Government Gazette
Staatskoerant

REPUBLIC OF SOUTH AFRICA
REPUBLIEK VAN SUID-AFRIKA

Vol. 450 Pretoria, 6 December Desember 2002 No. 24099

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

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GENERAL NOTICE

NOTICE 3028 OF 2002

DEPARTMENT OF HEALTH

MEDICINES AND RELATED SUBSTANCES CONTROL ACT, 1965 (ACT No. 101 OF 1965)

REGISTRATION OF MEDICINES

It is hereby notified in terms of section 17 of the Medicines and Related Substances Control Act, 1965 (Act No. 101 of 1965), that the Registrar of Medicines, with the approval of the Medicines Control Council established by section 2 of the said Act, has registered the following medicines described in the Schedule hereto:

The undermentioned Conditions of Registration of Medicines applies to the medicines following:

Conditions of registration:

1a. An acceptable standard of Good Manufacturing Practice must be maintained in the place of manufacture.

1b. An applicant shall ensure that the medicine is manufactured and controlled in terms of current Good Manufacturing Practice as determined by the Medicines Control Council.

2. The applicant must comply with all the legal requirements of the Medicines and Related Substances Control Act, 1965 (Act No. 101 of 1965).

3. The registration of this product shall be subject to review every three years.

4. The information in the package insert shall be updated on a regular basis to conform to a package insert recently approved by the Council.

5a. The first two production lots must be fully validated and the full details of the proposed process validation program to be followed by the applicant and/or manufacturer be submitted.

5b. The first two production lots of the locally manufactured products must be validated.

5c. The first two production lots after registration must be validated, unless this documentation is available.

5d. The first two production lots must be validated.

5e. The first two production lots manufactured by each local manufacturer must be validated.

6. The manufacture of this medicine is subject to regular investigation and inspection by inspectors to assess compliance with current Good Manufacturing Practice.

7. The registration dossier is subject to review at intervals as determined by Council.

8a. A post-registration inspection must be conducted on the first production lot of the locally manufactured product.

8b. A post-registration inspection must be conducted on the first production lot manufactured by each local manufacturer.

8c. A post-registration inspection must be conducted on the first production lot.

9. Marketing of the product may only commence following a satisfactory post-registration inspection report.

10. The product may be advertised to the professions only.

11. One sample of every lot, together with four copies of the protocols for testing of the bulk lot and filling lot, be submitted to Council for lot releasing purposes.

12. One sample of every lot, together with six copies of the protocols for testing of the bulk lot and filling lot and six copies of the certificate of release issued by the competent authority in the country in which the product was manufactured, be submitted to Council for lot releasing purposes.

13. The expiry date allocated shall be modified by adding to a statement that the virus strains are currently recommended for South African usage in the specified year.

14. The strains of the master seed viruses must be approved by the Department of Health for each year.

KENNISGEWING 3028 VAN 2001

DEPARTEMENT VAN GESONDHEID

WET OP BEHEER VAN MEDISYNE EN VERWANTE STOWWE, 1965 (WET No. 101 VAN 1965)

REGISTRASIE VAN MEDISYNE

Hierby word ingevolge artikel 17 van die Wet op die Beheer van Medisyne en Verwante Stowwe, 1965 (Wet No. 101 van 1965), bekendgemaak dat die Registrateur van Medisyne, met die goedkeuring van die Medisynebeheerraad ingestel by artikel 2 van genoemde Wet, die volgende medisyne soos in die Bylae hiervan omskryf, geregistreer het:

Die onderstaande Voorwaardes vir Registrasie van Medisyne is van toepassing op die hiernagemelde medisyne:

Voorwaardes vir registrasie:

1a. 'n Aanvaarbare standaard van Goeie Vervaardigingspraktyk moet by die plek van vervaardiging gehandhaaf word.

1b. Die applikant sal verseker dat die medisyne vervaardig en beheer word in terme van huidige Goeie Vervaardigingspraktyk soos bepaal deur die Medisynebeheerraad.

2. Die applikant moet voldoen aan al die wetlike vereistes van die Wet op die Beheer van Medisyne en Verwante Stowwe, 1965 (Wet No. 101 van 1965).

3. Die registrasie van die produk is onderhewig aan hersiening elke drie jaar.

4. Die inligting in die voubiljet moet op 'n gereelde basis opgedateer word in ooreenstemming met 'n voubiljet onlangs deur die Raad goedgekeur.

5a. Die eerste twee produksielotte moet ten volle gevalideer word en die volle besonderhede van die voorgestelde prosesvalidasieprogram wat gevolg gaan word deur die Applikant en/of die vervaardiger moet ingedien word.

5b. Die eerste twee produksielotte van die plaaslik vervaardigde produk moet gevalideer word.

5c. Die eerste twee produksielotte na registrasie moet gevalideer word, tensy die dokumentasie beskikbaar is.

5d. Die eerste twee produksielotte moet gevalideer word.

5e. Die eerste twee produksielotte van elke plaaslike vervaardiger moet gevalideer word.

6. Die vervaardiging van hierdie medisyne is onderhewig aan gereelde ondersoeke en inspeksies deur inspekteurs om die nakoming van Goeie Vervaardigingspraktyke te bepaal.

7. Die registrasie-aansoek is onderhewig aan hersiening met tussenpose soos deur die Raad bepaal.

8a. 'n Na-registrasie-inspeksie moet op die eerste produksielot van die plaaslik vervaardigde produk uitgevoer word.

8b. 'n Na-registrasie-inspeksie moet op die eerste produksielot van elke plaaslike vervaardiger uitgevoer word.

8c. 'n Na-registrasie-inspeksie moet op die eerste produksielot uitgevoer word.

9. Bemarking van die produk mag slegs 'n aanvang neem nadat 'n bevredigende na-registrasie-inspeksieverslag gedien het.

10. Die produk mag slegs aan die professies geadverteer word.

11. Een monster van elke lot moet tesame met vier kopieë van die protokolle vir die toets van die finale lot en die vullot ingedien word by die Raad vir lotvrystellingsdoeleindes.

12. Een monster van elke lot moet tesame met ses kopieë van die protokolle vir die toets van die finale lot en die vullot sowel as ses kopieë van die vrystellingsertifikaat wat uitgereik is deur die verantwoordelike beheerliggaam in die land waar die produk vervaardig word, ingedien word by die Raad vir lotvrystellingsdoeleindes.

13. Die vervaldatum toegeken moet verander word deur 'n toegevoegde stelling dat die virusstamme wat tans aanbeveel word vir Suid-Afrikaanse gebruik is vir die gespesifiseerde jaar.

14. Die stamme van die oorspronklike saadvirusse moet elke jaar deur die Departement van Gesondheid goedgekeur word.

SCHEDULE • B

Registration number/Registrasienommer: 35/5.7.1/0084

Name of medicine/Naam van medisyne: AP-LORATADINE 10 mg TABLETS

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: PHARMACARE LIMITED

Manufacturer/Vervaardiger: LENNON, PORT ELIZABETH RSA

Packer/Verpakker: LENNON, PORT ELIZABETH RSA

Laboratory/Laboratorium: LENNON, PORT ELIZABETH RSA
PHARMACARE LTD, PORT ELIZABETH RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 22 MAY 2002
Datum van registrasie 22 MEI 2002

Registration number/Registrasienommer: 34/17.1/0174

Name of medicine/Naam van medisyne: ESMERON 250 mg = 25 ml

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH 25,0 ml SOLUTION CONTAINS/ELKE 25,0 ml OPLOSSING BEVAT:
ROCURONIUM BROMIDE ... 250,0 mg

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

Applicant/Applikant: SANOFI-SYNTHELABO (PTY) LTD

Manufacturer/Vervaardiger: NV ORGANON, OSS NETHERLANDS

Packer/Verpakker: NV ORGANON, OSS NETHERLANDS
ORGANON LTD, NEWHOUSE SCOTLAND
ORGANON TEKNIKA, BOXTEL NETHERLANDS

Laboratory/Laboratorium: NV ORGANON, OSS NETHERLANDS
ORGANON TEKNIKA, BOXTEL NETHERLANDS
INSPECTORATE M & L, ORMONDE RSA
INSTITUTE FOR INDUSTRIAL PHARMACY,
POTCHEFSTROOM UNIVERSITY RSA
SANOFI-SYNTHELABO, WOODMEAD RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 31 JULY 2002
Datum van registrasie 31 JULIE 2002

Registration number/Registrasienommer: 35/7.1.3/0225

Name of medicine/Naam van medisyne: HEXAL-LISINOPRIL 5

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ ELKE TABLET BEVAT:
LISINOPRIL ... 5,0 mg

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

Applicant/Applikant:	HEXAL PHARMA (SA) (PTY) LTD
Manufacturer/Vervaardiger: Packer/Verpakker:	SALUTAS PHARMA, BARLEBEN GERMANY DIVPHARM MANUFACTURING AND PACKAGING, LONGDALE RSA
Laboratory/Laboratorium:	ANALYTICON, KEMPTON PARK RSA SALUTAS PHARMA, BARLEBEN GERMANY CONSULTING CHEMICAL LAB, STAR STREET BOKSBURG RSA HEXAL PHARMA , WESTMEAD RSA
Shelf-life/Rakleeftyd:	24 months/maande
Date of registration: Datum van registrasie	01 AUGUST 2002 01 AUGUSTUS 2002

Registration number/Registrasienommer: 35/7.1.3/0226

Name of medicine/Naam van medisyne: HEXAL-LISINOPRIL 10

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ ELKE TABLET BEVAT:
LISINOPRIL ... 10,0 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
Laboratory/Laboratorium:	ANALYTICON, KEMPTON PARK CONSULTING CHEMICAL LAB, STAR STREET BOKSBURG SALUTAS PHARMA, BARLEBEN GERMANY HEXAL PHARMA , WESTMEAD RSA
Shelf-life/Rakleeftyd:	24 months/maande
Date of registration: Datum van registrasie	01 AUGUST 2002 01 AUGUSTUS 2002

Registration number/Registrasienommer: 35/7.1.3/0227

Name of medicine/Naam van medisyne: HEXAL-LISINOPRIL 20

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ ELKE TABLET BEVAT:
LISINOPRIL ... 20,0 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

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

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 01 AUGUST 2002
Datum van registrasie 01 AUGUSTUS 2002

Registration number/Registrasienommer: 35/26/0196

Name of medicine/Naam van medisyne: TAXOL 300

Dosage form/Doseringsvorm: INFUSION (PARENTERAL)/
INFUSIE(PARENTERAAL)

Active ingredients/Aktiewe bestanddele:
EACH VIAL CONTAINS/ELKE FLESSIE BEVAT:
PACLITAXEL ... 300,0 mg

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

Applicant/Applikant: BRISTOL-MYERS SQUIBB (PTY) LTD

Manufacturer/Vervaardiger: BRISTOL-MYERS SQUIBB, MAYAGUEZ PUERTO RICO

Packer/Verpakker: BRISTOL-MYERS SQUIBB, MAYAGUEZ PUERTO RICO
BRISTOL-MYERS SQUIBB, SERMONETA ITALY
DIVPHARM MANUFACTURING AND PACKAGING, LONGDALE RSA
MERCK PHARMACEUTICALS MANUFACTURING, WADEVILLE GERMISTON RSA

Laboratory/Laboratorium: BRISTOL-MYERS SQUIBB, MAYAGUEZ PUERTO RICO
BRISTOL-MYERS SQUIBB, SERMONETA ITALY
CONSULTING CHEMICAL LAB, STAR STREET BOKSBURG RSA
MERCK PHARMACEUTICALS MANUFACTURING, WADEVILLE GERMISTON RSA
BRISTOL-MYERS SQUIBB, BEDFORDVIEW RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 02 AUGUST 2002
Datum van registrasie 02 AUGUSTUS 2002

Registration number/Registrasienommer: 35/3/0326

Name of medicine/Naam van medisyne: CELLUGEL

Dosage form/Doseringsvorm: SOLUTION/OPLOSSING

Active ingredients/Aktiewe bestanddele:
EACH 1,0 ml SOLUTION CONTAINS/ELKE 1,0 ml OPLOSSING BEVAT:
HYPROMELLOSE ... 23,0 mg (Inactive)

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

Applicant/Applikant: ALCON LABORATORIES (SA) (PTY) LTD

Manufacturer/Vervaardiger: SA ALCON-COUVREUR NV PUURS, BELGIUM

Packer/Verpakker: SA ALCON-COUVREUR NV PUURS, BELGIUM

Laboratory/Laboratorium: SA ALCON-COUVREUR NV PUURS, BELGIUM
ALCON, FORT WORTH,TEXAS USA
RESEARCH INSTITUTE FOR IND. PHARMACY, POTCHEFSTROOM RSA
ALCON, RANDBURG RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 02 AUGUST 2002
Datum van registrasie 02 AUGUSTUS 2002

Registration number/Registrasienommer: 36/7.1.3/0071

Name of medicine/Naam van medisyne: PRILOSIN 5

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
LISINOPRIL 5,0 mg

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

Applicant/Applikant: CIPLA-MEDPRO (PTY) LTD

Manufacturer/Vervaardiger: CIPLA LTD, VIKHROLI INDIA

Packer/Verpakker: CIPLA LTD, VIKHROLI INDIA

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

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 05 AUGUST 2002
Datum van registrasie 05 AUGUSTUS

Registration number/Registrasienommer: 35/7.1.3/0252

Name of medicine/Naam van medisyne: PRILOSIN 10

Dosage form/Doseringsvorm: TABLET

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

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

Applicant/Applikant: CIPLA-MEDPRO (PTY) LTD

Manufacturer/Vervaardiger: CIPLA LTD, VIKHROLI INDIA

Packer/Verpakker: CIPLA LTD, VIKHROLI INDIA

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

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 05 AUGUST 2002
Datum van registrasie 05 AUGUSTUS 2002

Registration number/Registrasienommer: 35/7.1.3/0282

Name of medicine/Naam van medisyne: ENALAPRIL MALEATE 2,5 MG - HEXAL

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT :
ENALAPRIL MALEATE ... 2,5 mg

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

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

Manufacturer/Vervaardiger: GEA FARMACEUTISK, HVIDOVRE, DENMARK

Packer/Verpakker: GEA FARMACEUTISK, HVIDOVRE, DENMARK
DIVPHARM MANUFACTURING AND PACKAGING, LONGDALE

Laboratory/Laboratorium: GEA FARMACEUTISK, HVIDOVRE, DENMARK
ANALYTICON, KEMPTON PARK
CONSULTING CHEMICAL LAB, STAR STREET BOKSBURG
HEXAL PHARMA , WESTMEAD RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 05 AUGUST 2002
Datum van registrasie 05 AUGUSTUS 2002

Registration number/Registrasienommer: 35/7.1.3/0283

Name of medicine/Naam van medisyne: ENALAPRIL MALEATE 5 MG - HEXAL

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
ENALAPRIL MALEATE ... 5,0 mg

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

Applicant/Applikant:	HEXAL PHARMA (SA) (PTY) LTD
Manufacturer/Vervaardiger:	GEA FARMACEUTISK, HVIDOVRE, DENMARK
Packer/Verpakker:	DIVPHARM MANUFACTURING AND PACKAGING, LONGDALE GEA FARMACEUTISK, HVIDOVRE, DENMARK
Laboratory/Laboratorium:	ANALYTICON, KEMPTON PARK CONSULTING CHEMICAL LAB, STAR STREET BOKSBURG GEA FARMACEUTISK, HVIDOVRE, DENMARK HEXAL PHARMA , WESTMEAD
Shelf-life/Rakleeftyd:	24 months/maande
Date of registration: Datum van registrasie	05 AUGUST 2002 05 AUGUSTUS 2002

Registration number/Registrasienommer: 35/7.1.3/0284

Name of medicine/Naam van medisyne: ENALAPRIL MALEATE 10 MG - HEXAL

Dosage form/Doseringsvorm: TABLET

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

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

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

Manufacturer/Vervaardiger: GEA FARMACEUTISK, HVIDOVRE, DENMARK

Packer/Verpakker: DIVPHARM MANUFACTURING AND PACKAGING, LONGDALE
GEA FARMACEUTISK, HVIDOVRE, DENMARK

Laboratory/Laboratorium: GEA FARMACEUTISK, HVIDOVRE, DENMARK
CONSULTING CHEMICAL LAB, STAR STREET BOKSBURG
HEXAL PHARMA , WESTMEAD

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 05 AUGUST 2002
Datum van registrasie 05 AUGUSTUS 2002

Registration number/Registrasienommer: 35/7.1.3/0285

Name of medicine/Naam van medisyne: ENALAPRIL MALEATE 20 MG - HEXAL

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT
ENALAPRIL MALEATE ... 20,0 mg

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

Applicant/Applikant:	HEXAL PHARMA (SA) (PTY) LTD
Manufacturer/Vervaardiger:	GEA FARMACEUTISK, HVIDOVRE, DENMARK
Packer/Verpakker:	GEA FARMACEUTISK, HVIDOVRE, DENMARK DIVPHARM MANUFACTURING AND PACKAGING, LONGDALE
Laboratory/Laboratorium:	GEA FARMACEUTISK, HVIDOVRE, DENMARK ANALYTICON, KEMPTON PARK CONSULTING CHEMICAL LAB, STAR STREET BOKSBURG HEXAL PHARMA , WESTMEAD RSA
Shelf-life/Rakleeftyd:	24 months/maande
Date of registration: Datum van registrasie	05 AUGUST 2002 05 AUGUSTUS 2002

Registration number/Registrasienommer: 35/5.4/0340

Name of medicine/Naam van medisyne: CIPLA-OXYBUTYNIN CHLORIDE

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS.ELKE TABLET BEVAT:
OXYBUTYNIN CHLORIDE ... 5,0 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: 05 AUGUST 2002
Datum van registrasie 05 AUGUSTUS 2002

Registration number/Registrasienommer: 32/7.1/0554

Name of medicine/Naam van medisyne: TEVETEN 300

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
EPROSARTAN MESYLATE EQUIVALENT TO EPROSARTAN ... 300 mg

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

Applicant/Applikant: SOLVAY PHARMA (PTY) LTD

Manufacturer/Vervaardiger: SMITHKLINE BEECHAM, CRAWLEY SUSSEX UK
SOLVAY PHARM BV, OLST, NETHERLANDS

Packer/Verpakker: SMITHKLINE BEECHAM, CRAWLEY SUSSEX UK
SOLVAY PHARM BV, OLST, NETHERLANDS

Laboratory/Laboratorium: SMITHKLINE BEECHAM, CRAWLEY SUSSEX UK
SOLVAY PHARM BV, OLST, NETHERLANDS
SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA RSA
SCHERING, MIDRAND RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 02 SEPTEMBER 2002
Datum van registrasie 02 SEPTEMBER 2002

Registration number/Registrasienommer: 32/7.1/0555

Name of medicine/Naam van medisyne: TEVETEN 400

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
EPROSARTAN MESYLATE EQUIVALENT TO EPROSARTAN ... 400 mg

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

Applicant/Applikant: SOLVAY PHARMA (PTY) LTD

Manufacturer/Vervaardiger: SMITHKLINE BEECHAM, CRAWLEY SUSSEX UK
SOLVAY PHARM BV, OLST, NETHERLANDS

Packer/Verpakker: SMITHKLINE BEECHAM, CRAWLEY SUSSEX UK
SOLVAY PHARM BV, OLST, NETHERLANDS

Laboratory/Laboratorium: SMITHKLINE BEECHAM, CRAWLEY SUSSEX UK
SOLVAY PHARM BV, OLST, NETHERLANDS
SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA RSA
SCHERING, MIDRAND RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 02 SEPTEMBER 2002
Datum van registrasie 02 SEPTEMBER 2002

Registration number/Registrasienommer: 33/20.2.8/0234

Name of medicine/Naam van medisyne: AVIREX CREAM

Dosage form/Doseringsvorm: CREAM/ROOM

Active ingredients/Aktiewe bestanddele:
EACH 100,0 g CREAM CONTAINS/ELKE 100,0 g ROOM BEVAT:
ACICLOVIR ... 5,0 g

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

Applicant/Applikant: TRIOMED (PTY) LTD

Manufacturer/Vervaardiger: AZUPHARMA GMBH,GERLINGEN, GERMANY

Packer/Verpakker: AZUPHARMA GMBH,GERLINGEN, GERMANY
DIVPHARM MANUFACTURING AND PACKAGING, LONGDALE RSA

Laboratory/Laboratorium: AZUPHARMA GMBH,GERLINGEN, GERMANY
HEUMANN PHARMA AND CO, NURNBERG GERMANY
INSTITUTE FOR PHARMACEUTICAL SERVICES,BOKSBURG RSA
TRIOMED, PINELANDS RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 19 SEPTEMBER 2002
Datum van registrasie 19 SEPTEMBER 2002

Registration number/Registrasienommer: 30/24/0135

Name of medicine/Naam van medisyne: MEDSOL CARDIOPLEGIC REPERFUSION SOLUTION

Dosage form/Doseringsvorm: INFUSION (PARENTERAL)/ INFUSIE(PARENTERAAL)

Active ingredients/Aktiewe bestanddele:
EACH 500,0 ml SOLUTION CONTAINS/ELKE 500,0 ml OPLOSSING BEVAT:
ASPARTATE SODIUM(LEVO) ... 9,8 g
L-GLUTAMATE (SODIUM) ... 10,7 g
POTASSIUM CHLORIDE ... 2,24 g

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

Applicant/Applikant: BODENE (PTY) LTD TRADING AS INTRAMED

Manufacturer/Vervaardiger: INMED, MIDRAND RSA

Packer/Verpakker: INMED, MIDRAND RSA

Laboratory/Laboratorium: INMED, MIDRAND RSA
BODENE (PTY) LTD TRADING AS INTRAMED RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 19 SEPTEMBER 2002
Datum van registrasie 19 SEPTEMBER 2002

Registration number/Registrasienommer: 33/5.4/0359

Name of medicine/Naam van medisyne: URIHEXAL

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
OXYBUTYNIN HYDROCHLORIDE ... 5,0 mg

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

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

Manufacturer/Vervaardiger: BIOGLAN GENERICS LTD, DUBLIN,IRELAND

Packer/Verpakker: BIOGLAN GENERICS LTD, DUBLIN,IRELAND
DIVPHARM MANUFACTURING AND PACKAGING, LONGDALE RSA

Laboratory/Laboratorium: BIOGLAN GENERICS LTD, DUBLIN,IRELAND
CONSULTING CHEMICAL LAB, STAR STREET BOKSBURG RSA
HEXAL PHARMA , WESTMEAD RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 19 SEPTEMBER 2002
Datum van registrasie 19 SEPTEMBER 2002

Registration number/Registrasienommer: 33/20.2.8/0233

Name of medicine/Naam van medisyne: TRIO-ACYCLOVIR CREAM

Dosage form/Doseringsvorm: CREAM/ROOM

Active ingredients/Aktiewe bestanddele:
EACH 100,0 g CREAM CONTAINS/ELKE 100,0 g ROOM BEVAT:
ACICLOVIR ... 5,0 g

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

Applicant/Applikant: TRIOMED (PTY) LTD

Manufacturer/Vervaardiger: AZUPHARMA GMBH,GERLINGEN, GERMANY

Packer/Verpakker: AZUPHARMA GMBH,GERLINGEN, GERMANY
DIVPHARM MANUFACTURING AND PACKAGING, LONGDALE RSA

Laboratory/Laboratorium: AZUPHARMA GMBH,GERLINGEN, GERMANY
HEUMANN PHARMA AND CO, NURNBERG GERMANY
INSTITUTE FOR PHARMACEUTICAL SERVICES,BOKSBURG RSA
TRIOMED, PINELANDS RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 19 SEPTEMBER 2002
Datum van registrasie 19 SEPTEMBER 2002

Registration number/Registrasienommer: 33/5.8/0317

Name of medicine/Naam van medisyne: CIRRUS CAPSULES

Dosage form/Doseringsvorm: CAPSULES/KAPSULES

Active ingredients/Aktiewe bestanddele:
EACH CAPSULE CONTAINS/ELKE KAPSULE BEVAT:
CETIRIZINE DIHYDROCHLORIDE ... 5,0 mg
PSEUDOEPHEDRINE HYDROCHLORIDE ... 120,0 mg

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

Applicant/Applikant: UCB SA (PTY) LTD

Manufacturer/Vervaardiger: UCB SA, BRAINE-l'ALLEUD BELGIUM

Packer/Verpakker: UCB SA, BRAINE-l'ALLEUD BELGIUM
LENNON LTD, PORT ELIZABETH RSA

Laboratory/Laboratorium: UCB SA, BRAINE-l'ALLEUD BELGIUM
LENNON LTD, PORT ELIZABETH RSA
CONSULTING CHEMICAL LAB, STAR STREET BOKSBURG RSA
SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA RSA
UCB, PARKTOWN, JHB, RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 19 SEPTEMBER 2002
Datum van registrasie 19 SEPTEMBER 2002

Registration number/Registrasienommer: 33/21.12/0516

Name of medicine/Naam van medisyne: FLUTAPLEX 250 mg

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
FLUTAMIDE ... 250,0 mg

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

Applicant/Applikant:	PHARMACHEMIE (PTY) LTD
Manufacturer/Vervaardiger:	PHARMACHEMIE BV, HAARLEM NETHERLANDS
Packer/Verpakker:	PHARMACHEMIE BV, HAARLEM NETHERLANDS
Laboratory/Laboratorium:	PHARMACHEMIE BV, HAARLEM NETHERLANDS CONSULTING CHEMICAL LAB, STAR STREET BOKSBURG RSA PHARMACHEMIE, MIDRAND RSA
Shelf-life/Rakleeftyd:	36 months/maande
Date of registration: Datum van registrasie	19 SEPTEMBER 2002 19 SEPTEMBER 2002

Registration number/Registrasienommer: 36/13.12/0028

Name of medicine/Naam van medisyne: SKINOREN ACNE GEL

Dosage form/Doseringsvorm: GEL/JEL

Active ingredients/Aktiewe bestanddele:
EACH 100,0 g GEL CONTAINS/ELKE 100,0 g JEL BEVAT :
AZELAIC ACID ... 15,0 g

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

Applicant/Applikant: SCHERING (PTY) LTD

Manufacturer/Vervaardiger: SCHERING, MILANO ITALY

Packer/Verpakker: SCHERING, MILANO ITALY

Laboratory/Laboratorium: SCHERING, MILANO ITALY
SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA RSA
SCHERING, MIDRAND RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 20 SEPTEMBER 2002
Datum van registrasie 20 SEPTEMBER 2002

Registration number/Registrasienommer: 34/13.9.2/0182

Name of medicine/Naam van medisyne: DERMAZOLE

Dosage form/Doseringsvorm: CREAM/ROOM

Active ingredients/Aktiewe bestanddele:
EACH 1,0 g CREAM CONTAINS/ELKE 1,0 g ROOM BEVAT:
MICONAZOLE NITRATE ... 20,0 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: SALUTAS PHARMA, BARLEBEN GERMANY
DIVPHARM MANUFACTURING AND PACKAGING, LONGDALE RSA

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

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 20 SEPTEMBER 2002
Datum van registrasie 20 SEPTEMBER 2002

Registration number/Registrasienommer: 34/18.6/0183

Name of medicine/Naam van medisyne: GYNOZOLE VC

Dosage form/Doseringsvorm: CREAM/ROOM

Active ingredients/Aktiewe bestanddele:
EACH 5,0 g CREAM CONTAINS/ELKE 5,0 g ROOM BEVAT :
MICONAZOLE NITRATE ... 100,0 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: SALUTAS PHARMA, BARLEBEN GERMANY
DIVPHARM MANUFACTURING AND PACKAGING, LONGDALE RSA

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

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 20 SEPTEMBER 2002
Datum van registrasie 20 SEPTEMBER 2002

Registration number/Registrasienommer: 30/5.4.1/0447

Name of medicine/Naam van medisyne: CABASER 2 MG

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
CABERGOLINE ... 2,0 mg

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

Applicant/Applikant: PHARMACIA SOUTH AFRICA (PTY) LTD

Manufacturer/Vervaardiger: PHARMACIA & UPJOHN, NERVIANO MILAN ITALY

Packer/Verpakker: PHARMACIA & UPJOHN, NERVIANO MILAN ITALY
PHARMACIA & UPJOHN, ASCOLI PICENO ITALY

Laboratory/Laboratorium: PHARMACIA & UPJOHN, NERVIANO MILAN ITALY
PHARMACIA & UPJOHN, ASCOLI PICENO ITALY
KHULULEKANI LABORATORY SERVICES, MIDRAND
SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA
PHARMACIA SOUTH AFRICA, MIDRAND RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 20 SEPTEMBER 2002
Datum van registrasie 20 SEPTEMBER 2002

Registration number/Registrasienommer: 30/5.4.1/0448

Name of medicine/Naam van medisyne: CABASER 4 mg

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
CABERGOLINE ... 4,0 mg

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

Applicant/Applikant: PHARMACIA SOUTH AFRICA (PTY) LTD

Manufacturer/Vervaardiger: PHARMACIA & UPJOHN, NERVIANO MILAN ITALY

Packer/Verpakker: PHARMACIA & UPJOHN, NERVIANO MILAN ITALY
PHARMACIA & UPJOHN, ASCOLI PICENO ITALY

Laboratory/Laboratorium: PHARMACIA & UPJOHN, NERVIANO MILAN ITALY
PHARMACIA & UPJOHN, ASCOLI PICENO ITALY
KHULULEKANI LABORATORY SERVICES, MIDRAND
SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA
PHARMACIA SOUTH AFRICA, MIDRAND RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 20 SEPTEMBER 2002
Datum van registrasie 20 SEPTEMBER 2002

Registration number/Registrasienommer: 33/20.2.2/0266

Name of medicine/Naam van medisyne: PIN-CLOTRIMAZOLE TOPICAL CREAM

Dosage form/Doseringsvorm: CREAM/ROOM

Active ingredients/Aktiewe bestanddele:
EACH 1,0 g CREAM CONTAINS/ELKE 1,0 g ROOM BEVAT:
CLOTRIMAZOLE ... 10,0 mg

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

Applicant/Applikant: MEDPRO PHARMACEUTICA (PTY) LTD

Manufacturer/Vervaardiger: CIPLA LTD, PATALGANGA MAHARASHTRA INDIA
ZENECA, ALRODE RSA

Packer/Verpakker: CIPLA LTD, PATALGANGA MAHARASHTRA INDIA
ZENECA, ALRODE RSA

Laboratory/Laboratorium: CIPLA LTD, PATALGANGA MAHARASHTRA INDIA
ZENECA, ALRODE RSA
MEDPRO PHARMACEUTICA, ROSENPARK RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 20 SEPTEMBER 2002
Datum van registrasie 20 SEPTEMBER 2002

Registration number/Registrasienommer: 33/2.8/0098

Name of medicine/Naam van medisyne: DOXY CO

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
CAFFEINE ... 30,0 mg
CODEINE PHOSPHATE ... 10,0 mg
DOXYLAMINE SUCCINATE ... 5,0 mg
PARACETAMOL ... 450,0 mg

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

Applicant/Applikant: MDI CC

Manufacturer/Vervaardiger: WRAPSA, CENTURION RSA

Packer/Verpakker: WRAPSA, CENTURION RSA

Laboratory/Laboratorium: WRAPSA, CENTURION RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 20 SEPTEMBER 2002
Datum van registrasie 20 SEPTEMBER 2002

Registration number/Registrasienommer: 30/20.1.2/0431

Name of medicine/Naam van medisyne: COMBICIN S

Dosage form/Doseringsvorm: SUSPENSION/SUSPENSIE

Active ingredients/Aktiewe bestanddele:
EACH 5,0 ml SUSPENSION CONTAINSELKE 5,0 ml SUSPENSIE BEVAT:
AMOXYCILLIN TRIHYDRATE EQUIVALENT TO AMOXYCILLIN ... 125,0 mg
POTASSIUM CLAVULANATE EQUIVALENT TO CLAVULANIC ACID ... 31,25 mg

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

Applicant/Applikant: GROUP LABORATORIES SA (PTY) LTD

Manufacturer/Vervaardiger: SMITHKLINE BEECHAM, WORTHING SUSSEX UK

Packer/Verpakker: SMITHKLINE BEECHAM, WORTHING SUSSEX UK
SMITHKLINE BEECHAM, EPPING RSA

Laboratory/Laboratorium: SMITHKLINE BEECHAM, WORTHING SUSSEX UK
SMITHKLINE BEECHAM, EPPING RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 20 SEPTEMBER 2002
Datum van registrasie 20 SEPTEMBER 2002

Registration number/Registrasienommer: 34/15.4/0302

Name of medicine/Naam van medisyne: BIOLONE PRIME

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH 0,8 ml SOLUTION CONTAINS/ELKE 0,8 ml OPLOSSING BEVAT:
SODIUM HYALURONATE ... 9,6 mg

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

Applicant/Applikant: PHARMAFRICA (PTY) LTD

Manufacturer/Vervaardiger: BIOTECHNOLOGY GENERAL, REHOVOT ISRAEL

Packer/Verpakker: BIOTECHNOLOGY GENERAL, REHOVOT ISRAEL

Laboratory/Laboratorium: BIOTECHNOLOGY GENERAL, REHOVOT ISRAEL
PHARMAFRICA, JOHANNESBURG RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 20 SEPTEMBER 2002
Datum van registrasie 20 SEPTEMBER 2002

Registration number/Registrasienommer: 34/3.1/0446

Name of medicine/Naam van medisyne: RANFEN 400 TABLETS

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
IBUPROFEN ... 400,0 mg

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

Applicant/Applikant: RANBAXY (SA) (PTY) LTD

Manufacturer/Vervaardiger: RANBAXY, DEWAS INDIA

Packer/Verpakker: RANBAXY, DEWAS INDIA

Laboratory/Laboratorium: RANBAXY, DEWAS INDIA
CENTRE FOR QUALITY ASSURANCE,
POTCHEFSTROOM RSA
KHULULEKANI LABORATORY SERVICES, MIDRAND RSA
RANBAXY, CENTURION RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 20 SEPTEMBER 2002
Datum van registrasie 20 SEPTEMBER 2002

Registration number/Registrasienommer: 35/2.8/0070

Name of medicine/Naam van medisyne: MYOGESIC CAPSULES

Dosage form/Doseringsvorm: CAPSULES/KAPSULES

Active ingredients/Aktiewe bestanddele:
EACH CAPSULE CONTAINS/ELKE KAPSULE BEVAT:
IBUPROFEN ... 200,0 mg
PARACETAMOL ... 250,0 mg

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

Applicant/Applikant: ADCOCK INGRAM LTD

Manufacturer/Vervaardiger: ADCOCK INGRAM LTD, CLAYVILLE, RSA
ADCOCK INGRAM LTD, WADEVILLE RSA

Packer/Verpakker: ADCOCK INGRAM LTD, CLAYVILLE, RSA
ADCOCK INGRAM LTD, WADEVILLE RSA

Laboratory/Laboratorium: ADCOCK INGRAM LTD, CLAYVILLE, RSA
ADCOCK INGRAM LTD, WADEVILLE RSA
SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 20 SEPTEMBER 2002
Datum van registrasie 20 SEPTEMBER 2002

Registration number/Registrasienommer: 35/20.1.1/0104

Name of medicine/Naam van medisyne: CYFLOC 250 MG TABLETS

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: PHARMACARE LIMITED

Manufacturer/Vervaardiger: LENNON LTD, PORT ELIZABETH RSA

Packer/Verpakker: LENNON LTD, PORT ELIZABETH RSA

Laboratory/Laboratorium: LENNON LTD, PORT ELIZABETH RSA
PHARMACARE LTD, PORT ELIZABETH RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 20 SEPTEMBER 2002
Datum van registrasie 20 SEPTEMBER 2002

Registration number/Registrasienommer: 35/20.1.1/0105

Name of medicine/Naam van medisyne: CYFLOC 500 MG TABLETS

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: PHARMACARE LIMITED

Manufacturer/Vervaardiger: LENNON LTD, PORT ELIZABETH RSA

Packer/Verpakker: LENNON LTD, PORT ELIZABETH RSA

Laboratory/Laboratorium: LENNON LTD, PORT ELIZABETH RSA
PHARMACARE LTD, PORT ELIZABETH RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 20 SEPTEMBER 2002
Datum van registrasie 20 SEPTEMBER 2002

Registration number/Registrasienommer: 35/20.1.1/0106

Name of medicine/Naam van medisyne: CYFLOC 750 MG TABLETS

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: PHARMACARE LIMITED

Manufacturer/Vervaardiger: LENNON LTD, PORT ELIZABETH RSA

Packer/Verpakker: LENNON LTD, PORT ELIZABETH RSA

Laboratory/Laboratorium: LENNON LTD, PORT ELIZABETH RSA
PHARMACARE LTD, PORT ELIZABETH RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 20 SEPTEMBER 2002
Datum van registrasie 20 SEPTEMBER 2002

Registration number/Registrasienommer: 35/15.4/0139

Name of medicine/Naam van medisyne: VISUDYNE

Dosage form/Doseringsvorm: INFUSION (PARENTERAL)/
INFUSIE(PARENTERAAL)

Active ingredients/Aktiewe bestanddele:
EACH VIAL CONTAINS/ELKE FLESSIE BEVAT:
VERTEPORFIN ... 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: PARKEDALE PHARM, MICHIGAN, USA

Packer/Verpakker: PARKEDALE PHARM, MICHIGAN, USA
LABORATOIRES CIBA VISION,CEDEX,FRANCE
NOVARTIS, SPARTAN KEMPTON PARK RSA

Laboratory/Laboratorium: PARKEDALE PHARM, MICHIGAN, USA
LABORATOIRES CIBA VISION,CEDEX,FRANCE
SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA RSA
NOVARTIS, SPARTAN KEMPTON PARK RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 20 SEPTEMBER 2002
Datum van registrasie 20 SEPTEMBER 2002

Registration number/Registrasienommer: 35/20.1.1/0267

Name of medicine/Naam van medisyne: ROXULIDE 150

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
ROXITHROMYCIN ... 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: HEINZ HAUPT CHEM-PHARM,BERLIN,GERMANY

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

Laboratory/Laboratorium: HEINZ HAUPT CHEM-PHARM,BERLIN,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: 20 SEPTEMBER 2002
Datum van registrasie 20 SEPTEMBER 2002

Registration number/Registrasienommer: 35/20.1.1/0268

Name of medicine/Naam van medisyne: ROXULIDE 300

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
ROXITHROMYCIN ... 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: HEINZ HAUPT CHEM-PHARM,BERLIN,GERMANY

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

Laboratory/Laboratorium: HEINZ HAUPT CHEM-PHARM,BERLIN,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: 20 SEPTEMBER 2002
Datum van registrasie 20 SEPTEMBER 2002

Registration number/Registrasienommer: 35/20.1.1/0286

Name of medicine/Naam van medisyne: KEFOTAX 0,5 G INJECTION

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH VIAL CONTAINS/ELKE FLESSIE BEVAT :
CEFOTAXIME SODIUM EQUIVALENT TO
CEFOTAXIME ... 500,0 mg

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

Applicant/Applikant: GENERIX INTERNATIONAL (SA) (PTY) LTD

Manufacturer/Vervaardiger: HARBIN GENERAL PHARM FACTORY, PEOPLES REP OF CHINA

Packer/Verpakker: HARBIN GENERAL PHARM FACTORY, PEOPLES REP OF CHINA

Laboratory/Laboratorium: HARBIN GENERAL PHARM FACTORY, PEOPLES REP OF CHINA
PHARMA-Q, INDUSTRIA
GENERIX INTERNATIONAL, CAPE TOWN

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 20 SEPTEMBER 2002
Datum van registrasie 20 SEPTEMBER 2002

Registration number/Registrasienommer: 35/20.1.1/0287

Name of medicine/Naam van medisyne: KEFOTAX 1,0 G INJECTION

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH VIAL CONTAINS/ELKE FLESSIE BEVAT :
CEFOTAXIME SODIUM EQUIVALENT TO
CEFOTAXIME ... 1,0 g

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

Applicant/Applikant: GENERIX INTERNATIONAL (SA) (PTY) LTD

Manufacturer/Vervaardiger: HARBIN GENERAL PHARM FACTORY, PEOPLES REP OF CHINA

Packer/Verpakker: HARBIN GENERAL PHARM FACTORY, PEOPLES REP OF CHINA

Laboratory/Laboratorium: HARBIN GENERAL PHARM FACTORY, PEOPLES REP OF CHINA
PHARMA-Q, INDUSTRIA
GENERIX, ATHLONE, CAPE TOWN RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 20 SEPTEMBER 2002
Datum van registrasie 20 SEPTEMBER2002

Registration number/Registrasienommer: 35/7.1.3/0347

Name of medicine/Naam van medisyne: CO-PRITOR 40/12,5 MG

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
HYDROCHLOROTHIAZIDE ... 12,5 mg
TELMISARTAN ... 40,0 mg

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

Applicant/Applikant: INGELHEIM PHARMACEUTICALS (PTY) LTD

Manufacturer/Vervaardiger: BOEHRINGER INGELHEIM, BIBERACH AN DER RISS GERMANY
BOEHRINGER INGELHEIM, INGELHEIM AM RHEIN, GERMANY

Packer/Verpakker: BOEHRINGER INGELHEIM, INGELHEIM AM RHEIN, GERMANY

Laboratory/Laboratorium: BOEHRINGER INGELHEIM, INGELHEIM AM RHEIN, GERMANY
HOECHST MARION ROUSSEL, WALTLOO RSA
INGELHEIM PHARMACEUTICALS, RANDBURG RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 20 SEPTEMBER 2002
Datum van registrasie 20 SEPTEMBER 2002

Registration number/Registrasienommer: 36/2.8/0009

Name of medicine/Naam van medisyne: COMPRAL HEADACHE POWDERS

Dosage form/Doseringsvorm: POWDER/POEIER

Active ingredients/Aktiewe bestanddele:
EACH SACHET CONTAINS/ELKE SAKKIE BEVAT:
ASPIRIN ... 453,60 mg
CAFFEINE ... 64,80 mg
PARACETAMOL ... 324,00 mg

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

Applicant/Applikant: ADCOCK INGRAM LTD

Manufacturer/Vervaardiger: ADCOCK INGRAM LTD, CLAYVILLE, RSA
PHARMA-Q, INDUSTRIA RSA

Packer/Verpakker: ADCOCK INGRAM LTD, CLAYVILLE, RSA
PHARMA-Q, INDUSTRIA RSA

Laboratory/Laboratorium: ADCOCK INGRAM LTD, CLAYVILLE, RSA
PHARMA-Q, INDUSTRIA RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 20 SEPTEMBER 2002
Datum van registrasie 20 SEPTEMBER 2002

Registration number/Registrasienommer: 36/2.8/0010

Name of medicine/Naam van medisyne: ASPIMOL POWDERS

Dosage form/Doseringsvorm: POWDER/POEIER

Active ingredients/Aktiewe bestanddele:
EACH SACHET CONTAINS/ELKE SAKKIE BEVAT:
ASPIRIN ... 453,60 mg
CAFFEINE ... 64,80 mg
PARACETAMOL ... 324,00 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, CLAYVILLE RSA

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

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

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 20 SEPTEMBER 2002
Datum van registrasie 20 SEPTEMBER 2002

Registration number/Registrasienommer: 36/2.1/0084

Name of medicine/Naam van medisyne: DIPRIVAN 2 % 50 ML

Dosage form/Doseringsvorm: INFUSION (PARENTERAL)/
INFUSIE (PARENTERAAL)

Active ingredients/Aktiewe bestanddele:
EACH 1,0 ml EMULSION CONTAINS/ELKE 1,0 ml EMULSIE BEVAT:
PROPOFOL ... 20,0 mg

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

Applicant/Applikant: ASTRAZENECA PHARMACEUTICALS (PTY) LTD

Manufacturer/Vervaardiger: ASTRAZENECA, CAPONAGO ITALY

Packer/Verpakker: ASTRAZENECA, CAPONAGO ITALY
ASTRAZENECA, CHESHIRE UK

Laboratory/Laboratorium: ASTRAZENECA, CAPONAGO ITALY
ASTRAZENECA, CHESHIRE UK
ASTRAZENECA, ALRODE, ALBERTON RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 20 SEPTEMBER 2002
Datum van registrasie 20 SEPTEMBER 2002

Registration number/Registrasienommer: 36/2.1/0085

Name of medicine/Naam van medisyne: DIPRIVAN 2 % PFS 10 ML

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH 1,0 ml EMULSION CONTAINS/ELKE 1,0 ml EMULSIE BEVAT :
PROPOFOL ... 20,0 mg

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

Applicant/Applikant: ASTRAZENECA PHARMACEUTICALS (PTY) LTD

Manufacturer/Vervaardiger: ASTRAZENECA, CAPONAGO ITALY

Packer/Verpakker: ASTRAZENECA, CAPONAGO ITALY
ASTRAZENECA, CHESHIRE UK

Laboratory/Laboratorium: ASTRAZENECA, CAPONAGO ITALY
ASTRAZENECA, CHESHIRE UK
ASTRAZENECA, ALRODE, ALBERTON RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 20 SEPTEMBER 2002
Datum van registrasie 20 SEPTEMBER 2002

Registration number/Registrasienommer: 36/2.1/0086

Name of medicine/Naam van medisyne: DIPRIVAN 2 % PFS 50 ML

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH 1,0 ml EMULSION CONTAINS/ELKE 1,0 ml EMULSIE BEVAT:
PROPOFOL ... 20,0 mg

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

Applicant/Applikant: ASTRAZENECA PHARMACEUTICALS (PTY) LTD

Manufacturer/Vervaardiger: ASTRAZENECA, CAPONAGO ITALY

Packer/Verpakker: ASTRAZENECA, CAPONAGO ITALY
ASTRAZENECA, CHESHIRE UK

Laboratory/Laboratorium: ASTRAZENECA, CAPONAGO ITALY
ASTRAZENECA, CHESHIRE UK
ASTRAZENECA, ALRODE, ALBERTON RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 20 SEPTEMBER 2002
Datum van registrasie 20 SEPTEMBER 2002

Registration number/Registrasienommer: 35/7.1/0224

Name of medicine/Naam van medisyne: CAVERJECT DC 40 UG

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH VIAL CONTAINS/ELKE FLESSIE BEVAT:
ALPROSTADIL ... 40,0 ug

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

Applicant/Applikant: PHARMACIA SOUTH AFRICA (PTY) LTD

Manufacturer/Vervaardiger: PHARMACIA & UPJOHN, RIJKSWEG, PUURS, BELGIUM

Packer/Verpakker: PHARMACIA & UPJOHN, RIJKSWEG, PUURS, BELGIUM
SANICO NV, TURNHOUT BELGIUM

Laboratory/Laboratorium: PHARMACIA & UPJOHN, RIJKSWEG, PUURS, BELGIUM
KHULULEKANI LABORATORY SERVICES, MIDRAND RSA
SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA RSA
PHARMACIA SOUTH AFRICA, MIDRAND RSA

Shelf-life/Rakleeftyd: 36 months/maande

Date of registration: 20 SEPTEMBER 2002
Datum van registrasie 20 SEPTEMBER 2002

Registration number/Registrasienommer: 35/7.1/0215

Name of medicine/Naam van medisyne: CAVERJECT DC 10 UG

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH 0,5 ml SOLUTION CONTAINS/ELKE 0,5 ml OPLOSSING BEVAT:
ALPROSTADIL ... 10,0 ug

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

Applicant/Applikant: PHARMACIA SOUTH AFRICA (PTY) LTD

Manufacturer/Vervaardiger: PHARMACIA & UPJOHN, LINDHAGENSGATAN SWEDEN

Packer/Verpakker: PHARMACIA & UPJOHN, LINDHAGENSGATAN SWEDEN

Laboratory/Laboratorium PHARMACIA & UPJOHN, LINDHAGENSGATAN SWEDEN
KHULULEKANI LABORATORY SERVICES, MIDRAND RSA
SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA RSA
PHARMACIA SOUTH AFRICA, MIDRAND RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 20 SEPTEMBER 2002
Datum van registrasie 20 SEPTEMBER 2002

Registration number/Registrasienommer: 35/7.1/0216

Name of medicine/Naam van medisyne: CAVERJECT DC 20 UG

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH 0,5 ml SOLUTION CONTAINS/ELKE 0,5 ml OPLOSSING BEVAT
ALPROSTADIL ... 20,0 ug

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

Applicant/Applikant: PHARMACIA SOUTH AFRICA (PTY) LTD

Manufacturer/Vervaardiger: PHARMACIA & UPJOHN, LINDHAGENSGATAN SWEDEN

Packer/Verpakker: PHARMACIA & UPJOHN, LINDHAGENSGATAN SWEDEN

Laboratory/Laboratorium: PHARMACIA & UPJOHN, LINDHAGENSGATAN SWEDEN
KHULULEKANI LABORATORY SERVICES, MIDRAND RSA
SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA RSA
PHARMACIA SOUTH AFRICA, MIDRAND RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 20 SEPTEMBER 2002
Datum van registrasie 20 SEPTEMBER 2002

Registration number/Registrasienommer: 34/21.2/0359

Name of medicine/Naam van medisyne: METFORAL 500

Dosage form/Doseringsvorm: TABLET

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

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

Applicant/Applikant: ADCOCK INGRAM LTD

Manufacturer/Vervaardiger: BERLIN-CHEMIE, TEMPELHOFER, BERLIN GERMANY

Packer/Verpakker: BERLIN-CHEMIE, GLIENICKER, BERLIN GERMANY
ADCOCK INGRAM LTD, CLAYVILLE, RSA

Laboratory/Laboratorium: BERLIN-CHEMIE, TEMPELHOFER, BERLIN GERMANY
BERLIN-CHEMIE, GLIENICKER, BERLIN GERMANY
ADCOCK INGRAM LTD, CLAYVILLE, RSA

Shelf-life/Rakleeftyd: 60 months/maande

Date of registration: 20 SEPTEMBER 2002
Datum van registrasie 20 SEPTEMBER 2002

Registration number/Registrasienommer: 34/21.2/0360

Name of medicine/Naam van medisyne: METFORAL 850

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
METFORMIN HYDROCHLORIDE ... 850,0 mg

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

Applicant/Applikant: ADCOCK INGRAM LTD

Manufacturer/Vervaardiger: BERLIN-CHEMIE, TEMPELHOFER, BERLIN GERMANY

Packer/Verpakker: BERLIN-CHEMIE, GLIENICKER, BERLIN GERMANY
ADCOCK INGRAM LTD, CLAYVILLE, RSA

Laboratory/Laboratorium: BERLIN-CHEMIE, TEMPELHOFER, BERLIN GERMANY
BERLIN-CHEMIE, GLIENICKER, BERLIN GERMANY
ADCOCK INGRAM LTD, CLAYVILLE, RSA

Shelf-life/Rakleeftyd: 60 months/maande

Date of registration: 20 SEPTEMBER 2002
Datum van registrasie 20 SEPTEMBER 2002

Registration number/Registrasienommer: 35/3.1/0019

Name of medicine/Naam van medisyne: FLAMLESS

Dosage form/Doseringsvorm: CAPSULES/KAPSULES

Active ingredients/Aktiewe bestanddele:
EACH CAPSULE CONTAINS/ELKE KAPSULE BEVAT:
KETOPROFEN ... 200,0 mg

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

Applicant/Applikant: TRIOMED (PTY) LTD

Manufacturer/Vervaardiger: ETHYPHARM LABORATORIES, HOUDAN FRANCE

Packer/Verpakker: ETHYPHARM LABORATORIES, HOUDAN FRANCE
DIVPHARM MANUFACTURING AND PACKAGING, LONGDALE RSA

Laboratory/Laboratorium: ETHYPHARM LABORATORIES, HOUDAN FRANCE
INSTITUTE FOR PHARMACEUTICAL SERVICES, BOKSBURG RSA
TRIOMED, PINELANDS, RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 20 SEPTEMBER 2002
Datum van registrasie 20 SEPTEMBER 2002

Registration number/Registrasienommer: 35/20.1.1/0101

Name of medicine/Naam van medisyne: ORPIC 250 MG TABLETS

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: PHARMACARE LIMITED

Manufacturer/Vervaardiger: LENNON LTD, PORT ELIZABETH RSA

Packer/Verpakker: LENNON LTD, PORT ELIZABETH RSA

Laboratory/Laboratorium: LENNON LTD, PORT ELIZABETH RSA
PHARMACARE LTD, PORT ELIZABETH RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 20 SEPTEMBER 2002
Datum van registrasie 20 SEPTEMBER 2002

Registration number/Registrasienommer: 35/20.1.1/0102

Name of medicine/Naam van medisyne: ORPIC 500 MG TABLETS

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: PHARMACARE LIMITED

Manufacturer/Vervaardiger: LENNON LTD, PORT ELIZABETH RSA

Packer/Verpakker: LENNON LTD, PORT ELIZABETH RSA

Laboratory/Laboratorium: LENNON LTD, PORT ELIZABETH RSA
PHARMACARE LTD, PORT ELIZABETH RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 20 SEPTEMBER 2002
Datum van registrasie 20 SEPTEMBER 2002

Registration number/Registrasienommer: 35/20.1.1/0103

Name of medicine/Naam van medisyne: ORPIC 750 MG TABLETS

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: PHARMACARE LIMITED

Manufacturer/Vervaardiger: LENNON LTD, PORT ELIZABETH RSA

Packer/Verpakker: LENNON LTD, PORT ELIZABETH RSA

Laboratory/Laboratorium: LENNON LTD, PORT ELIZABETH RSA
PHARMACARE LTD, PORT ELIZABETH RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 20 SEPTEMBER 2002
Datum van registrasie 20 SEPTEMBER 2002

Registration number/Registrasienommer: 35/14.2/0107

Name of medicine/Naam van medisyne: BURNAZIN

Dosage form/Doseringsvorm: CREAM/ROOM

Active ingredients/Aktiewe bestanddele:
EACH 100,0 g CREAM CONTAINS/ELKE 100,0 g ROOM BEVAT:
SILVER SULFADIAZINE ... 1,0 g

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

Applicant/Applikant: DANENE PHARMACEUTICALS (PTY) LTD

Manufacturer/Vervaardiger: PURNA PHARMACEUTICALS N.V.,PUURS,BELGIUM

Packer/Verpakker: PURNA PHARMACEUTICALS N.V.,PUURS,BELGIUM
DANENE PHARMACEUTICALS, PTA RSA

Laboratory/Laboratorium: PURNA PHARMACEUTICALS N.V.,PUURS,BELGIUM
RESEARCH INSTITUTE FOR IND. PHARMACY, POTCHEFSTROOM
SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA RSA
DANENE PHARMACEUTICALS, PTA RSA

Shelf-life/Rakleeftyd: 36 months/maande

Date of registration: 20 SEPTEMBER 2002
Datum van registrasie 20 SEPTEMBER 2002

Registration number/Registrasienommer: 35/7.5/0277

Name of medicine/Naam van medisyne: ADCO-SIMVASTATIN 10 MG

Dosage form/Doseringsvorm: TABLET

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

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

Applicant/Applikant: ADCOCK INGRAM LTD

Manufacturer/Vervaardiger: LECIVA AS, PRAGUE, CZECH REP
SYNTHON HISPANIA, SANT BOI DE LLOBREGAT SPAIN

Packer/Verpakker: LECIVA AS, PRAGUE, CZECH REP
SYNTHON HISPANIA, SANT BOI DE LLOBREGAT SPAIN
MANUFACTURING PACKAGING FARMACA , HEERENVEEN
THE NETHERLANDS

Laboratory/Laboratorium: LECIVA AS, PRAGUE, CZECH REP
SYNTHON HISPANIA, SANT BOI DE LLOBREGAT SPAIN
ADCOCK INGRAM LTD, CLAYVILLE, RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 20 SEPTEMBER 2002
Datum van registrasie 20 SEPTEMBER 2002

Registration number/Registrasienommer: 35/7.5/0278

Name of medicine/Naam van medisyne: ADCO-SIMVASTATIN 20 MG

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
SIMVASTATIN ... 20,0 mg

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

Applicant/Applikant: ADCOCK INGRAM LTD

Manufacturer/Vervaardiger: LECIVA AS, PRAGUE, CZECH REP
SYNTHON HISPANIA, SANT BOI DE LLOBREGAT, SPAIN

Packer/Verpakker: LECIVA AS, PRAGUE, CZECH REP
SYNTHON HISPANIA, SANT BOI DE LLOBREGAT, SPAIN
MANUFACTURING PACKAGING FARMACA , HEERENVEEN
THE NETHERLANDS

Laboratory/Laboratorium: LECIVA AS, PRAGUE, CZECH REP
SYNTHON HISPANIA, SANT BOI DE LLOBREGAT, SPAIN
ADCOCK INGRAM LTD, CLAYVILLE, RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 20 SEPTEMBER 2002
Datum van registrasie 20 SEPTEMBER 2002

Registration number/Registrasienommer: 35/7.5/0279

Name of medicine/Naam van medisyne: ADCO-SIMVASTATIN 40 MG

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
SIMVASTATIN .... 40,0 mg

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

Applicant/Applikant: ADCOCK INGRAM LTD

Manufacturer/Vervaardiger: LECIVA AS, PRAGUE, CZECH REP
SYNTHON HISPANIA, SANT BOI DE LLOBREGAT, SPAIN

Packer/Verpakker: LECIVA AS, PRAGUE, CZECH REP
SYNTHON HISPANIA, SANT BOI DE LLOBREGAT, SPAIN
MANUFACTURING PACKAGING FARMACA , HEERENVEEN
THE NETHERLANDS

Laboratory/Laboratorium: LECIVA AS, PRAGUE, CZECH REP
SYNTHON HISPANIA, SANT BOI DE LLOBREGAT, SPAIN
ADCOCK INGRAM LTD, CLAYVILLE, RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 20 SEPTEMBER 2002
Datum van registrasie 20 SEPTEMBER 2002

Registration number/Registrasienommer: 35/16.4/0320

Name of medicine/Naam van medisyne: ANDOLEX-C LOZENGES HONEY/LEMON

Dosage form/Doseringsvorm: LOZENGES/SUIGTABLETTE

Active ingredients/Aktiewe bestanddele:
EACH LOZENGE CONTAINS/ELKE SUIGTABLET BEVAT:
BENZYDAMINE HYDROCHLORIDE ... 3,0 mg
CETYLPYRIDINIUM CHLORIDE ... 1,33 mg

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

Applicant/Applikant: 3M PHARMACEUTICALS SA (PTY) LTD

Manufacturer/Vervaardiger: NESTLE, BLACKTOWN, AUSTRALIA

Packer/Verpakker: 3M, CHILVERS RD,THORNLEIGH, AUSTRALIA

Laboratory/Laboratorium: 3M, CHILVERS RD,THORNLEIGH, AUSTRALIA
ANALYTICON, KEMPTON PARK RSA
3M, ISANDO RSA

Shelf-life/Rakleeftyd: 36 months/maande

Date of registration: 20 SEPTEMBER 2002
Datum van registrasie 20 SEPTEMBER 2002

Registration number/Registrasienommer: 35/34/0290

Name of medicine/Naam van medisyne: EASY-CARE

Dosage form/Doseringsvorm: SOLUTION/OPLOSSING

Active ingredients/Aktiewe bestanddele:
EACH 1,0 ml SOLUTION CONTAINS/ELKE 1,0 ml OPLOSSING BEVAT:
POLIHEXANIDE ... 0,001 mg

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

Applicant/Applikant: NOVARTIS SOUTH AFRICA (PTY) LTD

Manufacturer/Vervaardiger: CIBA VISION, ONTARIO CANADA
CIBA VISION, MUNICH GERMANY
LABORATOIRES CIBA VISION,CEDEX,FRANCE

Packer/Verpakker: CIBA VISION, ONTARIO CANADA
CIBA VISION, MUNICH GERMANY
LABORATOIRES CIBA VISION,CEDEX,FRANCE
NOVARTIS, SPARTAN KEMPTON PARK RSA

Laboratory/Laboratorium: CIBA VISION, ONTARIO CANADA
CIBA VISION, MUNICH GERMANY
LABORATOIRES CIBA VISION,CEDEX,FRANCE
NOVARTIS, SPARTAN KEMPTON PARK RSA

Shelf-life/Rakleeftyd: 36 months/maande

Date of registration: 20 SEPTEMBER 2002
Datum van registrasie 20 SEPTEMBER 2002

Registration number/Registrasienommer: 35/20.1.2/0346

Name of medicine/Naam van medisyne: PENZYL 1 MIU (600 MG) INJECTION

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH VIAL CONTAINS/ELKE FLESSIE BEVAT:
BENZYLPENICILLIN ... 600,0 mg

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

Applicant/Applikant: GENERIX INTERNATIONAL (SA) (PTY) LTD

Manufacturer/Vervaardiger: HARBIN GENERAL PHARM FACTORY, PEOPLES REP OF CHINA

Packer/Verpakker: HARBIN GENERAL PHARM FACTORY, PEOPLES REP OF CHINA

Laboratory/Laboratorium: HARBIN GENERAL PHARM FACTORY, PEOPLES REP OF CHINA
CONSULTING CHEMICAL LAB, STAR STREET BOKSBURG RSA
GENERIX, ATHLONE, CAPE TOWN RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 20 SEPTEMBER 2002
Datum van registrasie 20 SEPTEMBER 2002

Registration number/Registrasienommer: 34/13.1/0424

Name of medicine/Naam van medisyne: BARRS POVIDONE-IODINE OINTMENT

Dosage form/Doseringsvorm: OINTMENT/SALF

Active ingredients/Aktiewe bestanddele:
EACH 100,0 g OINTMENT CONTAINS/ELKE 100,0 g SALF BEVAT:
POVIDONE-IODINE ... 10,0 g

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

Applicant/Applikant: BARRS PHARMACEUTICAL INDUSTRIES CC

Manufacturer/Vervaardiger: BARRS PHARM INDUSTRIES, OBSERVATORY RSA

Packer/Verpakker: BARRS PHARM INDUSTRIES, OBSERVATORY RSA

Laboratory/Laboratorium: BARRS PHARM INDUSTRIES, OBSERVATORY RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 20 SEPTEMBER 2002
Datum van registrasie 20 SEPTEMBER 2002

Registration number/Registrasienommer: 35/34/0291

Name of medicine/Naam van medisyne: ACTICLEAN

Dosage form/Doseringsvorm: SOLUTION/OPLOSSING

Active ingredients/Aktiewe bestanddele:
EACH 1,0 ml SOLUTION CONTAINS/ELKE 1,0 ml OPLOSSING BEVAT:
POLIHEXANIDE ... 0,001 mg

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

Applicant/Applikant: NOVARTIS SOUTH AFRICA (PTY) LTD

Manufacturer/Vervaardiger: CIBA VISION, ONTARIO CANADA
CIBA VISION, MUNICH GERMANY
LABORATOIRES CIBA VISION,CEDEX,FRANCE

Packer/Verpakker: CIBA VISION, ONTARIO CANADA
CIBA VISION, MUNICH GERMANY
LABORATOIRES CIBA VISION,CEDEX,FRANCE
NOVARTIS, SPARTAN KEMPTON PARK RSA

Laboratory/Laboratorium: CIBA VISION, ONTARIO CANADA
CIBA VISION, MUNICH GERMANY
LABORATOIRES CIBA VISION,CEDEX,FRANCE
NOVARTIS, SPARTAN KEMPTON PARK RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 20 SEPTEMBER 2002
Datum van registrasie 20 SEPTEMBER 2002

Registration number/Registrasienommer: 35/7.1.3/0317

Name of medicine/Naam van medisyne: RENIPRAL-CO

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT :
ENALAPRIL MALEATE ... 20,0 mg
HYDROCHLOROTHIAZIDE ... 12,50 mg

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

Applicant/Applikant: PHARMACARE LIMITED

Manufacturer/Vervaardiger: LENNON LTD, PORT ELIZABETH RSA

Packer/Verpakker: LENNON LTD, PORT ELIZABETH RSA

Laboratory/Laboratorium: LENNON LTD, PORT ELIZABETH RSA
PHARMACARE LTD, PORT ELIZABETH

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 20 SEPTEMBER 2002
Datum van registrasie 20 SEPTEMBER 2002

Registration number/Registrasienommer: 35/11.4.3/0341

Name of medicine/Naam van medisyne: ZANTAC EFFERVESCENT 75

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT :
RANITIDINE HYDROCHLORIDE EQUIVALENT TO
RANITIDINE ... 75,0 mg

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

Applicant/Applikant: GLAXO WELLCOME SA (PTY) LTD

Manufacturer/Vervaardiger: GLAXO WELLCOME, EVREUX FRANCE

Packer/Verpakker: GLAXO WELLCOME, EVREUX FRANCE
GLAXO WELLCOME, MIDRAND RSA

Laboratory/Laboratorium: GLAXO WELLCOME, EVREUX FRANCE
GLAXO WELLCOME, MIDRAND RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 20 SEPTEMBER 2002
Datum van registrasie 20 SEPTEMBER 2002

Registration number/Registrasienommer: 35/15.4/0408

Name of medicine/Naam van medisyne: CROMABAK 2 % EYE DROPS

Dosage form/Doseringsvorm: DROPS/DRUPPELS

Active ingredients/Aktiewe bestanddele:
EACH 100,0 ml LIQUID CONTAINS/ELKE 100,0 ml VLOEISTOF BEVAT:
SODIUM CROMOGLYCATE ... 2,0 g

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

Applicant/Applikant: GENOP HEALTHCARE (PTY) LTD

Manufacturer/Vervaardiger THISSEN LABORATOIRIES, L'ALLEUD BELGIUM

Packer/Verpakker: THISSEN LABORATOIRIES, L'ALLEUD BELGIUM

Laboratory/Laboratorium: THISSEN LABORATOIRIES, L'ALLEUD BELGIUM
INSTITUTE FOR PHARMACEUTICAL SERVICES,BOKSBURG
GENOP HEALTHCARE, HALFWAY HOUSE RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 20 SEPTEMBER 2002
Datum van registrasie 20 SEPTEMBER 2002

Registration number/Registrasienommer: 35/30.4/0414

Name of medicine/Naam van medisyne: EPREX 5 000 IU/0,5 ML

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH 1,0 ml SOLUTION CONTAINS/ELKE 1,0 ml OPLOSSING BEVAT:
EPOETIN ALFA ... 84,0 ug

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

Applicant/Applikant: JANSSEN PHARMACEUTICA (PTY) LTD

Manufacturer/Vervaardiger: VETTER PHARMA,SCHUTZENSTR,RAVENSBURG GERMANY

Packer/Verpakker: VETTER PHARMA,SCHUTZENSTR,RAVENSBURG GERMANY

Laboratory/Laboratorium: VETTER PHARMA,SCHUTZENSTR,RAVENSBURG GERMANY
CILAG AG, HOCHSTRASSE SWITZERLAND
JANSSEN PHARMACEUTICA, HALFWAY HOUSE RSA

Shelf-life/Rakleeftyd: 18 months/maande

Date of registration: 20 SEPTEMBER 2002
Datum van registrasie 20 SEPTEMBER 2002

Registration number/Registrasienommer: 35/30.4/0415

Name of medicine/Naam van medisyne: EPREX 6 000 IU/0,6 ML

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH 1,0 ml SOLUTION CONTAINS/ELKE 1,0 ml OPLOSSING BEVAT:
EPOETIN ALFA ... 84,0 ug

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

Applicant/Applikant: JANSSEN PHARMACEUTICA (PTY) LTD

Manufacturer/Vervaardiger: VETTER PHARMA,SCHUTZENSTR,RAVENSBURG GERMANY

Packer/Verpakker: VETTER PHARMA,SCHUTZENSTR,RAVENSBURG GERMANY

Laboratory/Laboratorium: VETTER PHARMA,SCHUTZENSTR,RAVENSBURG GERMANY
CILAG AG, HOCHSTRASSE SWITZERLAND
JANSSEN PHARMACEUTICA, HALFWAY HOUSE RSA

Shelf-life/Rakleeftyd: 18 months/maande

Date of registration: 20 SEPTEMBER 2002
Datum van registrasie 20 SEPTEMBER 2002

Registration number/Registrasienommer: 35/30.4/0416

Name of medicine/Naam van medisyne: EPREX 7 000 IU/0,7 ML

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH 1,0 ml SOLUTION CONTAINS/ELKE 1,0 ml OPLOSSING BEVAT:
EPOETIN ALFA ... 84,0 ug

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

Applicant/Applikant: JANSSEN PHARMACEUTICA (PTY) LTD

Manufacturer/Vervaardiger: VETTER PHARMA,SCHUTZENSTR,RAVENSBURG GERMANY

Packer/Verpakker: VETTER PHARMA,SCHUTZENSTR,RAVENSBURG GERMANY

Laboratory/Laboratorium: VETTER PHARMA,SCHUTZENSTR,RAVENSBURG GERMANY
CILAG AG, HOCHSTRASSE SWITZERLAN
JANSSEN PHARMACEUTICA, HALFWAY HOUSE RSA

Shelf-life/Rakleeftyd: 18 months/maande

Date of registration: 20 SEPTEMBER 2002
Datum van registrasie 20 SEPTEMBER 2002

Registration number/Registrasienommer: 35/30.4/0417

Name of medicine/Naam van medisyne: EPREX 8 000 IU/0,8 ML

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH 1,0 ML SOLUTION CONTAINS/ELKE 1,0 ml OPLOSSING BEVAT:
EPOETIN ALFA ... 84,0 ug

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

Applicant/Applikant: JANSSEN PHARMACEUTICA (PTY) LTD

Manufacturer/Vervaardiger: VETTER PHARMA,SCHUTZENSTR,RAVENSBURG GERMANY

Packer/Verpakker: VETTER PHARMA,SCHUTZENSTR,RAVENSBURG GERMANY

Laboratory/Laboratorium: VETTER PHARMA,SCHUTZENSTR,RAVENSBURG GERMANY
CILAG AG, HOCHSTRASSE SWITZERLAND
JANSSEN PHARMACEUTICA, HALFWAY HOUSE RSA

Shelf-life/Rakleeftyd: 18 months/maande

Date of registration: 20 SEPTEMBER 2002
Datum van registrasie 20 SEPTEMBER 2002

Registration number/Registrasienommer: 35/30.4/0418

Name of medicine/Naam van medisyne: EPREX 9 000 IU/0,9 ML

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH 1,0 ml SOLUTION CONTAINS/ELKE 1,0 ml OPLOSSING BEVAT:
EPOETIN ALFA ... 84,0 ug

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

Applicant/Applikant: JANSSEN PHARMACEUTICA (PTY) LTD

Manufacturer/Vervaardiger: VETTER PHARMA,SCHUTZENSTR,RAVENSBURG GERMANY

Packer/Verpakker: VETTER PHARMA,SCHUTZENSTR,RAVENSBURG GERMANY

Laboratory/Laboratorium: VETTER PHARMA,SCHUTZENSTR,RAVENSBURG GERMANY
CILAG AG, HOCHSTRASSE SWITZERLAND
JANSSEN PHARMACEUTICA, HALFWAY HOUSE RSA

Shelf-life/Rakleeftyd: 18 months/maande

Date of registration: 20 SEPTEMBER 2002
Datum van registrasie 20 SEPTEMBER 2002

Registration number/Registrasienommer: 36/2.7/0184

Name of medicine/Naam van medisyne: NUROFEN SOFT GEL CAPSULES

Dosage form/Doseringsvorm: CAPSULES/KAPSULES

Active ingredients/Aktiewe bestanddele:
EACH CAPSULE CONTAINS/ELKE KAPSULE 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: BANNER PHARMACAPS, TILBURG, NETHERLANDS

Packer/Verpakker: BOOTS, NOTTINGHAM UK

Laboratory/Laboratorium: BANNER PHARMACAPS, TILBURG, NETHERLANDS
BOOTS, NOTTINGHAM UK
PHARMACEUTICAL CONTRACTORS, ISANDO RSA
RECKITT BENCKISER PHARMACEUTICALS, MOBENI RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 20 SEPTEMBER 2002
Datum van registrasie 20 SEPTEMBER 2002

Registration number/Registrasienommer: 35/30.1/0181

Name of medicine/Naam van medisyne: FLUAD

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH 0,5 ml DOSE CONTAINS/ELKE 0,5 ml DOSIS BEVAT:
INFLUENZA VIRUS A/BEIJING/535/95 (H1N1) ... 15,0 ug
INFLUENZA VIRUS A/SYDNEY/5/97-LIKE (H3N2) ... 15,0 ug
INFUENZA VIRUS B/BEIJING/184/93-LIKE ... 15,0 ug

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

Applicant/Applikant: BIOVAC SA (PTY) LTD

Manufacturer/Vervaardiger: CHIRON S.P.A , SIENA ITALY

Packer/Verpakker: CHIRON S.P.A , SIENA ITALY
BIOVAC SA, WADEVILLE RSA

Laboratory/Laboratorium: CHIRON S.P.A , SIENA ITALY
BIOVAC SA, WADEVILLE RSA
THE NATIONAL CONTROL LABORATORY,BLOEMFONTEIN

Shelf-life/Rakleeftyd: 12 months/maande

Date of registration: 20 SEPTEMBER 2002
Datum van registrasie 20 SEPTEMBER 2002

Registration number/Registrasienommer: 99/21.1/9

Name of medicine/Naam van medisyne: HEXASOL HB

Dosage form/Doseringsvorm: INJECTION

Active ingredients/Aktiewe bestanddele:
EACH 1,0 ml SOLUTION CONTAINS
FLUNIXIN MEGLUMINE ... 20,0 mg
OXYTETRACYCLINE ... 300,0 mg

Conditions of registration/Voorwaardes vir registrasie:

Applicant/Applikant: NORBROOK LABORATORIES S.A. (PTY) LTD

Manufacturer/Vervaardiger: NORBROOK LABORATORIES, CAMLOUGH ROAD NEWRY N/IRELAND

Packer/Verpakker: NORBROOK LABORATORIES, CAMLOUGH ROAD NEWRY N/IRELAND

Laboratory/Laboratorium: NORBROOK LABORATORIES, CAMLOUGH ROAD NEWRY N/IRELAND
NORBROOK LABORATORIES S.A. (PTY) LTD RSA FPRR

Shelf-life/Rakleeftyd: 24 MONTHS/MAANDE

Date of registration: 20 SEPTEMBER 2002
Datum van registrasie 20 SEPTEMBER 2002

Registration number/Registrasienommer: 31/2.6/0515

Name of medicine/Naam van medisyne: CALMPOSE TABLETS

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
DIAZEPAM ... 5,0 mg

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

Applicant/Applikant: RANBAXY (SA) (PTY) LTD

Manufacturer/Vervaardiger: RANBAXY, PAONTA SAHIB INDIA
RANBAXY, DEWAS INDIA

Packer/Verpakker: RANBAXY, PAONTA SAHIB INDIA
RANBAXY, DEWAS INDIA

Laboratory/Laboratorium: RANBAXY, PAONTA SAHIB INDIA
RANBAXY, DEWAS INDIA
ALLIANCE PHARMA, VILLAGE MAIN RSA
BIOCHEMICAL & SCIENTIFIC CONSULTANTS, HILTON
KHULULEKANI LABORATORY SERVICES, MIDRAND
RANBAXY, CENTURION RSA

Shelf-life/Rakleeftyd: 36 months/maande

Date of registration: 25 SEPTEMBER 2002
Datum van registrasie 25 SEPTEMBER 2002

Registration number/Registrasienommer: 32/20.1.1/0444

Name of medicine/Naam van medisyne: RALCLOR GRANULES FOR ORAL SUSPENSION 250 mg/5 ml

Dosage form/Doseringsvorm: SUSPENSION/SUSPENSIE

Active ingredients/Aktiewe bestanddele:
EACH 5,0 ml SUSPENSION CONTAINS/ELKE 5,0 ml SUSPENSIE BEVAT:
CEFACLOR EQUIVALENT TO CEFACLOR ANHYDROUS ... 250,0 mg

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

Applicant/Applikant: RANBAXY (SA) (PTY) LTD

Manufacturer/Vervaardiger: RANBAXY, DEWAS INDIA

Packer/Verpakker: RANBAXY, DEWAS INDIA

Laboratory/Laboratorium: RANBAXY, DEWAS INDIA
ALLIANCE PHARMA, VILLAGE MAIN RSA
BIOCHEMICAL & SCIENTIFIC CONSULTANTS, HILTON
KHULULEKANI LABORATORY SERVICES, MIDRAND
RANBAXY, CENTURION RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 25 SEPTEMBER 2002
Datum van registrasie: 25 SEPTEMBER 2002

Registration number/Registrasienommer: 32/20.1.1/0445

Name of medicine/Naam van medisyne: RALCLOR GRANULES FOR ORAL SUSPENSION 375 mg/5 ml

Dosage form/Doseringsvorm: SUSPENSION/SUSPENSIE

Active ingredients/Aktiewe bestanddele:
EACH 5,0 ml SUSPENSION CONTAINS/ELKE 5,0 ml SUSPENSIE BEVAT:
CEFACLOR EQUIVALENT TO CEFACLOR ANHYDROUS ... 375,0 mg

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

Applicant/Applikant: RANBAXY (SA) (PTY) LTD

Manufacturer/Vervaardiger: RANBAXY, DEWAS INDIA

Packer/Verpakker: RANBAXY, DEWAS INDIA

Laboratory/Laboratorium: RANBAXY, DEWAS INDIA
ALLIANCE PHARMA, VILLAGE MAIN RSA
BIOCHEMICAL & SCIENTIFIC CONSULTANTS, HILTON
KHULULEKANI LABORATORY SERVICES, MIDRAND
RANBAXY, CENTURION RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 25 SEPTEMBER 2002
Datum van registrasie 25 SEPTEMBER 2002

Registration number/Registrasienommer: 33/19/0059

Name of medicine/Naam van medisyne: PROPESS

Dosage form/Doseringsvorm: PESSARIES/VAGINALE SETPILLE

Active ingredients/Aktiewe bestanddele:
EACH PESSARY CONTAINS/ELKE PESSARIUM BEVAT:
DINOPROSTONE ... 10,0 mg

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

Applicant/Applikant: FERRING (PTY) LTD

Manufacturer/Vervaardiger: CONTROLLED THERAPEUTICS, SCOTLAND

Packer/Verpakker: CONTROLLED THERAPEUTICS, SCOTLAND
FERRING AB, MALMO SWEDEN

Laboratory/Laboratorium: CONTROLLED THERAPEUTICS, SCOTLAND UNK
FERRING AB, MALMO SWEDEN
FERRING, KEMPTON PARK RSA

Shelf-life/Rakleeftyd: 36 months/maande

Date of registration: 25 SEPTEMBER 2002
Datum van registrasie 25 SEPTEMBER 2002

Registration number/Registrasienommer: 32/22.1.4/0727

Name of medicine/Naam van medisyne: CAL-D-VITA EFFERVESCENT

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH EFFERVESCENT TABLET CONTAINS/ELKE BRUISTABLET:
CALCIUM CARBONATE EQUIVALENT TO CALCIUM ... 600,0 mg
VITAMIN D ... 440,0 i.u.

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

Applicant/Applikant: ROCHE PRODUCTS (PTY) LTD

Manufacturer/Vervaardiger: LABORATORIES ROCHE NICHOLAS, GAILLARD

Packer/Verpakker: LABORATORIES ROCHE NICHOLAS, GAILLARD

Laboratory/Laboratorium: LABORATORIES ROCHE NICHOLAS, GAILLARD
ROCHE, ISANDO RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 25 SEPTEMBER 2002
Datum van registrasie 25 SEPTEMBER 2002

Printed by and obtainable from the Government Printer, Bosman Street, Private Bag X85, Pretoria, 0001
Publications: Tel: (012) 334-4508, 334-4509, 334-4510
Advertisements: Tel: (012) 334-4673, 334-4674, 334-4504
Subscriptions: Tel: (012) 334-4735, 334-4736, 334-4737
Cape Town Branch: Tel: (021) 465-7531

Gedruk deur en verkrygbaar by die Staatsdrukker, Bosmanstraat, Privaatsak X85, Pretoria, 0001
Publikasies: Tel: (012) 334-4508, 334-4509, 334-4510
Advertensies: Tel: (012) 334-4673, 334-4674, 334-4504
Subskripsies: Tel: (012) 334-4735, 334-4736, 334-4737
Kaapstad-tak: Tel: (021) 465-7531