Government Gazette
Staatskoerant

REPUBLIC OF SOUTH AFRICA
REPUBLIEK VAN SUID-AFRIKA

Vol. 436 Pretoria, 9 October / Oktober 2001 No. 22727

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

CONTENTS

INHOUD

NOTICE 2110 OF 2001

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 2110 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 • BYLAE

Registration number/Registrasienommer: 31/2.9/0647

Name of medicine/Naam van medisyne: TRAMAL SR 150 MG

Dosage form/Doseringsvorm: TABLET

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

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

Applicant/Applikant: JANSSEN PHARMACEUTICA (PTY) LTD

Manufacturer/Vervaardiger: GRUNENTHAL, STOLBERG, GERMANY

Packer/Verpakker: GRUNENTHAL, STOLBERG, GERMANY
JANSSEN PHARMACEUTICA, HALFWAY HOUSE RSA

Laboratory/Laboratorium: GRUNENTHAL, STOLBERG, GERMANY
JANSSEN PHARMACEUTICA, HALFWAY HOUSE RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 03 SEPTEMBER 2001
Datum van registrasie 03 SEPTEMBER 2001

Registration number/Registrasienommer: 31/2.9/0646

Name of medicine/Naam van medisyne: TRAMAL SR 100 MG

Dosage form/Doseringsvorm: TABLET

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

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

Applicant/Applikant: JANSSEN PHARMACEUTICA (PTY) LTD

Manufacturer/Vervaardiger: GRUNENTHAL, STOLBERG, GERMANY

Packer/Verpakker: GRUNENTHAL, STOLBERG, GERMANY
JANSSEN PHARMACEUTICA, HALFWAY HOUSE RSA

Laboratory/Laboratorium: GRUNENTHAL, STOLBERG, GERMANY
JANSSEN PHARMACEUTICA, HALFWAY HOUSE RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 03 SEPTEMBER 2001
Datum van registrasie 03 SEPTEMBER 2001

Registration number/Registrasienommer: T/30.2/745

Name of medicine/Naam van medisyne: MEASLEGAM IM

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH 2,0 ml SOLUTION CONTAINS/ELKE 2,0 ml OPLOSSING BEVAT:
HUMAN ANTIMEASLES IMMUNOGLOBULIN
TITRE EQUAL TO OR MORE THAN ... 1:640

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

Applicant/Applikant: NATAL BIOPRODUCTS INSTITUTE

Manufacturer/Vervaardiger: NATAL BIOPRODUCTS INSTITUTE, PINETOWN RSA

Packer/Verpakker: NATAL BIOPRODUCTS INSTITUTE, PINETOWN RSA

Laboratory/Laboratorium: NATAL BIOPRODUCTS INSTITUTE, PINETOWN RSA
NATIONAL CONTROL LAB (NCL) BLOEMFONTEIN, RSA

Shelf-life/Rakleeftyd: 36 months/maande

Date of registration: 03 SEPTEMBER 2001
Datum van registrasie 03 SEPTEMBER 2001

Registration number/Registrasienommer: 31/2.9/0648

Name of medicine/Naam van medisyne: TRAMAL SR 200 MG

Dosage form/Doseringsvorm: TABLET

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

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

Applicant/Applikant: JANSSEN PHARMACEUTICA (PTY) LTD

Manufacturer/Vervaardiger: GRUNENTHAL, STOLBERG, GERMANY

Packer/Verpakker: GRUNENTHAL, STOLBERG, GERMANY
JANSSEN PHARMACEUTICA, HALFWAY HOUSE RSA

Laboratory/Laboratorium: GRUNENTHAL, STOLBERG, GERMANY
JANSSEN PHARMACEUTICA, HALFWAY HOUSE RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 03 SEPTEMBER 2001
Datum van registrasie 03 SEPTEMBER 2001

Registration number/Registrasienommer: 34/34/0128

Name of medicine/Naam van medisyne: REBETRON

Dosage form/Doseringsvorm: COMBINATION OF DOSAGE FORMS

Active ingredients/Aktiewe bestanddele:
EACH 0,2 ml SOLUTION CONTAINS/ELKE 0,2 ml OPLOSSING BEVAT:
INTERFERON ALFA 2-b ... 3 million iu

EACH CAPSULE CONTAINS/ELKE KAPSULE BEVAT
RIBAVIRIN ... 200,0 mg

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

Applicant/Applikant: SCHERING-PLOUGH (PTY) LTD

Manufacturer/Vervaardiger: SCHERING-PLOUGH, INNISHANNON IRELAND
SCHERING-PLOUGH, LAS PIEDRAS PUERTO RICO

Packer/Verpakker: SCHERING-PLOUGH, INNISHANNON IRELAND
SCHERING-PLOUGH, LAS PIEDRAS PUERTO RICO
SCHERING-PLOUGH, HEIST-OP-DEN-BERG BELGIUM
SCHERING-PLOUGH, ISANDO RSA

Laboratory/Laboratorium: SCHERING-PLOUGH, INNISHANNON IRELAND
SCHERING-PLOUGH, LAS PIEDRAS PUERTO RICO
SCHERING-PLOUGH, ISANDO RSA

Shelf-life/Rakleeftyd: 15 months/maande

Date of registration: 01 AUGUST 2001
Datum van registrasie 01 AUGUSTUS 2001

Registration number/Registrasienommer: 33/34/0158

Name of medicine/Naam van medisyne: TURPENTINE OIL-DAROL

Dosage form/Doseringsvorm: OIL/OLIE

Active ingredients/Aktiewe bestanddele:
EACH 100,0 ml OIL CONTAINS/ELKE 100,0 ml OLIE BEVAT:
TURPENTINE OIL .... 100,0 ml

Conditions of registration/Voorwaardes vir registrasie:
1, 2, 3, 4, 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: 05 SEPTEMBER 2001
Datum van registrasie 05 SEPTEMBER 2001

Registration number/Registrasienommer: 33/34/0524

Name of medicine/Naam van medisyne: NIQUITIN CQ 14 mg

Dosage form/Doseringsvorm: TRANSDERMAL THERAPEUTIC SYSTEM
TRANSDERMALE TERAPEUTIESE SISTEEM

Active ingredients/Aktiewe bestanddele:
EACH 15 cm^2 PATCH CONTAINS/ELKE 15 cm^2 PLAKKER BEVAT:
NICOTINE ... 78,0 mg

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

Applicant/Applikant: GROUP LABORATORIES SA (PTY) LTD

Manufacturer/Vervaardiger: ALZA CORPORATION, VACAVILLE USA

Packer/Verpakker: ALZA CORPORATION, VACAVILLE USA
SMITHKLINE BEECHAM, EPPING RSA

Laboratory/Laboratorium: ALZA CORPORATION, VACAVILLE USA
SMITHKLINE BEECHAM, EPPING RSA

Shelf-life/Rakleeftyd: 30 months/maande

Date of registration: 01 AUGUST 2001
Datum van registrasie 01 AUGUSTUS 2001

Registration number/Registrasienommer: 33/34/0523

Name of medicine/Naam van medisyne: NIQUITIN CQ 7 mg

Dosage form/Doseringsvorm: TRANSDERMAL THERAPEUTIC SYSTEM
TRANSDERMALE TERAPEUTIESE SISTEEM

Active ingredients/Aktiewe bestanddele:
EACH 7 cm^2 PATCH CONTAINS/ELKE 7 cm^2 PLAKKER BEVAT:
NICOTINE ... 36,0 mg

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

Applicant/Applikant: GROUP LABORATORIES SA (PTY) LTD

Manufacturer/Vervaardiger: ALZA CORPORATION, VACAVILLE USA

Packer/Verpakker: ALZA CORPORATION, VACAVILLE USA
SMITHKLINE BEECHAM, EPPING RSA

Laboratory/Laboratorium: ALZA CORPORATION, VACAVILLE USA
SMITHKLINE BEECHAM, EPPING RSA

Shelf-life/Rakleeftyd: 30 months/maande

Date of registration: 01 AUGUST 2001
Datum van registrasie 01 AUGUSTUS 2001

Registration number/Registrasienommer: 34/15.4/0037

Name of medicine/Naam van medisyne: EMADINE

Dosage form/Doseringsvorm: SOLUTION/OPLOSSING

Active ingredients/Aktiewe bestanddele:
EACH 1,0 ml SOLUTION CONTAINS/ELKE 1,0 ml OPLOSSING NBEVBAT:
EMEDASTINE DIFUMARATE EQUIVALENT TO
EMEDASTINE ... 0,5 mg

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

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

Manufacturer/Vervaardiger: ALCON-COUVREUR, PUURS BELGIUM

Packer/Verpakker: ALCON-COUVREUR, PUURS BELGIUM

Laboratory/Laboratorium: ALCON-COUVREUR, PUURS BELGIUM
ALCON, RANDBURG RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 01 AUGUST 2001
Datum van registrasie 01 AUGUSTUS 2001

Registration number/Registrasienommer: 33/34/0525

Name of medicine/Naam van medisyne: NIQUITIN CQ 21 mg

Dosage form/Doseringsvorm: TRANSDERMAL THERAPEUTIC SYSTEM
TRANSDERMALE TERAPEUTIESE SISTEEM

Active ingredients/Aktiewe bestanddele:
EACH 22 cm^2 PATCH CONTAINS/ELKE 22 cm^2 PLAKKER BEVAT:
NICOTINE ... 114,0 mg

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

Applicant/Applikant: GROUP LABORATORIES SA (PTY) LTD

Manufacturer/Vervaardiger: ALZA CORPORATION, VACAVILLE USA

Packer/Verpakker: ALZA CORPORATION, VACAVILLE USA
SMITHKLINE BEECHAM, EPPING RSA

Laboratory/Laboratorium: ALZA CORPORATION, VACAVILLE USA
SMITHKLINE BEECHAM, EPPING RSA

Shelf-life/Rakleeftyd: 30 months/maande

Date of registration: 01 AUGUST 2001
Datum van registrasie 01 AUGUSTUS 2001

Registration number/Registrasienommer: 34/34/0329

Name of medicine/Naam van medisyne: NICORETTE INHALER

Dosage form/Doseringsvorm: INHALER/INHALEERDER

Active ingredients/Aktiewe bestanddele:
EACH CARTRIDGE CONTAINS/ELKE KASET BEVAT:
NICOTINE ... 10,0 mg

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

Applicant/Applikant: PHARMACIA & UPJOHN (PTY) LTD

Manufacturer/Vervaardiger: PHARMACIA & UPJOHN, HELSINBORG SWEDEN

Packer/Verpakker: PHARMACIA & UPJOHN, HELSINBORG SWEDEN

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

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 01 AUGUST 2001
Datum van registrasie 01 AUGUSTUS 2001

Registration number/Registrasienommer: 33/2.7/0435

Name of medicine/Naam van medisyne: VARIPAN 500 MG TABLET

Dosage form/Doseringsvorm: TABLET

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

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

Applicant/Applikant: DANENE PHARMACEUTICALS (PTY) LTD

Manufacturer/Vervaardiger: VARICHEM LABORATORIES,HARARE, ZIMBABWE

Packer/Verpakker: VARICHEM LABORATORIES,HARARE, ZIMBABWE

Laboratory/Laboratorium: VARICHEM LABORATORIES,HARARE, ZIMBABWE
RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, POTCHEFSTROOM
SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA RSA
DANENE PHARMACEUTICALS, PTA RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 01 AUGUST 2001
Datum van registrasie 01 AUGUSTUS 2001

Registration number/Registrasienommer: 34/20.1.1/0111

Name of medicine/Naam van medisyne: SCHEIN CEFUROXIME 750 MG

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH VIAL CONTAINS/ELKE FLESSIE BEVAT:
CEFUROXIME SODIUM EQUIVALENT TO
CEFUROXIME ... 750,0 mg

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

Applicant/Applikant: TRIOMED (PTY) LTD

Manufacturer/Vervaardiger: MARSAM PHARMACEUTICALS INC, NEW JERSEY USA

Packer/Verpakker: MARSAM PHARMACEUTICALS INC, NEW JERSEY USA

Laboratory/Laboratorium: MARSAM PHARMACEUTICALS INC, NEW JERSEY USA
INSTITUTE FOR PHARM & CHEM SERVICE,
TECHNIKON PRETORIA RSA
TRIOMED, DURBANVILLE RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 02 AUGUST 2001
Datum van registrasie 02 AUGUSTUS 2001

Registration number/Registrasienommer: 34/20.1.1/0112

Name of medicine/Naam van medisyne: SCHEIN CEFUROXIME 1,5 G

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH VIAL CONTAINS/ELKE FLESSIE BEVAT :
CEFUROXIME SODIUM EQUIVALENT TO
CEFUROXIME ... 1,5 g

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

Applicant/Applikant: TRIOMED (PTY) LTD

Manufacturer/Vervaardiger: MARSAM PHARMACEUTICALS INC, NEW JERSEY USA

Packer/Verpakker: MARSAM PHARMACEUTICALS INC, NEW JERSEY USA

Laboratory/Laboratorium: MARSAM PHARMACEUTICALS INC, NEW JERSEY USA
INSTITUTE FOR PHARM & CHEM SERVICE, TECHNIKON
PRETORIA RSA
TRIOMED, DURBANVILLE RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 01 AUGUST 2001
Datum van registrasie: 01 AUGUSTUS 2001

Registration number/Registrasienommer: 34/3.1/0189

Name of medicine/Naam van medisyne: MOBIC SUSPENSION 7,5 mg/5 ml

Dosage form/Doseringsvorm: SUSPENSION/SUSPENSIE

Active ingredients/Aktiewe bestanddele:
EACH 5,0 ml SUSPENSION CONTAINS/ELKE 5,0 ml SUSPENSIE BEVAT :
MELOXICAM ... 7,5 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
ROXANE LABORATORIES INC, OHIO USA

Packer/Verpakker: BOEHRINGER INGELHEIM, BIBERACH AN DER RISS GERMANY
ROXANE LABORATORIES INC, OHIO USA

Laboratory/Laboratorium: BOEHRINGER INGELHEIM, BIBERACH AN DER RISS GERMANY
ROXANE LABORATORIES INC, OHIO USA
HOECHST MARION ROUSSEL, WALTLOO RSA
INGELHEIM PHARMACEUTICALS, RANDBURG RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 02 AUGUST 2001
Datum van registrasie 02 AUGUSTUS 2001

Registration number/Registrasienommer: 34/7.1.3/0441

Name of medicine/Naam van medisyne: CO-DIOVAN 160

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
HYDROCHLOROTHIAZIDE ... 12,5 mg
VALSARTAN ... 160,0 mg

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

Applicant/Applikant: NOVARTIS SOUTH AFRICA (PTY) LTD

Manufacturer/Vervaardiger: NOVARTIS, STEIN SWITZERLAND

Packer/Verpakker: NOVARTIS, STEIN SWITZERLAND
NOVARTIS, SPARTAN KEMPTON PARK RSA

Laboratory/Laboratorium: NOVARTIS, STEIN SWITZERLAND
NOVARTIS, SPARTAN KEMPTON PARK RSA
INSPECTORATE M & L, ORMONDE RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 02 AUGUST 2001
Datum van registrasie 02 AUGUSTUS 2001

Registration number/Registrasienommer: 34/5.3/0203

Name of medicine/Naam van medisyne: REMINYL 8 mg

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
GALANTAMINE HYDROBROMIDE EQUIVALENT TO
GALANTAMINE ... 8,0 mg

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

Applicant/Applikant: JANSSEN PHARMACEUTICA (PTY) LTD

Manufacturer/Vervaardiger: JANSSEN-CILAG, LATINA ITALY

Packer/Verpakker: JANSSEN PHARMACEUTICA, HALFWAY HOUSE RSA
JANSSEN PHARMACEUTICA NV, BEERSE BELGIUM

Laboratory/Laboratorium: JANSSEN-CILAG, LATINA ITALY
JANSSEN PHARMACEUTICA, HALFWAY HOUSE RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 03 AUGUST 2001
Datum van registrasie 03 AUGUSTUS 2001

Registration number/Registrasienommer: 34/5.3/0202

Name of medicine/Naam van medisyne: REMINYL 4 mg

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
GALANTAMINE HYDROBROMIDE EQUIVALENT TO
GALANTAMINE ... 4,0 mg

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

Applicant/Applikant: JANSSEN PHARMACEUTICA (PTY) LTD

Manufacturer/Vervaardiger: JANSSEN-CILAG, LATINA ITALY

Packer/Verpakker: JANSSEN PHARMACEUTICA NV, BEERSE BELGIUM
JANSSEN PHARMACEUTICA, HALFWAY HOUSE RSA

Laboratory/Laboratorium: JANSSEN-CILAG, LATINA ITALY
JANSSEN PHARMACEUTICA, HALFWAY HOUSE RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 03 AUGUST 2001
Datum van registrasie 03 AUGUSTUS 2001

Registration number/Registrasienommer: 34/26/0226

Name of medicine/Naam van medisyne: P&U METHOTREXATE CSV 1000 mg/10 ml INJECTION

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH 1,0 ml SOLUTION CONTAINS/ELKE 1,0 ml OPLOSSING BEVAT:
METHOTREXATE ... 100,0 mg

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

Applicant/Applikant: PHARMACIA & UPJOHN (PTY) LTD

Manufacturer/Vervaardiger: PHARMACIA & UPJOHN, BENTLEY AUSTRALIA

Packer/Verpakker: PHARMACIA & UPJOHN, BENTLEY AUSTRALIA

Laboratory/Laboratorium: PHARMACIA & UPJOHN, BENTLEY AUSTRALIA
KHULULEKANI LABORATORY SERVICES, MIDRAND RSA
SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA RSA
PHARMACIA & UPJOHN, MIDRAND RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 06 AUGUST 2001
Datum van registrasie 06 AUGUSTUS 2001

Registration number/Registrasienommer: 34/5.3/0204

Name of medicine/Naam van medisyne: REMINYL 12 mg

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
GALANTAMINE HYDROBROMIDE EQUIVALENT TO GALANTAMINE ... 12,0 mg

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

Applicant/Applikant: JANSSEN PHARMACEUTICA (PTY) LTD

Manufacturer/Vervaardiger: JANSSEN-CILAG, LATINA ITALY

Packer/Verpakker: JANSSEN PHARMACEUTICA, HALFWAY HOUSE RSA
JANSSEN PHARMACEUTICA NV, BEERSE BELGIUM

Laboratory/Laboratorium: JANSSEN-CILAG, LATINA ITALY
JANSSEN PHARMACEUTICA, HALFWAY HOUSE RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 03 AUGUST 2001
Datum van registrasie 03 AUGUSTUS 2001

Registration number/Registrasienommer: 33/21.10/0522

Name of medicine/Naam van medisyne: GONAL-F 150

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH AMPOULE CONTAINS/ELKE AMPUUL BEVAT:
FOLLITROPIN ALFA ... 150,0 iu

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

Applicant/Applikant: SERONO SOUTH AFRICA (PTY)LTD

Manufacturer/Vervaardiger: INDUSTRIA FARMACEUTICA SERONO, BARI ITALY

Packer/Verpakker: INDUSTRIA FARMACEUTICA SERONO, BARI ITALY

Laboratory/Laboratorium: INDUSTRIA FARMACEUTICA SERONO, BARI ITALY
SERONO SOUTH AFRICA, CENTURION RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 15 AUGUST 2001
Datum van registrasie 15 AUGUSTUS 2001

Registration number/Registrasienommer: 33/21.10/0521

Name of medicine/Naam van medisyne: GONAL-F 75

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH AMPOULE CONTAINS/ELKE AMPUUL BEVAT:
FOLLITROPIN ALFA ... 75,0 iu

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

Applicant/Applikant: SERONO SOUTH AFRICA (PTY)LTD

Manufacturer/Vervaardiger: INDUSTRIA FARMACEUTICA SERONO, BARI ITALY

Packer/Verpakker: INDUSTRIA FARMACEUTICA SERONO, BARI ITALY

Laboratory/Laboratorium: INDUSTRIA FARMACEUTICA SERONO, BARI ITALY
SERONO SOUTH AFRICA, CENTURION RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 15 AUGUST 2001
Datum van registrasie 15 AUGUSTUS 2001

Registration number/Registrasienommer: 32/11.4.3/0375

Name of medicine/Naam van medisyne: BE-TABS RANITIDINE 150mg TABLETS

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
RANITIDINE HYDROCHLORIDE EQUIVALENT TO
RANITIDINE ... 150,0 mg

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

Applicant/Applikant: BE-TABS PHARMACEUTICALS (PTY) LTD

Manufacturer/Vervaardiger: CADILA, AHMEDABAD INDIA

Packer/Verpakker: CADILA, AHMEDABAD INDIA

Laboratory/Laboratorium: CADILA, AHMEDABAD INDIA
BE-TABS PHARMACEUTICALS,
ROODEPOORT RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 16 AUGUST 2001
Datum van registrasie 16 AUGUSTUS 2001

Registration number/Registrasienommer: 32/20.2.8/0257

Name of medicine/Naam van medisyne: PHARMACARE-ACYCLOVIR 250 MG

Dosage form/Doseringsvorm: POWDER/POEIER

Active ingredients/Aktiewe bestanddele:
EACH 20,0 ml VIAL CONTAINS/ELKE 20,0 ml FLESSIE BEVAT:
ACICLOVIR ... 250,0 mg

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

Applicant/Applikant: PHARMACARE LIMITED

Manufacturer/Vervaardiger: DR MADAUS GmbH, WASSERBURG, GERMANY

Packer/Verpakker: DR MADAUS GmbH, WASSERBURG, GERMANY

Laboratory/Laboratorium: DR MADAUS GmbH, WASSERBURG, GERMANY
INTRAMED, PORT ELIZABETH RSA RSA
PHARMACARE LTD, PORT ELIZABETH, RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 16 AUGUST 2001
Datum van registrasie 16 AUGUSTUS 2001

Registration number/Registrasienommer: 33/10.2.2/0010

Name of medicine/Naam van medisyne: ACCOLATE 20

Dosage form/Doseringsvorm: TABLET

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

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

Applicant/Applikant: ASTRAZENECA PHARMACEUTICALS (PTY) LTD

Manufacturer/Vervaardiger: ASTRAZENECA, REIMS CEDEX 2, FRANCE
ASTRAZENECA, CHESHIRE UK

Packer/Verpakker: ASTRAZENECA, CHESHIRE UK
ASTRAZENECA, ALBERTON RSA
JANSSEN PHARMACEUTICA, HALFWAY HOUSE RSA

Laboratory/Laboratorium: ASTRAZENECA, REIMS CEDEX 2, FRANCE
ASTRAZENECA, CHESHIRE UK
ANALYTICON, KEMPTON PARK RSA
ASTRAZENECA, ALBERTON RSA
COVANCE, NORTH YORKSHIRE UK
JANSSEN PHARMACEUTICA, HALFWAY HOUSE RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 27 August 2001
Datum van registrasie 27 AUGUSTUS 2001

Registration number/Registrasienommer: 32/11.4.3/0376

Name of medicine/Naam van medisyne: BE-TABS RANITIDINE 300mg TABLETS

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
RANITIDINE HYDROCHLORIDE EQUIVALENT TO
RANITIDINE ... 300,0 mg

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

Applicant/Applikant: BE-TABS PHARMACEUTICALS (PTY) LTD

Manufacturer/Vervaardiger: CADILA, AHMEDABAD INDIA

Packer/Verpakker: CADILA, AHMEDABAD INDIA

Laboratory/Laboratorium: CADILA, AHMEDABAD INDIA
BE-TABS PHARMACEUTICALS,
ROODEPOORT RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 16 AUGUST 2001
Datum van registrasie 16 AUGUSTUS 2001

Registration number/Registrasienommer: 33/1.2/0336

Name of medicine/Naam van medisyne: BIO-CLOMIPRAMINE HYDROCHLORIDE 25

Dosage form/Doseringsvorm: CAPSULES/KAPSULES

Active ingredients/Aktiewe bestanddele:
EACH CAPSULE CONTAINS/ELKE KAPSULE BEVAT:
CLOMIPRAMINE HYDROCHLORIDE ... 25,0 mg

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

Applicant/Applikant: BIOTECH LABORATORIES (PTY) LTD

Manufacturer/Vervaardiger: TARO PHARMACEUTICAL, HAIFA, ISRAEL

Packer/Verpakker: TARO PHARMACEUTICAL, HAIFA, ISRAEL
WRAPSA, CENTURION RSA

Laboratory/Laboratorium: TARO PHARMACEUTICAL, HAIFA, ISRAEL
WRAPSA, CENTURION RSA
INSTITUTE FOR PHARM & CHEM SERVICE, TECHNIKON PRETORIA RSA
BIOTECH LAB, MIDRAND RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 28 AUGUST 2001
Datum van registrasie 28 AUGUSTUS 2001

Registration number/Registrasienommer: 33/20.1.1/0269

Name of medicine/Naam van medisyne: AZEE

Dosage form/Doseringsvorm: CAPSULES/KAPSULES

Active ingredients/Aktiewe bestanddele:
EACH CAPSULE CONTAINS/ELKE KAPSULE BEVAT:
AZITHROMYCIN DIHYDRATE EQUIVALENT TO AZITHROMYCIN ... 250,0 mg

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

Applicant/Applikant: CIPLA-MEDPRO (PTY) LTD

Manufacturer/Vervaardiger: CIPLA, MUMBAI INDIA

Packer/Verpakker: CIPLA, MUMBAI INDIA

Laboratory/Laboratorium: CIPLA, MUMBAI INDIA
CIPLA-MEDPRO, ROSENPARK RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 28 AUGUST 2001
Datum van registrasie 28 AUGUSTUS 2001

Registration number/Registrasienommer: 33/1.2/0338

Name of medicine/Naam van medisyne: BIO-CLOMIPRAMINE HYDROCHLORIDE 75

Dosage form/Doseringsvorm: CAPSULES/KAPSULES

Active ingredients/Aktiewe bestanddele:
EACH CAPSULE CONTAINS/ELKE KAPSULE BEVAT:
CLOMIPRAMINE HYDROCHLORIDE ... 75,0 mg

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

Applicant/Applikant: BIOTECH LABORATORIES (PTY) LTD

Manufacturer/Vervaardiger: TARO PHARMACEUTICAL, HAIFA, ISRAEL

Packer/Verpakker: TARO PHARMACEUTICAL, HAIFA, ISRAEL
WRAPSA, CENTURION RSA

Laboratory/Laboratorium: TARO PHARMACEUTICAL, HAIFA, ISRAEL
WRAPSA, CENTURION RSA
INSTITUTE FOR PHARM & CHEM SERVICE, TECHNIKON PRETORIA RSA
BIOTECH LAB, MIDRAND RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 28 AUGUST 2001
Datum van registrasie 28 AUGUSTUS 2001

Registration number/Registrasienommer: 33/1.2/0337

Name of medicine/Naam van medisyne: BIO-CLOMIPRAMINE HYDROCHLORIDE 50

Dosage form/Doseringsvorm: CAPSULES/KAPSULES

Active ingredients/Aktiewe bestanddele:
EACH CAPSULE CONTAINS/ELKE KAPSULE BEVAT:
CLOMIPRAMINE HYDROCHLORIDE ... 50,0 mg

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

Applicant/Applikant: BIOTECH LABORATORIES (PTY) LTD

Manufacturer/Vervaardiger: TARO PHARMACEUTICAL, HAIFA,ISRAEL

Packer/Verpakker: TARO PHARMACEUTICAL, HAIFA,ISRAEL
WRAPSA, CENTURION RSA

Laboratory/Laboratorium: TARO PHARMACEUTICAL, HAIFA,ISRAEL
WRAPSA, CENTURION RSA
INSTITUTE FOR PHARM & CHEM SERVICE, TECHNIKON PRETORIA RSA
BIOTECH LAB, MIDRAND RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 28 AUGUST 2001
Datum van registrasie 28 AUGUSTUS 2001

Registration number/Registrasienommer: 95/21/3

Name of medicine/Naam van medisyne: MENOROX

Dosage form/Doseringsvorm: LIQUID/VLOEISTOF

Active ingredients/Aktiewe bestanddele:
EACH 1,0 ml LIQUID CONTAINS/ELKE 1,0 ml VLOEISTOF BEVAT:
NORFLOXACIN ... 100,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: ANCHORPHARM ANIMAL HEALTH (PTY) LTD

Manufacturer/Vervaardiger: NUTEC LTD LINCHFIELD UK

Packer/Verpakker: NUTEC LTD LINCHFIELD UK

Laboratory/Laboratorium: NUTEC LTD LINCHFIELD UK
CONSULTING MICROBIOL LAB, MOREHILL BENONI RSA
KHULULEKANI LABORATORY SERVICES, MIDRAND RSA
LABHOUSE, EPSOM DOWNS, BRYANSTON
ANCHORPHARM ANIMAL HEALTH, BRAMLEY RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 29 AUGUST 2001
Datum van registrasie 29 AUGUSTUS 2001

Registration number/Registrasienommer: 32/5.7.1/0680

Name of medicine/Naam van medisyne: LORATYNE EFFERVESCENT

Dosage form/Doseringsvorm: TABLET

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

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

Applicant/Applikant: SCHERING-PLOUGH (PTY) LTD

Manufacturer/Vervaardiger: ASTA MEDICA ARZNEIMITTEL GmBH, WOLFSBERG AUSTRIA

Packer/Verpakker: SCHERING-PLOUGH, COMAZZO ITALY
SCHERING-PLOUGH, ISANDO RSA

Laboratory/Laboratorium: ASTA MEDICA ARZNEIMITTEL GmBH, WOLFSBERG AUSTRIA
SCHERING-PLOUGH, ISANDO RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 29 AUGUST 2001
Datum van registrasie 29 AUGUSTUS 2001

Registration number/Registrasienommer: 33/2.6.5/0111

Name of medicine/Naam van medisyne: RISPERDAL 0,5 MG

Dosage form/Doseringsvorm: TABLET

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

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

Applicant/Applikant: JANSSEN PHARMACEUTICA (PTY) LTD

Manufacturer/Vervaardiger: JANSSEN-CILAG, LATINA ITALY

Packer/Verpakker: JANSSEN-CILAG, LATINA ITALY
JANSSEN PHARMACEUTICA, HALFWAY HOUSE RSA

Laboratory/Laboratorium: JANSSEN-CILAG, LATINA ITALY
JANSSEN PHARMACEUTICA, HALFWAY HOUSE RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 18 JULY 2001
Datum van registrasie 18 JULIE 2001

Registration number/Registrasienommer: 33/2.6.5/0110

Name of medicine/Naam van medisyne: RISPERDAL 0,25 MG

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
RISPERIDONE ... 0,25 mg

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

Applicant/Applikant: JANSSEN PHARMACEUTICA (PTY) LTD

Manufacturer/Vervaardiger: JANSSEN-CILAG, LATINA ITALY

Packer/Verpakker: JANSSEN-CILAG, LATINA ITALY
JANSSEN PHARMACEUTICA, HALFWAY HOUSE RSA

Laboratory/Laboratorium: JANSSEN-CILAG, LATINA ITALY
JANSSEN PHARMACEUTICA, HALFWAY HOUSE RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 18 JULY 2001
Datum van registrasie 18 JULIE 2001

Registration number/Registrasienommer: 32/11/0121

Name of medicine/Naam van medisyne: SANTIZA 10

Dosage form/Doseringsvorm: TABLET

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

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

Applicant/Applikant: BE-TABS PHARMACEUTICALS (PTY) LTD

Manufacturer/Vervaardiger: CADILA, AHMEDABAD INDIA

Packer/Verpakker: CADILA, AHMEDABAD INDIA

Laboratory/Laboratorium: CADILA, AHMEDABAD INDIA
BE-TABS PHARMACEUTICALS, ROODEPOORT RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 18 JULY 2001
Datum van registrasie 18 JULIE 2001

Registration number/Registrasienommer: 32/11/0120

Name of medicine/Naam van medisyne: SANTIZA 5

Dosage form/Doseringsvorm: TABLET

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

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

Applicant/Applikant: BE-TABS PHARMACEUTICALS (PTY) LTD

Manufacturer/Vervaardiger: CADILA, AHMEDABAD INDIA

Packer/Verpakker: CADILA, AHMEDABAD INDIA

Laboratory/Laboratorium: CADILA, AHMEDABAD INDIA
BE-TABS PHARMACEUTICALS, ROODEPOORT RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 18 JULY 2001
Datum van registrasie 18 JULIE 2001

Registration number/Registrasienommer: 31/20.1.1/0411

Name of medicine/Naam van medisyne: ZOLIN 1000

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH VIAL CONTAINS/ELKE FLESSIE BEVAT :
CEFAZOLIN SODIUM EQUIVALENT TO
CEFAZOLIN ... 1000,0 mg

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

Applicant/Applikant: COMPU PHARMACEUTICAL PRODUCTS LTD

Manufacturer/Vervaardiger: IBSA, LUGANO SWITZERLAND

Packer/Verpakker: IBSA, LUGANO SWITZERLAND

Laboratory/Laboratorium: IBSA, LUGANO SWITZERLAND
INSTITUTE FOR PHARM & CHEM SERVICE,
TECHNIKON PRETORIA RSA
COMPU PHARMACEUTICAL PRODUCTS,
LYNNWOOD RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 18 JULY 2001
Datum van registrasie 18 JULIE 2001

Registration number/Registrasienommer: 29/2.9/0145

Name of medicine/Naam van medisyne: TRAMAL DROPS

Dosage form/Doseringsvorm: DROPS/DRUPPELS

Active ingredients/Aktiewe bestanddele:
EACH 1,0 ml SOLUTION CONTAINS/ELKE 1,0 ml OPLOSSING BEVAT:
TRAMADOL HYDROCHLORIDE ... 100,0 mg

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

Applicant/Applikant: JANSSEN PHARMACEUTICA (PTY) LTD

Manufacturer/Vervaardiger: GRUNENTHAL, STOLBERG, GERMANY

Packer/Verpakker: GRUNENTHAL, STOLBERG, GERMANY

Laboratory/Laboratorium: GRUNENTHAL, STOLBERG, GERMANY
JANSSEN PHARMACEUTICA, HALFWAY HOUSE RSA

Shelf-life/Rakleeftyd: 36 months/maande

Date of registration: 18 JULY 2001
Datum van registrasie 18 JULIE 2001

Registration number/Registrasienommer: 31/20.1.1/0408

Name of medicine/Naam van medisyne: MANCEF 750

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH VIAL CONTAINS/ELKE FLESSIE BEVAT:
CEFAMANDOLE NAFATE EQUIVALENT TO CEFAMANDOLE ... 750,0 mg

Conditions of registration/Voorwaardes vir registrasie:
1, 2, 3, 4, 5a, 6, 7, 8a, 9

Applicant/Applikant: BRAINWARE COMPU (PTY) LTD

Manufacturer/Vervaardiger: IBSA, LUGANO SWITZERLAND

Packer/Verpakker: IBSA. LUGANO SWITZERLAND

Laboratory/Laboratorium: IBSA, LUGANO SWITZERLAND
INSTITUTE FOR PHARM & CHEM SERVICE, TECHNIKON PRETORIA RSA
SEDEK AGRIKEM, KAMEELDRIFT RSA
BRAINWARE COMPU, LYNWOOD RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 18 JULY 2001
Datum van registrasie 18 JULIE 2001

Registration number/Registrasienommer: 33/20.1.2/0048

Name of medicine/Naam van medisyne: ATHLONE PHENOXYMETHYL-PENICILLIN 250/5 ml

Dosage form/Doseringsvorm: POWDER/POEIER

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

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

Applicant/Applikant: COMPUPHARM (PTY) LTD

Manufacturer/Vervaardiger: ATHLONE LABORATORIES,ROSCOMMON, IRELAND

Packer/Verpakker: ATHLONE LABORATORIES,ROSCOMMON, IRELAND

Laboratory/Laboratorium: ATHLONE LABORATORIES,ROSCOMMON, IRELAND
INSTITUTE FOR PHARM & CHEM SERVICE, TECHNIKON PRETORIA RSA
SEDEK AGRIKEM, KAMEELDRIFT RSA
COMPUPHARM LYNNWOOD, RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 18 JULY 2001
Datum van registrasie 18 JULIE 2001

Registration number/Registrasienommer: 32/11.4.3/0255

Name of medicine/Naam van medisyne: HEXAL RANITIDINE 150 MG FILM COATED TABLETS

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
RANITIDINE HYDROCHLORIDE EQUIVALENT TO RANITIDINE ... 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: 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: 18 JULY 2001
Datum van registrasie 18 JULIE 2001

Registration number/Registrasienommer: 31/20.1.1/0409

Name of medicine/Naam van medisyne: MANCEF 1000

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH VIAL CONTAINS/ELKE FLESSIE BEVAT :
CEFAMANDOLE NAFATE EQUIVALENT TO CEFAMANDOLE ... 1000,0 mg

Conditions of registration/Voorwaardes vir registrasie:
1, 2, 3, 4, 5a, 6, 7, 8a, 9

Applicant/Applikant: BRAINWARE COMPU (PTY) LTD

Manufacturer/Vervaardiger: IBSA, LUGANO SWITZERLAND

Packer/Verpakker: IBSA, LUGANO SWITZERLAND

Laboratory/Laboratorium: IBSA, LUGANO SWITZERLAND
INSTITUTE FOR PHARM & CHEM SERVICE, TECHNIKON PRETORIA RSA
SEDEK AGRIKEM, KAMEELDRIFT RSA
BRAINWARE COMPU, LYNWOOD RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 18 JULY 2001
Datum van registrasie 18 JULIE 2001

Registration number/Registrasienommer: 32/11.4.3/0256

Name of medicine/Naam van medisyne: HEXAL RANITIDINE 300 MG FILM COATED TABLETS

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
RANITIDINE HYDROCHLORIDE EQUIVALENT TO RANITIDINE ... 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: 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: 19 JULY 2001
Datum van registrasie 19 JULIE 2001

Registration number/Registrasienommer: 32/2.8/0726

Name of medicine/Naam van medisyne: MDI DOL

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, 8a, 9

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: 19 JULY 2001
Datum van registrasie 19 JULIE 2001

Registration number/Registrasienommer: 32/11.2/0598

Name of medicine/Naam van medisyne: MERCK-MEBEVERINE HYDROCHLORIDE

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
MEBEVERINE HYDROCHLORIDE ... 135,0 mg

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

Applicant/Applikant: MERCK GENERICS RSA (PTY) LTD

Manufacturer/Vervaardiger: ALPHAPHARM,BRISBANE QUEENSLAND AUSTRALIA

Packer/Verpakker: ALPHAPHARM,BRISBANE QUEENSLAND AUSTRALIA

Laboratory/Laboratorium: ALPHAPHARM,BRISBANE QUEENSLAND AUSTRALIA
MERCK PHARMACEUTICAL MANUFACTURING (PTY) LTD, MIDRAND RSA
RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY,POTCHEFSTROOM RSA
MERCK GENERICS RSA, MIDRAND RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 19 JULY 2001
Datum van registrasie 19 JULIE 2001

Registration number/Registrasienommer: 33/2.7/0463

Name of medicine/Naam van medisyne: PARACETAMOL-HEXAL 500

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
PARACETAMOL ... 500,0 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: 19 JULY 2001
Datum van registrasie 19 JULIE 2001

Registration number/Registrasienommer: 33/7.5/0257

Name of medicine/Naam van medisyne: APO-LOVASTATIN 20 MG

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
LOVASTATIN ... 20.0 mg

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

Applicant/Applikant: APOTEX SA (PTY) LTD

Manufacturer/Vervaardiger: APOTEX INC. SIGNET DRIVE WESTON, ONTARIO CANADA

Packer/Verpakker: APOTEX INC. WESTON ROAD WESTON, ONTARIO CANADA

Laboratory/Laboratorium: APOTEX INC. SIGNET DRIVE WESTON, ONTARIO CANADA
APOTEX INC. WESTON ROAD WESTON, ONTARIO CANADA
INSTITUTE FOR PHARM & CHEM SERVICE, TECHNIKON PRETORIA RSA
APOTEX, SANDTON RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 24 JULY 2001
Datum van registrasie 24 JULIE 2001

Registration number/Registrasienommer: 33/20.2.2/0503

Name of medicine/Naam van medisyne: KETAZOL CREAM

Dosage form/Doseringsvorm: CREAM/ROOM

Active ingredients/Aktiewe bestanddele:
EACH 1.0 g CREAM CONTAINS/ELKE 1.0 g ROOM BEVAT:
KETOCONAZOLE ... 20.0 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

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 24 JULY 2001
Datum van registrasie 24 JULIE 2001

Registration number/Registrasienommer: 34/34/0096

Name of medicine/Naam van medisyne: REBIF 22

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH 0,5 ml SYRINGE CONTAINS/ELKE 0,5 ml SPUIT BEVAT:
INTERFERON BETA -1a ... 22,0 ug

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

Applicant/Applikant: SERONO SOUTH AFRICA (PTY)LTD

Manufacturer/Vervaardiger: VETTER PHARMA,SCHUTZENSTR,RAVENSBURG GERMANY

Packer/Verpakker: VETTER PHARMA,SCHUTZENSTR,RAVENSBURG GERMANY
INDUSTRIA FARMACEUTICA SERONO, BARI ITALY

Laboratory/Laboratorium: VETTER PHARMA,SCHUTZENSTR,RAVENSBURG GERMANY
RBM, COLLERETTO GIACOSA, ITALY
SERONO SOUTH AFRICA, SANDTON RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 24 JULY 2001
Datum van registrasie 24 JULIE 2001

Registration number/Registrasienommer: 33/7.5/0258

Name of medicine/Naam van medisyne: APO-LOVASTATIN 40 MG

Dosage form Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
LOVASTATIN ... 40.0 mg

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

Applicant/Applikant: APOTEX SA (PTY) LTD

Manufacturer/Vervaardiger: APOTEX INC. SIGNET DRIVE WESTON. ONTARIO CANADA

Packer/Verpakker: APOTEX INC. WESTON ROAD WESTON. ONTARIO CANADA

Laboratory/Laboratorium: APOTEX INC. WESTON ROAD WESTON. ONTARIO CANADA
APOTEX INC. SIGNET DRIVE WESTON. ONTARIO CANADA
INSTITUTE FOR PHARM & CHEM SERVICE. TECHNIKON PRETORIA RSA
APOTEX. SANDTON. RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 24 JULY 2001
Datum van registrasie 24 JULIE 2001

Registration number/Registrasienommer: 32/5.6/0035

Name of medicine/Naam van medisyne: SERC 16

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
BETAHISTINE HYDROCHLORIDE ... 16,0 mg

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

Applicant/Applikant: SCHERING (PTY) LTD

Manufacturer/Vervaardiger: SOLVAY PHARM BV, OLST, NETHERLANDS

Packer/Verpakker: SOLVAY PHARM BV, OLST, NETHERLANDS

Laboratory/Laboratorium: SOLVAY PHARM BV, OLST, NETHERLANDS
SCHERING, MIDRAND RSA

Shelf-life/Rakleeftyd: 60 months/maande

Date of registration: 25 JULY 2001
Datum van registrasie 25 JULIE 2001

Registration number/Registrasienommer: A/20.1.7/0150

Name of medicine/Naam van medisyne: FUNGIZONE INTRAVENOUS

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH 1,0 ml VIAL CONTAINS/ELKE 1,0 ml FLESSIE BEVAT:
AMPHOTERICIN B ... 50,0 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, NEW JERSEY USA

Packer/Verpakker: BRISTOL-MYERS SQUIBB, NEW JERSEY USA
DIVPHARM MANUFACTURING AND PACKAGING, LONGDALE RSA
MERCK PHARMACEUTICAL MANUFACTURING (PTY) LTD, MIDRAND RSA

Laboratory/Laboratorium: BRISTOL-MYERS SQUIBB, NEW JERSEY USA
CONSULTING CHEMICAL LAB, STAR STREET BOKSBURG, RSA
MERCK PHARMACEUTICAL MANUFACTURING (PTY) LTD, MIDRAND RSA
BRISTOL-MYERS SQUIBB, BEDFORDVIEW RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 24 JULY 2001
Datum van registrasie 24 JULIE 2001

Registration number/Registrasienommer: 32/5.4.1/0299

Name of medicine/Naam van medisyne: PEXOLA 0,25 mg

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
PRAMIPEXOLE DIHYDROCHLORIDE MONOHYDRATE ... 0,25 mg

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

Applicant/Applikant: INGELHEIM PHARMACEUTICALS (PTY) LTD

Manufacturer/Vervaardiger: BOEHRINGER INGELHEIM, INGELHEIM AM RHEIN, GERMANY

Packer/Verpakker: BOEHRINGER INGELHEIM, INGELHEIM AM RHEIN, GERMANY
HOECHST MARION ROUSSEL, WALTLOO RSA

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: 25 JULY 2001
Datum van registrasie 25 JULIE 2001

Registration number/Registrasienommer: 32/5.4.1/0298

Name of medicine/Naam van medisyne: PEXOLA 0,125 mg

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
PRAMIPEXOLE DIHYDROCHLORIDE MONOHYDRATE ... 0,125 mg

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

Applicant/Applikant: INGELHEIM PHARMACEUTICALS (PTY) LTD

Manufacturer/Vervaardiger: BOEHRINGER INGELHEIM, INGELHEIM AM RHEIN, GERMANY

Packer/Verpakker: BOEHRINGER INGELHEIM, INGELHEIM AM RHEIN, GERMANY
HOECHST MARION ROUSSEL, WALTLOO RSA

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: 25 JULY 2001
Datum van registrasie 25 JULIE 2001

Registration number/Registrasienommer: 32/5.4.1/0301

Name of medicine/Naam van medisyne: PEXOLA 1,25 mg

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
PRAMIPEXOLE DIHYDROCHLORIDE MONOHYDRATE ... 1,25 mg

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

Applicant/Applikant: INGELHEIM PHARMACEUTICALS (PTY) LTD

Manufacturer/Vervaardiger: BOEHRINGER INGELHEIM, INGELHEIM AM RHEIN, GERMANY

Packer/Verpakker: BOEHRINGER INGELHEIM, INGELHEIM AM RHEIN, GERMANY
MARION ROUSSEL, WALTLOO RSA

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: 25 JULY 2001
Datum van registrasie 25 JULIE 2001

Registration number/Registrasienommer: 32/5.4.1/0300

Name of medicine/Naam van medisyne: PEXOLA 1,0 mg

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT :
PRAMIPEXOLE DIHYDROCHLORIDE MONOHYDRATE ... 1,0 mg

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

Applicant/Applikant: INGELHEIM PHARMACEUTICALS (PTY) LTD

Manufacturer/Vervaardiger: BOEHRINGER INGELHEIM, INGELHEIM AM RHEIN, GERMANY

Packer/Verpakker: BOEHRINGER INGELHEIM, INGELHEIM AM RHEIN, GERMANY
HOECHST MARION ROUSSEL, WALTLOO RSA

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: 25 JULY 2001
Datum van registrasie 25 JULIE 2001

Registration number/Registrasienommer: 34/28/0075

Name of medicine/Naam van medisyne: OPTISON

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH 1,0 ml SUSPENSION CONTAINS/ELKE 1,0 ml SUSPENSIE BEVAT:
OCTAFLUOROPROPANE ... 0,22 mg

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

Applicant/Applikant: RHONE-POULENC RORER SA (PTY) LTD

Manufacturer/Vervaardiger: MOLECULAR BIOSYSTEMS, CALIFORNIA, USA

Packer/Verpakker: MOLECULAR BIOSYSTEMS, CALIFORNIA, USA
MALLINCKRODT MEDICAL, DUBLIN, IRELAND

Laboratory/Laboratorium: MOLECULAR BIOSYSTEMS, CALIFORNIA, USA
MALLINCKRODT MEDICAL, DUBLIN, IRELAND
RHONE-POULENC RORER, PORT ELIZABETH RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 31 JULY 2001
Datum van registrasie 31 JULIE 2001

Registration number/Registrasienommer: 32/5.4.1/0302

Name of medicine/Naam van medisyne: PEXOLA 1,5 MG

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
PRAMIPEXOLE DIHYDROCHLORIDE MONOHYDRATE ... 1,5 mg

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

Applicant/Applikant: INGELHEIM PHARMACEUTICALS (PTY) LTD

Manufacturer/Vervaardiger: BOEHRINGER INGELHEIM, INGELHEIM AM RHEIN, GERMANY

Packer/Verpakker: BOEHRINGER INGELHEIM, INGELHEIM AM RHEIN, GERMANY
HOECHST MARION ROUSSEL, WALTLOO RSA RSA

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

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 25 JULY 2001
Datum van registrasie 25 JULIE 2001

Registration number/Registrasienommer: 33/8.3/0006

Name of medicine/Naam van medisyne: RECORMON 20 000 FOR RECO-PEN

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH CARTRIDGE CONTAINS/ELKE GLASBUISIE BEVAT:
EPOETIN BETA 166.0 ug EQUIVALENT TO RECOMBINANT HUMAN ERYTHROPOETIN ... 20 000 iu

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

Applicant/Applikant: ROCHE PRODUCTS (PTY) LTD

Manufacturer/Vervaardiger: VETTER PHARMA, SCHUTZENSTR, RAVENSBURG GERMANY

Packer/Verpakker: VETTER PHARMA, SCHUTZENSTR, RAVENSBURG GERMANY
ROCHE DIAGNOSTICS, MANNHEIM, GERMANY
ROCHE, ISANDO RSA

Laboratory/Laboratorium: ROCHE DIAGNOSTICS, MANNHEIM, GERMANY
ROCHE, ISANDO RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 31 JULY 2001
Datum van registrasie 31 JULIE 2001

Registration number/Registrasienommer: 33/8.3/0005

Name of medicine/Naam van medisyne: RECORMON 10 000 FOR RECO-PEN

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH CARTRIDGE CONTAINS/ELKE GLASBUISIE BEVAT:
EPOETIN BETA 83,0 ug EQUIVALENT TO RECOMBINANT HUMAN ERYTHROPOETIN ... 10 000 iu

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

Applicant/Applikant: ROCHE PRODUCTS (PTY) LTD

Manufacturer/Vervaardiger: VETTER PHARMA,SCHUTZENSTR,RAVENSBURG GERMANY

Packer/Verpakker: VETTER PHARMA,SCHUTZENSTR,RAVENSBURG GERMANY
ROCHE DIAGNOSTICS, MANNHEIM, GERMANY
ROCHE, ISANDO RSA

Laboratory/Laboratorium: ROCHE DIAGNOSTICS, MANNHEIM, GERMANY
ROCHE, ISANDO RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 31 JULY 2001
Datum van registrasie 31 JULIE 2001

Registration number/Registrasienommer: 33/8.3/0008

Name of medicine/Naam van medisyne: RECORMON 100 000 MULTIDOSE

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH VIAL CONTAINS/ELKE FLESSIE BEVAT:
EPOETIN BETA 830,0 ug EQUIVALENT TO RECOMBINANT
HUMAN ERYTHROPOETIN ... 100 000 iu

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

Applicant/Applikant: ROCHE PRODUCTS (PTY) LTD

Manufacturer/Vervaardiger: ROCHE DIAGNOSTICS, MANNHEIM, GERMANY

Packer/Verpakker: ROCHE DIAGNOSTICS, MANNHEIM, GERMANY
ROCHE, ISANDO RSA

Laboratory/Laboratorium: ROCHE DIAGNOSTICS, MANNHEIM, GERMANY
ROCHE, ISANDO RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 31 JULY 2001
Datum van registrasie 31 JULIE 2001

Registration number/Registrasienommer: 33/8.3/0007

Name of medicine/Naam van medisyne: RECORMON 50 000 MULTIDOSE

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH VIAL CONTAINS/ELKE FLESSIE BEVAT :
EPOETIN BETA 415,0 ug EQUIVALENT TO RECOMBINANT
HUMAN ERYTHROPOETIN ... 50 000 iu

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

Applicant/Applikant: ROCHE PRODUCTS (PTY) LTD

Manufacturer/Vervaardiger: ROCHE DIAGNOSTICS, MANNHEIM, GERMANY

Packer/Verpakker: ROCHE DIAGNOSTICS, MANNHEIM, GERMANY
ROCHE, ISANDO RSA

Laboratory/Laboratorium: ROCHE DIAGNOSTICS, MANNHEIM, GERMANY
ROCHE, ISANDO RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 31 JULY 2001
Datum van registrasie 31 JULIE 2001

Registration number/Registrasienommer: 34/20.2.8/0032

Name of medicine/Naam van medisyne: RELENZA

Dosage form/Doseringsvorm: POWDER/POEIER

Active ingredients/Aktiewe bestanddele:
EACH BLISTER CONTAINS/ELKE STULPVERPAKKING BEVAT:
ZANAMIVIR ... 5,0 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: 15 JUNE 2001
Datum van registrasie 15 JUNIE2001

Registration number/Registrasienommer: 33/34/0009

Name of medicine/Naam van medisyne: DILUENT FOR RECORMON MULTIDOSE

Dosage form/Doseringsvorm: SOLUTION/OPLOSSING

Active ingredients/Aktiewe bestanddele:
EACH 1,0 ml SOLUTION CONTAINS/ELKE 1,0 ml OPLOSSING BEVAT :
BENZALKONIUM CHLORIDE ... 0,02 mg AS PRESERVATIVE
BENZYL ALCOHOL ... 4,0 mg AS PRESERVATIVE

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

Applicant/Applikant: ROCHE PRODUCTS (PTY) LTD

Manufacturer/Vervaardiger: ROCHE DIAGNOSTICS, MANNHEIM, GERMANY

Packer/Verpakker: ROCHE DIAGNOSTICS, MANNHEIM, GERMANY
ROCHE, ISANDO RSA

Laboratory/Laboratorium: ROCHE DIAGNOSTICS, MANNHEIM, GERMANY
ROCHE, ISANDO RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 31 JULY 2001
Datum van registrasie 31 JULIE 2001

Registration number/Registrasienommer: 34/11.4.3/0296

Name of medicine/Naam van medisyne: ULZEC 10

Dosage form/Doseringsvorm: CAPSULES/KAPSULES

Active ingredients/Aktiewe bestanddele:
EACH CAPSULE CONTAINS/ELKE KAPSULE BEVAT:
OMEPRAZOLE ... 10,0 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 PHARM & CHEM SERVICE,
TECHNIKON PRETORIA RSA
TRIOMED, MONTAGUE GARDENS RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 15 JUNE 2001
Datum van registrasie 15 JUNIE 2001

Registration number/Registrasienommer: 34/26/0435

Name of medicine/Naam van medisyne: CYTOBLASTIN AQUEOUS

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH 10,0 ml SOLUTION CONTAINS/ELKE 10,0 ml OPLOSSING BEVAT:
VINBLASTINE SULPHATE ... 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, KURKUMBH, PUNE INDIA

Packer/Verpakker: CIPLA LTD, KURKUMBH, PUNE INDIA

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

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 15 JUNE 2001
Datum van registrasie 15 JUNIE 2001

Registration number/Registrasienommer: 34/11.4.3/0299

Name of medicine/Naam van medisyne: TRIO-OMEPRAZOLE 10

Dosage form/Doseringsvorm: CAPSULES/KAPSULES

Active ingredients/Aktiewe bestanddele:
EACH CAPSULE CONTAINS/ELKE KAPSULE BEVAT:
OMEPRAZOLE ... 10,0 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 PHARM & CHEM SERVICE,
TECHNIKON PRETORIA RSA
TRIOMED, MONTAGUE GARDENS RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 15 JUNE 2001
Datum van registrasie 15 JUNIE 2001

Registration number/Registrasienommer: 34/11.4.3/0298

Name of medicine/Naam van medisyne: ULZEC 40

Dosage form/Doseringsvorm: CAPSULES/KAPSULES

Active ingredients/Aktiewe bestanddele:
EACH CAPSULE CONTAINS/ELKE KAPSULE BEVAT:
OMEPRAZOLE ... 40,0 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 PHARM & CHEM SERVICE,
TECHNIKON PRETORIA RSA
TRIOMED, MONTAGUE GARDENS RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 15 JUNE 2001
Datum van registrasie 15 JUNIE 2001

Registration number/Registrasienommer: 34/2.6.5/0117

Name of medicine/Naam van medisyne: SOLIAN 200 mg

Dosage form/Doseringsvorm: TABLET

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

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

Applicant/Applikant: SANOFI - SYNTHELABO (PTY) LTD

Manufacturer/Vervaardiger: SYNTHELABO GROUPE, QUETIGNY FRANCE

Packer/Verpakker: SYNTHELABO GROUPE, QUETIGNY FRANCE
HOECHST MARION ROUSSEL, WALTLOO RSA

Laboratory/Laboratorium: SYNTHELABO GROUPE, QUETIGNY FRANCE
HOECHST MARION ROUSSEL, WALTLOO RSA
SANOFI - SYNTHELABO, WOODMEAD RSA

Shelf-life/Rakleeftyd: 36 months/maande

Date of registration: 15 JUNE 2001
Datum van registrasie 15 JUNIE 2001

Registration number/Registrasienommer: 34/2.6.5/0116

Name of medicine/Naam van medisyne: SOLIAN 50 mg

Dosage form/Doseringsvorm: TABLET

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

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

Applicant/Applikant: SANOFI - SYNTHELABO (PTY) LTD

Manufacturer/Vervaardiger: SYNTHELABO GROUPE, QUETIGNY FRANCE

Packer/Verpakker: SYNTHELABO GROUPE, QUETIGNY FRANCE
HOECHST MARION ROUSSEL, WALTLOO RSA

Laboratory/Laboratorium: SYNTHELABO GROUPE, QUETIGNY FRANCE
HOECHST MARION ROUSSEL, WALTLOO RSA
SANOFI - SYNTHELABO, WOODMEAD RSA

Shelf-life/Rakleeftyd: 36 months/maande

Date of registration: 15 JUNE 2001
Datum van registrasie 15 JUNIE 2001

Registration number/Registrasienommer: 34/11.4.3/0300

Name of medicine/Naam van medisyne: TRIO-OMEPRAZOLE 20

Dosage form/Doseringsvorm: CAPSULES/KAPSULES

Active ingredients/Aktiewe bestanddele:
EACH CAPSULE CONTAINS/ELKE KAPSULE BEVAT :
OMEPRAZOLE ... 20,0 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 PHARM & CHEM SERVICE, TECHNIKON PRETORIA RSA
TRIOMED, MONTAGUE GARDENS RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 15 JUNE 2001
Datum van registrasie 15 JUNIE 2001

Registration number/Registrasienommer: 34/11.4.3/0297

Name of medicine/Naam van medisyne: ULZEC 20

Dosage form/Doseringsvorm: CAPSULES/KAPSULES

Active ingredients/Aktiewe bestanddele:
EACH CAPSULE CONTAINS/ELKE KAPSULE BEVAT:
OMEPRAZOLE ... 20,0 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 PHARM & CHEM SERVICE, TECHNIKON PRETORIA RSA
TRIOMED, MONTAGUE GARDENS RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 15 JUNE 2001
Datum van registrasie 15 JUNIE 2001

Registration number/Registrasienommer: 34/21.12/0108

Name of medicine/Naam van medisyne: DANOGEN-50

Dosage form/Doseringsvorm: CAPSULES/KAPSULES

Active ingredients/Aktiewe bestanddele:
EACH CAPSULE CONTAINS/ELKE KAPSULE BEVAT :
DANAZOL ... 50.0 mg

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

Applicant/Applikant: CIPLA-MEDPRO (PTY) LTD

Manufacturer/Vervaardiger: CIPLA, MUMBAI INDIA

Packer/Verpakker: CIPLA, MUMBAI INDIA

Laboratory/Laboratorium: CIPLA, MUMBAI INDIA
CIPLA-MEDPRO, ROSENPARK RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 15 JUNE 2001
Datum van registrasie 15 JUNIE 2001

Registration number/Registrasienommer: 34/11.4.3/0301

Name of medicine/Naam van medisyne: TRIO-OMEPRAZOLE 40

Dosage form/Doseringsvorm: CAPSULES/KAPSULES

Active ingredients/Aktiewe bestanddele:
EACH CAPSULE CONTAINS/ELKE KAPSULE BEVAT :
OMEPRAZOLE ... 40,0 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 PHARM & CHEM SERVICE,
TECHNIKON PRETORIA RSA
TRIOMED, MONTAGUE GARDENS RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 15 JUNE 2001
Datum van registrasie 15 JUNIE 2001

Registration number/Registrasienommer: 34/21.12/0110

Name of medicine/Naam van medisyne: DANOGEN-200

Dosage form/Doseringsvorm: CAPSULES/KAPSULES

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

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

Applicant/Applikant: CIPLA-MEDPRO (PTY) LTD

Manufacturer/Vervaardiger: CIPLA, MUMBAI INDIA

Packer/Verpakker: CIPLA, MUMBAI INDIA

Laboratory/Laboratorium: CIPLA, MUMBAI INDIA
CIPLA-MEDPRO, ROSENPARK RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 15 JUNE 2001
Datum van registrasie 15 JUNIE2001

Registration number/Registrasienommer: 34/21.12/0109

Name of medicine/Naam van medisyne: DANOGEN-100

Dosage form/Doseringsvorm: CAPSULES/KAPSULES

Active ingredients/Aktiewe bestanddele:
EACH CAPSULE CONTAINS/ELKE KAPSULE BEVAT :
DANAZOL ... 100,0 mg

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

Applicant/Applikant: CIPLA-MEDPRO (PTY) LTD

Manufacturer/Vervaardiger: CIPLA, MUMBAI INDIA

Packer/Verpakker: CIPLA, MUMBAI INDIA

Laboratory/Laboratorium: CIPLA, MUMBAI INDIA
CIPLA-MEDPRO, ROSENPARK RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 15 JUNE 2001
Datum van registrasie 15 JUNIE2001

Registration number/Registrasienommer: 34/34/0420

Name of medicine/Naam van medisyne: BACTERIOSTATIC WATER FOR INJECTION FOR HERCEPTIN

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH VIAL CONTAINS/ELKE FLESSIE BEVAT:
WATER FOR INJECTIONS ... 1,0 ml PER ml

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

Applicant/Applikant: ROCHE PRODUCTS (PTY) LTD

Manufacturer/Vervaardiger: F HOFFMANN-LA ROCHE, BASLE SWITZERLAND

Packer/Verpakker: F HOFFMANN-LA ROCHE, BASLE SWITZERLAND
F HOFFMANN-LA ROCHE, WYHLEN GERMANY
F HOFFMANN-LA ROCHE, KAISERAUGST, SWITZERLAND
ROCHE, ISANDO RSA

Laboratory/Laboratorium: F HOFFMANN-LA ROCHE, BASLE SWITZERLAND
ROCHE, ISANDO RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 18 JUNE 2001
Datum van registrasie 18 JUNE 2001

Registration number/Registrasienommer: H/7.1.3/0528

Name of medicine/Naam van medisyne: ISMELIN AMPOULES

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH 1,0 ml SOLUTION CONTAINS/ELKE 1,0 ml OPLOSSING BEVAT:
GUANETHIDINE SULFATE ... 10,0 mg

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

Applicant/Applikant: NOVARTIS SOUTH AFRICA (PTY) LTD

Manufacturer/Vervaardiger: NOVARTIS, STEIN SWITZERLAND

Packer/Verpakker: NOVARTIS, SPARTAN KEMPTON PARK RSA

Laboratory/Laboratorium: NOVARTIS, STEIN SWITZERLAND
NOVARTIS, SPARTAN KEMPTON PARK RSA

Shelf-life/Rakleeftyd: 60 months/maande

Date of registration: 18 JUNE 2001
Datum van registrasie 18 JUNIE 2001

Registration number/Registrasienommer: 34/20.2.2/0270

Name of medicine/Naam van medisyne: ADCO-KETOCONAZOLE SHAMPOO 1 % CARMOISINE RED

Dosage form/Doseringsvorm: SHAMPOO/SJAMPOE

Active ingredients/Aktiewe bestanddele:
EACH 1,0 ml SHAMPOO CONTAINS/ELKE 1,0 ml SJAMPOE BEVAT:
KETOCONAZOLE ... 10,0 mg

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

Applicant/Applikant: ADCOCK INGRAM LTD

Manufacturer/Vervaardiger: ADCOCK INGRAM HEALTHCARE, WADEVILLE RSA

Packer/Verpakker: ADCOCK INGRAM HEALTHCARE, WADEVILLE RSA

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

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 18 JUNE 2001
Datum van registrasie 18 JUNIE 2001

Registration number/Registrasienommer: 34/20.2.2/0269

Name of medicine/Naam van medisyne: ADCO-KETOCONAZOLE SHAMPOO 1 % CARAMEL COLOUR

Dosage form/Doseringsvorm: SHAMPOO/SJAMPOE

Active ingredients/Aktiewe bestanddele:
EACH 1,0 ml SHAMPOO CONTAINS/ELKE 1,0 ml SJAMPOE BEVAT:
KETOCONAZOLE ... 10,0 mg

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

Applicant/Applikant: ADCOCK INGRAM LTD

Manufacturer/Vervaardiger: ADCOCK INGRAM HEALTHCARE, WADEVILLE RSA

Packer/Verpakker: ADCOCK INGRAM HEALTHCARE, WADEVILLE RSA

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

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 18 JUNE 2001
Datum van registrasie 18 JUNIE 2001

Registration number/Registrasienommer: 34/20.1.1/0048

Name of medicine/Naam van medisyne: PHARMACARE-CEFOTAXIME 1 g INJECTION

Dosage form/Doseringsvorm: INJECTION/INSPUITING

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

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

Applicant/Applikant: PHARMACARE LIMITED

Manufacturer/Vervaardiger: ECZACIBASI PHARMACEUTICALS,LULEBURGAZ, TURKEY

Packer/Verpakker: ECZACIBASI PHARMACEUTICALS,LULEBURGAZ, TURKEY
INTRAMED, PORT ELIZABETH RSA

Laboratory/Laboratorium: ECZACIBASI PHARMACEUTICALS,LULEBURGAZ, TURKEY
NTRAMED, PORT ELIZABETH RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 19 JUNE 2001
Datum van registrasie 19 JUNIE 2001

Registration number/Registrasienommer: 34/20.1.1/0047

Name of medicine/Naam van medisyne: PHARMACARE-CEFOTAXIME 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: PHARMACARE LIMITED

Manufacturer/Vervaardiger: ECZACIBASI PHARMACEUTICALS,LULEBURGAZ, TURKEY

Packer/Verpakker: ECZACIBASI PHARMACEUTICALS,LULEBURGAZ, TURKEY
INTRAMED, PORT ELIZABETH RSA

Laboratory/Laboratorium: ECZACIBASI PHARMACEUTICALS,LULEBURGAZ, TURKEY
NTRAMED, PORT ELIZABETH RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 19 JUNE 2001
Datum van registrasie 19 JUNIE 2001

Registration number/Registrasienommer: 34/20.1.1/0050

Name of medicine/Naam van medisyne: PHARMACARE-CEFOTAXIME 2 g INFUSION

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

Active ingredients/Aktiewe bestanddele:
EACH VIAL CONTAINS/ELKE FLESSIE BEVAT:
CEFOTAXIME SODIUM EQUIVALENT TO CEFOTAXIME ... 2,0 mg

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

Applicant/Applikant: PHARMACARE LIMITED

Manufacturer/Vervaardiger: ECZACIBASI PHARMACEUTICALS,LULEBURGAZ, TURKEY

Packer/Verpakker: ECZACIBASI PHARMACEUTICALS,LULEBURGAZ, TURKEY
INTRAMED, PORT ELIZABETH RSA

Laboratory/Laboratorium: ECZACIBASI PHARMACEUTICALS,LULEBURGAZ, TURKEY
NTRAMED, PORT ELIZABETH RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 19 JUNE 2001
Datum van registrasie 19 JUNIE 2001

Registration number/Registrasienommer: 34/20.1.1/0049

Name of medicine/Naam van medisyne: PHARMACARE-CEFOTAXIME 2 g INJECTION

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH VIAL CONTAINS/ELKE FLESSIE BEVAT:
CEFOTAXIME SODIUM EQUIVALENT TO CEFOTAXIME ... 2,0 mg

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

Applicant/Applikant: PHARMACARE LIMITED

Manufacturer/Vervaardiger: ECZACIBASI PHARMACEUTICALS,LULEBURGAZ, TURKEY

Packer/Verpakker: ECZACIBASI PHARMACEUTICALS,LULEBURGAZ, TURKEY
INTRAMED, PORT ELIZABETH RSA

Laboratory/Laboratorium: ECZACIBASI PHARMACEUTICALS,LULEBURGAZ, TURKEY
NTRAMED, PORT ELIZABETH RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 19 JUNE 2001
Datum van registrasie 19 JUNIE 2001

Registration number/Registrasienommer: 34/15.4/0288

Name of medicine/Naam van medisyne: CLERZ SD

Dosage form/Doseringsvorm: SOLUTION/OPLOSSING

Active ingredients/Aktiewe bestanddele:
EACH 1,0 ml SOLUTION CONTAINS/ELKE 1,0 ml OPLOSSING BEVAT :
POVIDONE 25 ... 50,0 mg

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

Applicant/Applikant: NOVARTIS SOUTH AFRICA (PTY) LTD

Manufacturer/Vervaardiger: LABORATOIRES CIBA VISION,CEDEX,FRANCE

Packer/Verpakker: LABORATOIRES CIBA VISION,CEDEX,FRANCE
NOVARTIS, SPARTAN KEMPTON PARK RSA

Laboratory/Laboratorium: 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 JUNE 2001
Datum van registrasie 20 JUNIE 2001

Registration number/Registrasienommer: 34/34/0154

Name of medicine/Naam van medisyne: ZENERGY 40 mg

Dosage form/Doseringsvorm: TABLET

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

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

Applicant/Applikant: SCHERING-PLOUGH (PTY) LTD

Manufacturer/Vervaardiger: SCHERING-PLOUGH, LAS PIEDRAS PUERTO RICO

Packer/Verpakker: SCHERING-PLOUGH, SUFFOLK, U.K
SCHERING-PLOUGH, ISANDO RSA

Laboratory/Laboratorium: SCHERING-PLOUGH, LAS PIEDRAS PUERTO RICO
SCHERING-PLOUGH, ISANDO RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 20 JUNE 2001
Datum van registrasie 20 JUNIE 2001

Registration number/Registrasienommer: 34/6.1/0041

Name of medicine/Naam van medisyne: SCHEIN DOBUTAMINE 12,5 MG/ML

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH 1,0 ml SOLUTION CONTAINS/ELKE 1,0 ml OPLOSSING BEVAT :
DOBUTAMINE HYDROCHLORIDE EQUIVALENT TO DOBUTAMINE ... 12,5 mg

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

Applicant/Applikant: TRIOMED (PTY) LTD

Manufacturer/Vervaardiger MARSAM PHARMACEUTICALS INC, NEW JERSEY USA

Packer/Verpakker: MARSAM PHARMACEUTICALS INC, NEW JERSEY USA

Laboratory/Laboratorium: MARSAM PHARMACEUTICALS INC, NEW JERSEY USA
INSTITUTE FOR PHARM & CHEM SERVICE,
TECHNIKON PRETORIA RSA
TRIOMED, DURBANVILLE RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 20 JUNE 2001
Datum van registrasie 20 JUNIE 2001

Registration number/Registrasienommer: 34/34/0042

Name of medicine/Naam van medisyne: ZENAPAX

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

Active ingredients/Aktiewe bestanddele:
EACH 5,0 ml SOLUTION CONTAINS/ELKE 5,0 ml OPLOSSING BEVAT:
DACLIXIMAB ... 25,0 mg

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

Applicant/Applikant: ROCHE PRODUCTS (PTY) LTD

Manufacturer/Vervaardiger: HOFFMANN-LA ROCHE INC, NEW JERSEY USA

Packer/Verpakker: HOFFMANN-LA ROCHE INC, NEW JERSEY USA
F HOFFMANN-LA ROCHE, BETRIEBSTATTEN
KAISERAUGST SWITZERLAND
F HOFFMANN-LA ROCHE, WYHLEN GERMANY
ROCHE, ISANDO RSA

Laboratory/Laboratorium: F HOFFMANN-LA ROCHE, WYHLEN GERMANY
F HOFFMANN-LA ROCHE, GREN, BASLE SWITZERLAND
ROCHE, ISANDO RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 20 JUNE 2001
Datum van registrasie 20 JUNIE 2001

Registration number/Registrasienommer: 33/20.2.8/0464

Name of medicine/Naam van medisyne: ZIAGEN TABLETS

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
ABACAVIR ... 300,0 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, HERTFORDSHIRE UK

Packer/Verpakker: GLAXO WELLCOME, HERTFORDSHIRE UK
GLAXO WELLCOME, MIDRAND RSA

Laboratory/Laboratorium: GLAXO WELLCOME, HERTFORDSHIRE UK
GLAXO WELLCOME, KENT UK
GLAXO WELLCOME, MIDRAND RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 20 JUNE 2001
Datum van registrasie 20 JUNIE 2001

Registration number/Registrasienommer: 34/18.1/0316

Name of medicine/Naam van medisyne: BE-TABS HYDROCHLOROTHIAZIDE 25 mg TABLETS

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
HYDROCHLOROTHIAZIDE ... 25.0 mg

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

Applicant/Applikant: BE-TABS PHARMACEUTICALS (PTY) LTD

Manufacturer/Vervaardiger: BE-TABS PHARMACEUTICALS, ROODEPOORT RSA

Packer/Verpakker: BE-TABS PHARMACEUTICALS, ROODEPOORT RSA

Laboratory/Laboratorium: BE-TABS PHARMACEUTICALS, ROODEPOORT RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 20 JUNE 2001
Datum van registrasie 20 JUNIE 2001

Registration number/Registrasienommer: 34/13.4.1/0221

Name of medicine/Naam van medisyne: LOCOID CRELO

Dosage form/Doseringsvorm: EMULSION/EMULSIE

Active ingredients/Aktiewe bestanddele:
EACH 1,0 g EMULSION CONTAINS/ELKE 1,0 g EMULSIE BEVAT:
HYDROCORTISONE BUTYRATE ... 1,0 mg

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

Applicant/Applikant: PHARMAPLAN (PTY) LTD

Manufacturer/Vervaardiger: YAMANOUCHI EUROPE BV, MEPPEL NETHERLAND

Packer/Verpakker: YAMANOUCHI EUROPE BV, MEPPEL NETHERLAND

Laboratory/Laboratorium: YAMANOUCHI EUROPE BV, MEPPEL NETHERLAND
CONSULTING CHEMICAL LAB. STAR STREET BOKSBURG, RSA
PHARMAPLAN, MIDRAND RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 20 JUNE 2001
Datum van registrasie 20 JUNIE 2001

Registration number/Registrasienommer: 33/20.2.8/0465

Name of medicine/Naam van medisyne: ZIAGEN ORAL SOLUTION

Dosage form/Doseringsvorm: SOLUTION/OPLOSSING

Active ingredients/Aktiewe bestanddele:
EACH 1,0 ml SOLUTION CONTAINS/ELKE 1,0 ml OPLOSSING BEVAT:
ABACAVIR ... 20,0 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, LIVERPOOL U.K

Packer/Verpakker: GLAXO WELLCOME, LIVERPOOL U.K
GLAXO WELLCOME, MIDRAND RSA

Laboratory/Laboratorium: GLAXO WELLCOME, LIVERPOOL U.K
GLAXO WELLCOME, DURHAM UK
GLAXO WELLCOME, MIDRAND RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 20 JUNE 2001
Datum van registrasie 20 JUNIE 2001

Registration number/Registrasienommer: 31/21.12/0512

Name of medicine/Naam van medisyne: FUGEREL TABLETS

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: SCHERING-PLOUGH (PTY) LTD

Manufacturer/Vervaardiger: SCHERING-PLOUGH, HEIST-OP-DEN-BERG BELGIUM

Packer/Verpakker: SCHERING-PLOUGH, HEIST-OP-DEN-BERG BELGIUM
SCHERING-PLOUGH, ISANDO RSA

Laboratory/Laboratorium: SCHERING-PLOUGH, HEIST-OP-DEN-BERG BELGIUM
SCHERING-PLOUGH, ISANDO RSA

Shelf-life/Rakleeftyd: 48 months/maande

Date of registration: 29 MAY 2001
Datum van registrasie 29 MEI 2001

Registration number/Registrasienommer: 34/25.2/0267

Name of medicine/Naam van medisyne: STRUCTOLIPID

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

Active ingredients/Aktiewe bestanddele:
EACH 1,0 ml EMULSION CONTAINS/ELKE 1,0 ml EMULSIE BEVAT:
PURIFIED STRUCTURED TRIGLYCERIDE ... 200,0 mg

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

Applicant/Applikant: FRESENIUS KABI SA (PTY) LTD

Manufacturer/Vervaardiger: FRESENIUS KABI, UPPSALA, SWEDEN

Packer/Verpakker: FRESENIUS KABI, UPPSALA, SWEDEN

Laboratory/Laboratorium: FRESENIUS KABI, UPPSALA, SWEDEN
KHULULEKANI LABORATORY SERVICES, MIDRAND RSA
FRESENIUS KABI, MIDRAND, RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 20 JUNE 2001
Datum van registrasie 20 JUNIE 2001

Registration number/Registrasienommer: 31/20.2.8/0431

Name of medicine/Naam van medisyne: ZOCLOVAR 800 mg

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
ACICLOVIR ... 800,0 mg

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

Applicant/Applikant: GAREC (PTY) LTD

Manufacturer/Vervaardiger: APOTEX INC, SIGNET DRIVE W/ONTARIO CANADA

Packer/Verpakker: NU-PHARM INC, ONTARIO CANADA

Laboratory/Laboratorium: APOTEX INC, SIGNET DRIVE W/ONTARIO CANADA
NU-PHARM INC, ONTARIO CANADA
INSTITUTE FOR PHARM & CHEM SERVICE, TECHNIKON PRETORIA RSA
GAREC HALFWAY HOUSE RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 29 MAY 2001
Datum van registrasie 29 MEI 2001

Registration number/Registrasienommer: 31/20.2.8/0430

Name of medicine/Naam van medisyne: ZOCLOVAR 200 mg

Dosage form/Doseringsvorm: TABLET

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

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

Applicant/Applikant: GAREC (PTY) LTD

Manufacturer/Vervaardiger: APOTEX INC, SIGNET DRIVE W/ONTARIO CANADA

Packer/Verpakker: NU-PHARM INC, ONTARIO CANADA

Laboratory/Laboratorium: APOTEX INC, SIGNET DRIVE W/ONTARIO CANADA
NU-PHARM INC, ONTARIO CANADA
INSTITUTE FOR PHARM & CHEM SERVICE, TECHNIKON PRETORIA RSA
GAREC HALFWAY HOUSE RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 29 MAY 2001
Datum van registrasie 29 MEI 2001

Registration number/Registrasienommer: 33/11/0088

Name of medicine/Naam van medisyne: PENTASA 500 MG

Dosage form/Doseringsvorm: TABLET

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

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

Applicant/Applikant: FERRING (PTY) LTD

Manufacturer/Vervaardiger: FERRING A/S, VANLOSE, DENMARK

Packer/Verpakker: FERRING A/S, VANLOSE, DENMARK

Laboratory/Laboratorium: FERRING A/S, VANLOSE, DENMARK
CONSULTING CHEMICAL LAB, STAR STREET
BOKSBURG, RSA
FERRING, MIDRAND RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 17 MAY 2001
Datum van registrasie 17 MEI 2001

Registration number/Registrasienommer: 93/21.9/5

Name of medicine/Naam van medisyne: QUINABIC 7 %

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH 1,0 ml SOLUTION CONTAINS/ELKE 1,0 ml OPLOSSING BEVAT:
NORFLOXACIN NICOTINATE ... 70,0 mg

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

Applicant/Applikant: TEVA PHARMACEUTICALS (PTY) LTD

Manufacturer/Vervaardiger: ABIC LTD, NETANYA ISRAEL

Packer/Verpakker: ABIC LTD, NETANYA ISRAEL

Laboratory/Laboratorium: ABIC LTD, NETANYA ISRAEL
SOUTH AFRICAN BUREAU OF STANDARDS,
PRETORIA RSA
TEVA, INDUSTRIA RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 29 MAY 2001
Datum van registrasie 29 MEI 2001

Registration number/Registrasienommer: 33/1.2/0043

Name of medicine/Naam van medisyne: REZAK

Dosage form/Doseringsvorm: CAPSULES/KAPSULES

Active ingredients/Aktiewe bestanddele:
EACH CAPSULE CONTAINS/ELKE KAPSULE BEVAT:
FLUOXETINE HYDROCHLORIDE EQUIVALENT TO FLUOXETINE ... 20, 0 mg

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

Applicant/Applikant: TRIOMED (PTY) LTD

Manufacturer/Vervaardiger: SIEGFRIED PHARMA, ZOFINGEN, SWITZERLAND

Packer/Verpakker: DIVPHARM MANUFACTURING AND PACKAGING, LONGDALE RSA

Laboratory/Laboratorium: SIEGFRIED PHARMA, ZOFINGEN, SWITZERLAND
DIVPHARM MANUFACTURING AND PACKAGING, LONGDALE RSA
INSTITUTE FOR PHARM & CHEM SERVICE, TECHNIKON PRETORIA RSA
TRIOMED, DURBANVILLE RSA

Shelf-life/Rakleeftyd: 12 months/maande

Date of registration: 11 MAY 2001
Datum van registrasie 11 MEI 2001

Registration number/Registrasienommer: 33/34/0254

Name of medicine/Naam van medisyne: HYDROGEN PEROXIDE SOLUTION 30 VOLUMES - DAROL

Dosage form/Doseringsvorm: SOLUTION/OPLOSSING

Active ingredients/Aktiewe bestanddele:
EACH 1000,0 ml SOLUTION CONTAINS/ELKE 1000,0 ml OPLOSSING BEVAT :
HYDROGEN PEROXIDE SOLUTION ... 192,57 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: 17 MAY 2001
Datum van registrasie 17 MEI 2001

Registration number/Registrasienommer: 29/10.2.2/0156

Name of medicine/Naam van medisyne: GAREC-CARBOSISTEINE

Dosage form/Doseringsvorm SYRUP/STROOP

Active ingredients/Aktiewe bestanddele:
EACH 5,0 ml SYRUP CONTAINS/ELKE 5,0 ml STROOP BEVAT :
CARBOCISTEINE ... 250,0 mg

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

Applicant/Applikant: GAREC (PTY) LTD

Manufacturer/Vervaardiger: SAD SELF MEDICATION, EAST LONDON RSA
WRAPSA, CENTURION RSA

Packer/Verpakker: SAD SELF MEDICATION, EAST LONDON RSA
WRAPSA, CENTURION RSA

Laboratory/Laboratorium: SAD SELF MEDICATION, EAST LONDON RSA
WRAPSA, CENTURION RSA
GAREC, WOODMEAD SANDTON RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 30 MARCH 2001
Datum van registrasie 30 MAART 2001

Registration number/Registrasienommer: 34/34/0447

Name of medicine/Naam van medisyne: BSS PLUS

Dosage form/Doseringsvorm: SOLUTION/OPLOSSING

Active ingredients/Aktiewe bestanddele:
EACH 1,0 ml SOLUTION CONTAINS/ELKE 1,0 ml OPLOSSING BEVAT:
CALCIUM CHLORIDE DIHYDRATE ... 0,154 mg
GLUCOSE ... 0,92 mg
GLUTATHIONE ... 0,184 mg
MAGNESIUM CHLORIDE ... 0,2 mg
POTASSIUM CHLORIDE ... 0,38 mg
SODIUM CHLORIDE ... 7,14 mg

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

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

Manufacturer/Vervaardiger: ALCON, FORT WORTH,TEXAS USA
BAXTER, ILLINOIS USA
SA ALCON-COUVREUR NV PUURS, BELGIUM

Packer/Verpakker: ALCON, FORT WORTH,TEXAS USA
BAXTER, ILLINOIS USA

Laboratory/Laboratorium: ALCON, FORT WORTH,TEXAS USA
BAXTER, ILLINOIS USA
ALCON, RANDBURG RSA
SOUTH AFRICAN BUREAU OF STANDARDS,
PRETORIA RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 01 AUGUST 2001
Datum van registrasie 01 AUGUSTUS 2001

Registration number/Registrasienommer: 34/7.1.3/0495

Name of medicine/Naam van medisyne: NEBILET 5 MG

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
NEBIVOLOL HYDROCHLORIDE EQUIVALENT TO
NEBIVOLOL ... 5,0 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 HEALTHCARE, CLAYVILLE RSA

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

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 03 AUGUST 2001
Datum van registrasie 03 AUGUSTUS 2001

Registration number/Registrasienommer: 33/30.1/0346

Name of medicine/Naam van medisyne: PRIORIX

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH 0,5 ml DOSE CONTAINS/ELKE 0,5 ml DOSIS BEVAT:
MEASLES VACCINE(LIVE ATTENUATED) ... $10^{3.0}$ $CCID_{50}$
MUMPS VIRUS ... $10^{3.7}$ $CCID_{50}$
RUBELLA VACCINE (LIVE ATTENUATED) ... $10^{3.0}$ $CCID_{50}$

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

Applicant/Applikant: SMITHKLINE BEECHAM PHARMACEUTICALS (PTY) LTD

Manufacturer/Vervaardiger: SACHSISCHE SERUMWERKGmbH, DRESDEN, GERMANY
SMITHKLINE BEECHAM, (BIO MAN) RIXENSART BELGIUM

Packer/Verpakker: SACHSISCHE SERUMWE GmbH,DRESDEN,GERMANY
SMITHKLINE BEECHAM, (BIO MAN) RIXENSART BELGIUM
SMITHKLINE BEECHAM, (BIO MAN) WAVRE BELGIUM
SMITHKLINE BEECHAM, (BIO) GENVAL BELGIUM
SMITHKLINE BEECHAM, EPPING RSA

Laboratory/Laboratorium: SMITHKLINE BEECHAM, (BIO MAN) RIXENSART BELGIUM
SMITHKLINE BEECHAM, EPPING RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 15 JUNE 2001
Datum van registrasie 15 JUNIE 2001

Registration number/Registrasienommer: 34/3.2/0115

Name of medicine/Naam van medisyne: ACTONEL 30 mg

Dosage form/Doseringsvorm: TABLET

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

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

Applicant/Applikant: AVENTIS PHARMA (PTY) LTD

Manufacturer/Vervaardiger: PROCTER & GAMBLE, NORTH NORWICH, NEW YORK USA

Packer/Verpakker: AVENTIS PHARMA, SCOPPITO, ITALY
PROCTER & GAMBLE, LONGJUMEAU,FRANCE
PROCTER & GAMBLE, WEITERSTADT, GERMANY
AVENTIS PHARMA, WALTLOO RSA

Laboratory/Laboratorium: PROCTER & GAMBLE, NORTH NORWICH, NEW YORK USA
AVENTIS PHARMA, SCOPPITO, ITALY
PROCTER & GAMBLE, LONGJUMEAU,FRANCE
PROCTER & GAMBLE, WEITERSTADT, GERMANY
AVENTIS PHARMA, WALTLOO RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 18 JUNE 2001
Datum van registrasie 18 JUNIE 2001

Registration number/Registrasienommer: 98/3.1/4

Name of medicine/Naam van medisyne: LEGEND

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH 1,0 ml SOLUTION CONTAINS/ELKE 1,0 ml OPLOSSING BEVAT:
SODIUM HYALURONATE ... 10,0 mg

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

Applicant/Applikant: BAYER (PTY) LTD

Manufacturer/Vervaardiger: BAYER, SHAWNEE MISSION, USA

Packer/Verpakker: BAYER, SHAWNEE MISSION, USA
BAYER ANIMAL HEALTH, PIETERMARITZBURG RSA
KVP PHARMA-UND VETERN„RPRODUKTE, KIEL GERMANY

Laboratory/Laboratorium: BAYER, SHAWNEE MISSION,USA
KVP PHARMA-UND VETERN„RPRODUKTE, KIEL GERMANY
BIOCHEMICAL & SCIENTIFIC CONSULTANTS, HILTON RSA
SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA RSA
BAYER, ISANDO RSA

Shelf-life/Rakleeftyd: 36 months/maande

Date of registration: 28 MAY 2001
Datum van registrasie 28 MEI 2001

Registration number/Registrasienommer: 98/3.1/4

Name of medicine/Naam van medisyne: LEGEND

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH 1,0 ml SOLUTION CONTAINS/ELKE 1,0 ml OPLOSSING BEVAT:
SODIUM HYALURONATE ... 10,0 mg

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

Applicant/Applikant: BAYER (PTY) LTD

Manufacturer/Vervaardiger: BAYER, SHAWNEE MISSION,USA

Packer/Verpakker: BAYER, SHAWNEE MISSION,USA
BAYER ANIMAL HEALTH, PIETERMARITZBURG RSA
KVP PHARMA-UND VETERN,,RPRODUKTE, KIEL GERMANY

Laboratory/Laboratorium: BAYER, SHAWNEE MISSION,USA
BIOCHEMICAL & SCIENTIFIC CONSULTANTS, HILTON RSA
KVP PHARMA-UND VETERN,,RPRODUKTE, KIEL GERMANY
SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA RSA
BAYER, ISANDO RSA

Shelf-life/Rakleeftyd: 36 months/maande

Date of registration: 28 MAY 2001
Datum van registrasie 28 MEI 2001

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
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