 3, 4, 5a, 6, 7

Applicant/Applikant: ROLAB (PTY) LTD

Manufacturer/Vervaardiger: NOVARTIS, SPARTAN KEMPTON PARK RSA

Packer/Verpakker: NOVARTIS, SPARTAN KEMPTON PARK RSA

Laboratory/Laboratorium: NOVARTIS, SPARTAN KEMPTON PARK RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 24 JANUARY 2002
Datum van registrasie 24 JANUARIE 2002

Registration number/Registrasienommer: 36/1.2/0050

Name of medicine/Naam van medisyne: MOCLOBIX 150

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
MOCLOBEMIDE ... 150,0 mg

Conditions of registration/Voorwaardes vir registrasie:
1, 2, 3, 4, 5a, 6, 7

Applicant/Applikant: HEXAL PHARMA (SA) (PTY) LTD

Manufacturer/Vervaardiger: SALUTAS PHARMA, BARLEBEN GERMANY

Packer/Verpakker: DIVPHARM MANUFACTURING AND PACKAGING, LONGDALE RSA
PHARMA-Q, INDUSTRIA RSA

Laboratory/Laboratorium: SALUTAS PHARMA, BARLEBEN GERMANY
ANALYTICON, KEMPTON PARK RSA
CONSULTING CHEMICAL LAB, STAR STREET BOKSBURG RSA
HEXAL PHARMA , WESTMEAD RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 24 JANUARY 2003
Datum van registrasie 24 JANUARIE 2003

Registration number/Registrasienommer: 36/1.2/0051

Name of medicine/Naam van medisyne: MOCLOBIX 300

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
MOCLOBEMIDE ... 300,0 mg

Conditions of registration/Voorwaardes vir registrasie:
1, 2, 3, 4, 5a, 6, 7

Applicant/Applikant:	HEXAL PHARMA (SA) (PTY) LTD
Manufacturer/Vervaardiger:	SALUTAS PHARMA, BARLEBEN GERMANY
Packer/Verpakker:	DIVPHARM MANUFACTURING AND PACKAGING, LONGDALE RSA PHARMA-Q, INDUSTRIA RSA
Laboratory/Laboratorium:	SALUTAS PHARMA, BARLEBEN GERMANY ANALYTICON, KEMPTON PARK RSA CONSULTING CHEMICAL LAB, STAR STREET BOKSBURG RSA HEXAL PHARMA , WESTMEAD RSA
Shelf-life/Rakleeftyd:	24 months/maande
Date of registration: Datum van registrasie	24 JANUARY 2003 24 JANUARIE 2003

Registration number/Registrasienommer: 35/21.1/0178

Name of medicine/Naam van medisyne: DIAMICRON MR 30 MG

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
GLICLAZIDE ... 30,0 mg

Conditions of registration/Voorwaardes vir registrasie:
1, 2, 3, 4, 5, 6, 7

Applicant/Applikant: SERVIER LABORATORIES SA (PTY) LTD

Manufacturer/Vervaardiger: LES LABORATOIRES SERVIER IND.
FLEURY-LES-AUBRAIS FRANCE
SERVIER, WICKLOW, IRELAND

Packer/Verpakker: LES LABORATOIRES SERVIER IND.
FLEURY-LES-AUBRAIS FRANCE
SERVIER, WICKLOW, IRELAND
TECHNIKON LABORATORIES, FLORIDA RSA

Laboratory/Laboratorium: LES LABORATOIRES SERVIER IND.
FLEURY-LES-AUBRAIS FRANCE
SERVIER, WICKLOW, IRELAND
INSPECTORATE M & L, ORMONDE RSA
SERVIER LABORATORIES SA, RIVONIA RSA

Shelf-life/Rakleeftyd: 36 months/maande

Date of registration: 24 JANUARY 2003
Datum van registrasie 24 JANUARIE 2003

Registration number/Registrasienommer: 36/20.1.1/0376

Name of medicine/Naam van medisyne: CIPLA CIPROFLOXACIN 250

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT :
CIPROFLOXACIN HYDROCHLORIDE EQUIVALENT TO
CIPROFLOXACIN ... 250,0 mg

Conditions of registration/Voorwaardes vir registrasie:
1, 2, 3, 4, 5a, 6, 7

Applicant/Applikant:	CIPLA LIFE SCIENCES (PTY) LTD
Manufacturer/Vervaardiger:	CIPLA LTD, KURKUMBH, PUNE INDIA
Packer/Verpakker:	CIPLA LTD, KURKUMBH, PUNE INDIA
Laboratory/Laboratorium:	CIPLA LTD, KURKUMBH, PUNE INDIA CIPLA LIFE SCIENCES, ROSENPARK RSA
Shelf-life/Rakleeftyd:	24 months/maande
Date of registration: Datum van registrasie	24 JANUARY 2003 24 JANUARIE 2003

Registration number/Registrasienommer: 36/20.1.1/0377

Name of medicine/Naam van medisyne: CIPLA CIPROFLOXACIN 500

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT :
CIPROFLOXACIN HYDROCHLORIDE EQUIVALENT TO
CIPROFLOXACIN .... 500,0 mg

Conditions of registration/Voorwaardes vir registrasie:
1, 2, 3, 4, 5a, 6, 7

Applicant/Applikant: CIPLA LIFE SCIENCES (PTY) LTD

Manufacturer/Vervaardiger: CIPLA LTD, KURKUMBH, PUNE INDIA

Packer/Verpakker: CIPLA LTD, KURKUMBH, PUNE INDIA

Laboratory/Laboratorium: CIPLA LTD, KURKUMBH, PUNE INDIA
CIPLA LIFE SCIENCES, ROSENPARK RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 24 JANUARY 2003
Datum van registrasie 24 JANUARIE 2003

Registration number/Registrasienommer: 33/13.1/0436

Name of medicine/Naam van medisyne: SAVLON ANTISEPTIC POWDER

Dosage form/Doseringsvorm: POWDER/POEIER

Active ingredients/Aktiewe bestanddele:
EACH 100,0 g POWDER CONTAINS/
ELKE 100,0 g POEIER BEVAT:
CHLORHEXIDINE HYDROCHLORIDE ... 0,50 g
ZINC OXIDE ... 5,0 g

Conditions of registration/Voorwaardes vir registrasie:
1, 2, 3, 4, 5a, 6, 7

Applicant/Applikant: PHARMEDICA LABORATORIES (PTY) LTD

Manufacturer/Vervaardiger: PHARMEDICA LABORATORIES, EAST LONDON

Packer/Verpakker: PHARMEDICA LABORATORIES, EAST LONDON

Laboratory/Laboratorium: PHARMEDICA LABORATORIES, EAST LONDON
JOHNSON & JOHNSON/PHARMEDICA, EAST LONDON

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 24 JANUARY 2003
Datum van registrasie 24 JANUARIE 2003

Registration number/Registrasienommer: 34/1.2/0169

Name of medicine/Naam van medisyne: CLORIX 150

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
MOCLOBEMIDE ... 150,0 mg

Conditions of registration/Voorwaardes vir registrasie:
1, 2, 3, 4, 5a, 6, 7

Applicant/Applikant: PHARMA DYNAMICS (PTY) LTD

Manufacturer/Vervaardiger: DELTA LIMITED,HAFNARFJOROUR,ICELAND

Packer/Verpakker: DELTA LIMITED,HAFNARFJOROUR,ICELAND

Laboratory/Laboratorium: DELTA LIMITED,HAFNARFJOROUR,ICELAND
CONSULTING CHEMICAL LAB, STAR STREET
BOKSBURG RSA
PHARMA DYNAMICS, SIVERWOOD, WESTLAKE RSA

Shelf-life/Rakleeftyd: 36 months/maande

Date of registration: 24 JANUARY 2003
Datum van registrasie 24 JANUARIE 2003

Registration number/Registrasienommer: 34/1.2/0170

Name of medicine/Naam van medisyne: CLORIX 300

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT :
MOCLOBEMIDE ... 300,0 mg

Conditions of registration/Voorwaardes vir registrasie:
1, 2, 3, 4, 5a, 6, 7

Applicant/Applikant: PHARMA DYNAMICS (PTY) LTD

Manufacturer/Vervaardiger: DELTA LIMITED,HAFNARFJOROUR,ICELAND

Packer/Verpakker: DELTA LIMITED,HAFNARFJOROUR,ICELAND

Laboratory/Laboratorium: DELTA LIMITED,HAFNARFJOROUR,ICELAND
CONSULTING CHEMICAL LAB, STAR STREET
BOKSBURG RSA
PHARMA DYNAMICS, SIVERWOOD, WESTLAKE RSA

Shelf-life/Rakleeftyd: 36 months/maande

Date of registration: 24 JANUARY 2003
Datum van registrasie 24 JANUARIE 2003

Registration number/Registrasienommer: 36/3.1/0436

Name of medicine/Naam van medisyne: IBUMAX PAEDIATRIC SUSPENSION

Dosage form/Doseringsvorm: SUSPENSION/SUSPENSIE

Active ingredients/Aktiewe bestanddele:
EACH 5,0 ml SUSPENSION CONTAINS/
ELKE 5,0 ml SUSPENSIE BEVAT:
IBUPROFEN ... 100,0 mg

Conditions of registration/Voorwaardes vir registrasie:
1, 2, 3, 4, 5a, 6, 7

Applicant/Applikant: XERAGEN LABORATORIES (PTY) LTD

Manufacturer/Vervaardiger: PHARMACEUTICAL CONTRACTORS, ISANDO RSA

Packer/Verpakker: PHARMACEUTICAL CONTRACTORS, ISANDO RSA

Laboratory/Laboratorium: PHARMACEUTICAL CONTRACTORS, ISANDO RSA
XERAGEN LABORATORIES, GLEN ANIL, RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 24 JANUARY 2003
Datum van registrasie 24 JANUARIE 2003

Registration number/Registrasienommer: 36/26/0006

Name of medicine/Naam van medisyne: AZAMUN 50 MG

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT :
AZATHIOPRINE ... 50,0 mg

Conditions of registration/Voorwaardes vir registrasie:
1., 2, 3, 4, 5a, 6, 7

Applicant/Applikant: PHARMAPLAN (PTY) LTD

Manufacturer/Vervaardiger: DOUGLAS PHARMACEUTICALS, AUCKLAND, NEW ZEALAND

Packer/Verpakker: DOUGLAS PHARMACEUTICALS, AUCKLAND, NEW ZEALAND

Laboratory/Laboratorium: DOUGLAS PHARMACEUTICALS, AUCKLAND, NEW ZEALAND
CONSULTING CHEMICAL LAB, STAR STREET BOKSBURG RSA
PHARMAPLAN, MIDRAND RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 24 JANUARY 2003
Datum van registrasie 24 JANUARIE 2003

Registration number/Registrasienommer: 36/8.2/0126

Name of medicine/Naam van medisyne: CLEXANE 150

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH 1,0 ml SOLUTION CONTAINS/ELKE 1,0 ml OPLOSSING BEVAT:
ENOXAPARIN SODIUM ... 150,0 mg

Conditions of registration/Voorwaardes vir registrasie:
1, 2, 3, 4, 5a, 6, 7

Applicant/Applikant: AVENTIS PHARMA (PTY) LTD

Manufacturer/Vervaardiger: AVENTIS PHARMA SPECIALITIES, CEDEX, FRANCE

Packer/Verpakker: AVENTIS PHARMA SPECIALITIES, CEDEX, FRANCE
AVENTIS PHARMA, WALTLOO RSA

Laboratory/Laboratorium: AVENTIS PHARMA SPECIALITIES, CEDEX, FRANCE
AVENTIS PHARMA, WALTLOO RSA

Shelf-life/Rakleeftyd: 18 months/maande

Date of registration: 24 JANUARY 2003
Datum van registrasie 24 JANUARIE 2003

Registration number/Registrasienommer: 36/8.2/0124

Name of medicine/Naam van medisyne: CLEXANE 90

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH 0,6 ml SOLUTION CONTAINS/ELKE 0,6 ml OPLOSSING BEVAT:
ENOXAPARIN SODIUM ... 90,0 mg

Conditions of registration/Voorwaardes vir registrasie:
1, 2, 3, 4, 5a, 6, 7

Applicant/Applikant: AVENTIS PHARMA (PTY) LTD

Manufacturer/Vervaardiger: AVENTIS PHARMA SPECIALITIES, CEDEX, FRANCE

Packer/Verpakker: AVENTIS PHARMA SPECIALITIES, CEDEX, FRANCE
AVENTIS PHARMA, WALTLOO RSA

Laboratory/Laboratorium: AVENTIS PHARMA SPECIALITIES, CEDEX, FRANCE
AVENTIS PHARMA, WALTLOO RSA

Shelf-life/Rakleeftyd: 18 months/maande

Date of registration: 24 JANUARY 2003
Datum van registrasie 24 JANUARIE 2003

Registration number/Registrasienommer: 36/8.2/0125

Name of medicine/Naam van medisyne: CLEXANE 120

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH 0,8 ml SOLUTION CONTAINS/ELKE 0,8 ml OPLOSSING BEVAT:
ENOXAPARIN SODIUM ... 120,0 mg

Conditions of registration/Voorwaardes vir registrasie:
1, 2, 3, 4, 5a, 6, 7

Applicant/Applikant: AVENTIS PHARMA (PTY) LTD

Manufacturer/Vervaardiger: AVENTIS PHARMA SPECIALITIES, CEDEX, FRANCE

Packer/Verpakker: AVENTIS PHARMA SPECIALITIES, CEDEX, FRANCE
AVENTIS PHARMA, WALTLOO RSA

Laboratory/Laboratorium: AVENTIS PHARMA SPECIALITIES, CEDEX, FRANCE
AVENTIS PHARMA, WALTLOO RSA

Shelf-life/Rakleeftyd: 18 months/maande

Date of registration: 24 JANUARY 2002
Datum van registrasie 24 JANUARIE 2003

Registration number/Registrasienommer: 34/1.2/0168

Name of medicine/Naam van medisyne: CLORIX 100

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
MOCLOBEMIDE ... 100,0 mg

Conditions of registration/Voorwaardes vir registrasie:
1, 2, 3, 4, 5a, 6, 7

Applicant/Applikant:	PHARMA DYNAMICS (PTY) LTD
Manufacturer/Vervaardiger:	DELTA LIMITED,HAFNARFJOROUR,ICELAND
Packer/Verpakker:	DELTA LIMITED,HAFNARFJOROUR,ICELAND
Laboratory/Laboratorium:	DELTA LIMITED,HAFNARFJOROUR,ICELAND CONSULTING CHEMICAL LAB, STAR STREET BOKSBURG RSA PHARMA DYNAMICS, SIVERWOOD, WESTLAKE RSA
Shelf-life/Rakleeftyd:	36 months/maande
Date of registration: Datum van registrasie	24 JANUARY 2003 24 JANUARIE 2003

Registration number/Registrasienommer: 34/20.1.1/0311

Name of medicine/Naam van medisyne: CILOFLOC 100

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
CIPROFLOXACIN HYDROCHLORIDE EQUIVALENT TO
CIPROFLOXACIN 100,0 mg

Conditions of registration/Voorwaardes vir registrasie:
1, 2, 3, 4, 5a, 6, 7

Applicant/Applikant: TRIOMED (PTY) LTD

Manufacturer/Vervaardiger: CHEMINOR DRUGS LTD, BACHEPALLI, INDIA

Packer/Verpakker: CHEMINOR DRUGS LTD, BACHEPALLI, INDIA

Laboratory/Laboratorium: CHEMINOR DRUGS LTD, BACHEPALLI, INDIA
INSTITUTE FOR PHARMACEUTICAL SERVICES,BOKSBURG RSA
TRIOMED, PINELANDS RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 24 JANUARY 2003
Datum van registrasie 24 JANUARIE 2003

Registration number/Registrasienommer: 34/20.1.1/0312

Name of medicine/Naam van medisyne: CILOFLOC 250

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT :
CIPROFLOXACIN HYDROCHLORIDE EQUIVALENT TO
CIPROFLOXACIN ... 250,0 mg

Conditions of registration/Voorwaardes vir registrasie:
1, 2, 3, 4, 5a, 6, 7

Applicant/Applikant: TRIOMED (PTY) LTD

Manufacturer/Vervaardiger: CHEMINOR DRUGS LTD, BACHEPALLI, INDIA

Packer/Verpakker: CHEMINOR DRUGS LTD, BACHEPALLI, INDIA

Laboratory/Laboratorium: CHEMINOR DRUGS LTD, BACHEPALLI, INDIA
INSTITUTE FOR PHARMACEUTICAL SERVICES,BOKSBURG RSA
TRIOMED, PINELANDS RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 24 JANUARY 2003
Datum van registrasie 24 JANUARIE 2003

Registration number/Registrasienommer: 34/20.1.1/0313

Name of medicine/Naam van medisyne: CILOFLOC 500

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
CIPROFLOXACIN HYDROCHLORIDE EQUIVALENT TO
CIPROFLOXACIN 500,0 mg

Conditions of registration/Voorwaardes vir registrasie:
1, 2, 3, 4, 5, 6, 7

Applicant/Applikant: TRIOMED (PTY) LTD

Manufacturer/Vervaardiger: CHEMINOR DRUGS LTD, BACHEPALLI, INDIA

Packer/Verpakker: CHEMINOR DRUGS LTD, BACHEPALLI, INDIA

Laboratory/Laboratorium: CHEMINOR DRUGS LTD, BACHEPALLI, INDIA
INSTITUTE FOR PHARMACEUTICAL SERVICES,BOKSBURG RSA
TRIOMED, PINELANDS RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 24 JANUARY 2003
Datum van registrasie 24 JANUARIE 2003

Registration number/Registrasienommer: 34/20.1.1/0314

Name of medicine/Naam van medisyne: CILOFLOC 750

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
CIPROFLOXACIN HYDROCHLORIDE EQUIVALENT TO
CIPROFLOXACIN ... 750,0 mg

Conditions of registration/Voorwaardes vir registrasie:
1, 2, 3, 4, 5a, 6, 7

Applicant/Applikant: TRIOMED (PTY) LTD

Manufacturer/Vervaardiger: CHEMINOR DRUGS LTD, BACHEPALLI, INDIA

Packer/Verpakker: CHEMINOR DRUGS LTD, BACHEPALLI, INDIA

Laboratory/Laboratorium: CHEMINOR DRUGS LTD, BACHEPALLI, INDIA
INSTITUTE FOR PHARMACEUTICAL SERVICES,BOKSBURG RSA
TRIOMED, PINELANDS RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 24 JANUARY 2003
Datum van registrasie 24 JANUARIE 2003

Registration number/Registrasienommer: 35/11.5/0365

Name of medicine/Naam van medisyne: EX-LAX SENNA

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
SENNOSIDE A & B ... 15,0 mg

Conditions of registration/Voorwaardes vir registrasie:
1, 2, 3, 4, 5, 6, 7

Applicant/Applikant: NOVARTIS SOUTH AFRICA (PTY) LTD

Manufacturer/Vervaardiger: NOVARTIS, SPARTAN KEMPTON PARK RSA

Packer/Verpakker: NOVARTIS, SPARTAN KEMPTON PARK RSA

Laboratory/Laboratorium: NOVARTIS, SPARTAN KEMPTON PARK RSA

Shelf-life/Rakleeftyd: 36 months/maande

Date of registration: 24 JANUARY 2003
Datum van registrasie 24 JANUARIE 2003

Registration number/Registrasienommer: 35/11.5/0366

Name of medicine/Naam van medisyne: EX-LAX SENNA CHOCOLATE

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
SENNOSIDE A & B ... 15,0 mg

Conditions of registration/Voorwaardes vir registrasie:
1, 2, 3, 4, 5a, 6, 7

Applicant/Applikant: NOVARTIS SOUTH AFRICA (PTY) LTD

Manufacturer/Vervaardiger: NOVARTIS HOLDING, HUMACAO, PUERTO RICO

Packer/Verpakker: NOVARTIS HOLDING, HUMACAO, PUERTO RICO
NOVARTIS, SPARTAN KEMPTON PARK RSA

Laboratory/Laboratorium: NOVARTIS HOLDING, HUMACAO, PUERTO RICO
NOVARTIS, SPARTAN KEMPTON PARK RSA

Shelf-life/Rakleeftyd: 36 months/maande

Date of registration: 24 JANUARY 2003
Datum van registrasie 24 JANUARY 2003

Registration number/Registrasienommer: 35/11.5/0367

Name of medicine/Naam van medisyne: REG-U-LETTS SENNA

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
SENNOSIDE A & B ... 15,0 mg

Conditions of registration/Voorwaardes vir registrasie:
1, 2, 3, 4, 5a, 6, 7

Applicant/Applikant: NOVARTIS SOUTH AFRICA (PTY) LTD

Manufacturer/Vervaardiger: NOVARTIS, SPARTAN KEMPTON PARK RSA

Packer/Verpakker: NOVARTIS, SPARTAN KEMPTON PARK RSA

Laboratory/Laboratorium: NOVARTIS, SPARTAN KEMPTON PARK RSA

Shelf-life/Rakleeftyd: 36 months/maande

Date of registration: 24 JANUARY 2003
Datum van registrasie 24 JANUARIE 2003

Registration number/Registrasienommer: 35/11.5/0368

Name of medicine/Naam van medisyne: REG-U-LETTS SENNA CHOCOLATE

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
SENNOSIDE A & B ... 15,0 mg

Conditions of registration/Voorwaardes vir registrasie:
1, 2, 3, 4, 5a, 6, 7

Applicant/Applikant: NOVARTIS SOUTH AFRICA (PTY) LTD

Manufacturer/Vervaardiger: NOVARTIS HOLDING, HUMACAO, PUERTO RICO

Packer/Verpakker: NOVARTIS HOLDING, HUMACAO, PUERTO RICO
NOVARTIS, SPARTAN KEMPTON PARK RSA

Laboratory/Laboratorium: NOVARTIS HOLDING, HUMACAO, PUERTO RICO
NOVARTIS, SPARTAN KEMPTON PARK RSA

Shelf-life/Rakleeftyd: 36 months/maande

Date of registration: 24 JANUARY 2003
Datum van registrasie 24 JANUARIE 2003

Registration number/Registrasienommer: 34/7.1.4/0377

Name of medicine/Naam van medisyne: DINOSPRAY

Dosage form/Doseringsvorm: SPRAY/SPROEI

Active ingredients/Aktiewe bestanddele:
EACH ACTUATION OF 0,1 ml SOLUTION CONTAINS/
ELKE SPROEI VAN 0,1 ml OPLOSSING BEVAT:
ISOSORBIDE DINITRATE ... 1,25 mg

Conditions of registration/Voorwaardes vir registrasie:
1, 2, 3, 4, 5a, 6, 7

Applicant/Applikant: CIPLA-MEDPRO (PTY) LTD

Manufacturer/Vervaardiger: CIPLA LTD, BOMBAY INDIA

Packer/Verpakker: CIPLA LTD, BOMBAY INDIA

Laboratory/Laboratorium: CIPLA LTD, BOMBAY INDIA
CIPLA-MEDPRO, ROSENPARK RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 24 JANUARY 2003
Datum van registrasie 24 JANUARY 2003

Registration number/Registrasienommer: 36/20.1.1/0378

Name of medicine/Naam van medisyne: CIPLA CIPROFLOXACIN 750

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
CIPROFLOXACIN HYDROCHLORIDE EQUIVALENT TO
CIPROFLOXACIN ... 750,0 mg

Conditions of registration/Voorwaardes vir registrasie:
1, 2, 3, 4, 5a, 6, 7

Applicant/Applikant: CIPLA LIFE SCIENCES (PTY) LTD

Manufacturer/Vervaardiger: CIPLA LTD, KURKUMBH, PUNE INDIA

Packer/Verpakker: CIPLA LTD, KURKUMBH, PUNE INDIA

Laboratory/Laboratorium: CIPLA LTD, KURKUMBH, PUNE INDIA
CIPLA LIFE SCIENCES, ROSENPARK RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 24 JANUARY 2003
Datum van registrasie 24 JANUARIE 2003

Registration number/Registrasienommer: 36/5.7.1/0008

Name of medicine/Naam van medisyne: LORAHIST SYRUP

Dosage form/Doseringsvorm: SYRUP/STROOP

Active ingredients/Aktiewe bestanddele:
EACH 5,0 ml SYRUP CONTAINS/
ELKE 5,0 ml STROOP BEVAT :
LORATADINE ... 5,0 mg

Conditions of registration/Voorwaardes vir registrasie:
1, 2, 3, 4, 5a, 6, 7

Applicant/Applikant: ADCOCK INGRAM LTD

Manufacturer/Vervaardiger: PHARMA-Q, INDUSTRIA RSA
ADCOCK INGRAM HEALTHCARE, WADEVILLE RSA

Packer/Verpakker: PHARMA-Q, INDUSTRIA RSA
ADCOCK INGRAM HEALTHCARE, WADEVILLE RSA

Laboratory/Laboratorium: PHARMA-Q, INDUSTRIA RSA
ADCOCK INGRAM HEALTHCARE, WADEVILLE RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 24 JANUARY 2003
Datum van registrasie 24 JANUARIE 2003

Registration number/Registrasienommer: 36/15.1/0002

Name of medicine/Naam van medisyne: OCTIN

Dosage form/Doseringsvorm: SOLUTION/OPLOSSING

Active ingredients/Aktiewe bestanddele:
EACH 5,0 ml SOLUTION CONTAINS/
ELKE 5,0 ml OPLOSSING BEVAT:
OFLOXACINE ... 15,0 mg

Conditions of registration/Voorwaardes vir registrasie:
1., 2, 3, 4, 5a, 6, 7

Applicant/Applikant: CIPLA LIFE SCIENCES (PTY) LTD

Manufacturer/Vervaardiger: CIPLA LTD, VIKHROLI INDIA

Packer/Verpakker: CIPLA LTD, VIKHROLI INDIA

Laboratory/Laboratorium: CIPLA LTD, VIKHROLI INDIA
CIPLA LIFE SCIENCES, ROSENPARK RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 24 JANUARY 2003
Datum van registrasie 24 JANUARIE 2003

Registration number/Registrasienommer: 36/15.1/0002

Name of medicine/Naam van medisyne: OCTIN

Dosage form/Doseringsvorm: SOLUTION/OPLOSSING

Active ingredients/Aktiewe bestanddele:
EACH 5,0 ml SOLUTION CONTAINS/
ELKE 5,0 ml OPLOSSING BEVAT:
OFLOXACINE ... 15,0 mg

Conditions of registration/Voorwaardes vir registrasie:
1., 2, 3, 4, 5a, 6, 7

Applicant/Applikant: CIPLA LIFE SCIENCES (PTY) LTD

Manufacturer/Vervaardiger: CIPLA LTD, VIKHROLI INDIA

Packer/Verpakker: CIPLA LTD, VIKHROLI INDIA

Laboratory/Laboratorium: CIPLA LTD, VIKHROLI INDIA
CIPLA LIFE SCIENCES, ROSENPARK RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 24 JANUARY 2003
Datum van registrasie 24 JANUARIE 2003

Registration number/Registrasienommer:	37/11.4.3/0380
Name of medicine/Naam van medisyne:	LANZOR HB
Dosage form/Doseringsvorm:	CAPSULES/KAPSULES

Active ingredients/Aktiewe bestanddele:
EACH CAPSULE CONTAINS/ELKE KAPSULE BEVAT :
LANSOPRAZOLE...15,0 mg

Conditions of registration/Voorwaardes vir registrasie:
1, 2, 3, 4, 5a, 6, 7

Applicant/Applikant:	AVENTIS PHARMA (PTY) LTD
Manufacturer/Vervaardiger:	TAKEDA CHEMICAL INDUSTRIES, OSAKA JAPAN USIPHAR, COMPIEGNE FRANCE
Packer/Verpakker:	AVENTIS PHARMA, WALTLOO RSA
Laboratory/Laboratorium:	SOUTH AFRICAN BUREAU OF STANDARDS,PRETORIA RSA USIPHAR, COMPIEGNE FRANCE AVENTIS PHARMA, WALTLOO RSA
Shelf-life/Rakleeftyd:	24 months/maande
Date of registration: Datum van registrasie	25 February 2003 25 Februarie 2003

Registration number/Registrasienommer: 36/18.3/0037

Name of medicine/Naam van medisyne: UROSODA

Dosage form/Doseringsvorm: GRANULES

Active ingredients/Aktiewe bestanddele:
EACH 4,0 g GRANULES CONTAIN/ELKE 4,0 g GRANULES BEVAT:

CITRIC ACID	0,702 g
SODIUM BICARBONATE	1,716 g
SODIUM CITRATE	0,613 g
TARTARIC ACID	0,858 g

Conditions of registration/Voorwaardes vir registrasie:

1, 2, 3,4, 5a, 6, 7

Applicant/Applikant: ADCOCK INGRAM LTD

Manufacturer/Vervaardiger: ADCOCK INGRAM LTD, WADEVILLE RSA
MICRO HEALTHCARE, BETHLEHEM RSA

Packer/Verpakker: ADCOCK INGRAM LTD, WADEVILLE RSA
MICRO HEALTHCARE, BETHLEHEM RSA

Laboratory/Laboratorium: ADCOCK INGRAM LTD, WADEVILLE RSA
MICRO HEALTHCARE, BETHLEHEM RSA

Shelf-life/Rakleeftyd: 48 months/maande

Date of registration: 15 NOVEMBER 2003
Datum van registrasie 15 NOVEMBER 2003

Registration number/Registrasienommer: 32/2.9/0088

Name of medicine/Naam van medisyne: NUBAIN 20 mg/1 ml

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH 1,0 ml SOLUTION CONTAINS/ELKE 1,0 ml OPLOSSING BEVAT:
NALBUPHINE HYDROCHLORIDE ... 20,0 mg

Conditions of registration/Voorwaardes vir registrasie:
1, 2, 3, 4, 6, 7

Applicant/Applikant: SANOFI - SYNTHELABO (PTY) LTD

Manufacturer/Vervaardiger: DU PONT, MONATI PUERTO RICO

Packer/Verpakker: DU PONT, MONATI PUERTO RICO
PHARMACEUTICAL CONTRACTORS, ISANDO RSA
DIVPHARM MANUFACTURING AND PACKAGING, LONGDALE RSA

Laboratory/Laboratorium: DU PONT, MONATI PUERTO RICO
PHARMACEUTICAL CONTRACTORS, ISANDO RSA
INSPECTORATE M & L, ORMONDE RSA
SANOFI - SYNTHELABO, WOODMEAD RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 20 DECEMBER 2002
Datum van registrasie 20 DESEMBER 2002

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