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GENERAL NOTICE

NOTICE 259 OF 2003

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 259 VAN 2003

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: 34/8.1/0465

Name of medicine/Naam van medisyne: COLLATAMP

Dosage form/Doseringsvorm: DRESSING/VERBAND

Active ingredients/Aktiewe bestanddele:
EACH 1,0 cm3 FLEECE CONTAINS/ELKE 1,0 cm3 VERBAND BEVAT:
BOVINE COLLAGEN ... 5,6 mg

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

Applicant/Applikant: SYNTACOLL (PTY) LTD

Manufacturer/Vervaardiger: INNOCOLL GmbH, DONAU, GERMANY
SYNTACOLL, MIDRAND RSA

Packer/Verpakker: SYNTACOLL, MIDRAND RSA

Laboratory/Laboratorium: INNOCOLL GmbH, DONAU, GERMANY
SYNTACOLL, MIDRAND RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 20 SEPTEMBER 200
Datum van registrasie 20 SEPTEMBER 2002

Registration number/Registrasienommer: 32/11.4.3/0196

Name of medicine/Naam van medisyne: MICRO CIMETIDINE INJECTION 200 MG/2 ML

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH 2,0 ml AMPOULE CONTAINS/ELKE 2,0 ml INSPUITING BEVAT :
CIMETIDINE ... 200,0 mg

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

Applicant/Applikant: MICRO HEALTHCARE (PTY) LTD

Manufacturer/Vervaardiger: MICRO HEALTHCARE, BETHLEHEM RSA

Packer/Verpakker: MICRO HEALTHCARE, BETHLEHEM RSA

Laboratory/Laboratorium: MICRO HEALTHCARE, BETHLEHEM RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 13 NOVEMBER 2002
Datum van registrasie 13 NOVEMBER 2002

Registration number/Registrasienommer: 34/7.1/0020

Name of medicine/Naam van medisyne: DOXA TABLETS 1 mg

Dosage form/Doseringsvorm: TABLET

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

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

Applicant/Applikant:	PFIZER LABORATORIES (PTY) LTD
Manufacturer/Vervaardiger:	PFIZER LABS, PIETERMARITZBURG RSA
Packer/Verpakker:	PFIZER LABS, PIETERMARITZBURG RSA
Laboratory/Laboratorium:	PFIZER LABS, PIETERMARITZBURG RSA SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA RSA
Shelf-life/Rakleeftyd:	60 months/maande
Date of registration: Datum van registrasie	13 NOVEMBER 2002 13 NOVEMBER 2002

Registration number/Registrasienommer: 34/7.1/0021

Name of medicine/Naam van medisyne: DOXA TABLETS 2 mg

Dosage form/Doseringsvorm: TABLET

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

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

Applicant/Applikant:	PFIZER LABORATORIES (PTY) LTD
Manufacturer/Vervaardiger:	PFIZER LABS, PIETERMARITZBURG RSA
Packer/Verpakker:	PFIZER LABS, PIETERMARITZBURG RSA
Laboratory/Laboratorium:	PFIZER LABS, PIETERMARITZBURG RSA SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA RSA
Shelf-life/Rakleeftyd:	60 months/maande
Date of registration: Datum van registrasie	13 NOVEMBER 2002 13 NOVEMBER 2002

Registration number/Registrasienommer: 34/7.1/0022

Name of medicine/Naam van medisyne: DOXA TABLETS 4 mg

Dosage form/Doseringsvorm: TABLET

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

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

Applicant/Applikant:	PFIZER LABORATORIES (PTY) LTD
Manufacturer/Vervaardiger:	PFIZER LABS, PIETERMARITZBURG RSA
Packer/Verpakker:	PFIZER LABS, PIETERMARITZBURG RSA
Laboratory/Laboratorium:	PFIZER LABS, PIETERMARITZBURG RSA SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA RSA
Shelf-life/Rakleeftyd:	60 months/maande
Date of registration: Datum van registrasie	13 NOVEMBER 2002 13 NOVEMBER 2002

Registration number/Registrasienommer: 34/7.1/0023

Name of medicine/Naam van medisyne: DOXA TABLETS 8 mg

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
DOXAZOSIN ... 8.0 mg

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

Applicant/Applikant:	PFIZER LABORATORIES (PTY) LTD
Manufacturer/Vervaardiger:	PFIZER LABS, PIETERMARITZBURG RSA
Packer/Verpakker:	PFIZER LABS, PIETERMARITZBURG RSA
Laboratory/Laboratorium:	PFIZER LABS, PIETERMARITZBURG RSA SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA RSA
Shelf-life/Rakleeftyd:	60 months/maande
Date of registration: Datum van registrasie	13 NOVEMBER 2002 13 NOVEMBER 2002

Registration number/Registrasienommer: 30/34/0272

Name of medicine/Naam van medisyne: NICORETTE MINT 2 mg

Dosage form/Doseringsvorm: GUM/KOUGOM

Active ingredients/Aktiewe bestanddele:
EACH PIECE OF GUM CONTAINS/ELKE KOUGOM BEVAT :
NICOTINE ... 2,0 mg

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

Applicant/Applikant: PHARMACIA SOUTH AFRICA (PTY) LTD

Manufacturer/Vervaardiger: PHARMACIA & UPJOHN, HELSINBORG SWEDEN
SCAN-GUM ApS, ESBJERG DENMARK

Packer/Verpakker: PHARMACIA & UPJOHN, HELSINBORG SWEDEN

Laboratory/Laboratorium: PHARMACIA & UPJOHN, HELSINBORG SWEDEN
KHULULEKANI LABORATORY SERVICES, MIDRAND RSA
PHARMACIA & UPJOHN, CORK, IRELAND
SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA RSA
SCAN-GUM ApS, ESBJERG DENMARK
PHARMACIA SOUTH AFRICA, MIDRAND RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 13 NOVEMBER 2002
Datum van registrasie 13 NOVEMBER 2002

Registration number/Registrasienommer: 30/34/0273

Name of medicine/Naam van medisyne: NICORETTE MINT 4 mg

Dosage form/Doseringsvorm: GUM/KOUGOM

Active ingredients/Aktiewe bestanddele:
EACH GUM CONTAINS/ELKE KOUGOM BEVAT :
NICOTINE ... 4,0 mg

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

Applicant/Applikant: PHARMACIA SOUTH AFRICA (PTY) LTD

Manufacturer/Vervaardiger: PHARMACIA & UPJOHN, HELSINBORG SWEDEN
SCAN-GUM ApS, ESBJERG DENMARK

Packer/Verpakker: PHARMACIA & UPJOHN, HELSINBORG SWEDEN

Laboratory/Laboratorium: PHARMACIA & UPJOHN, HELSINBORG SWEDEN
KHULULEKANI LABORATORY SERVICES, MIDRAND RSA
PHARMACIA & UPJOHN, CORK, IRELAND
SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA RSA
SCAN-GUM ApS, ESBJERG DENMARK
PHARMACIA SOUTH AFRICA, MIDRAND RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 13 NOVEMBER 2002
Datum van registrasie 13 NOVEMBER2002

Registration number/Registrasienommer: 32/20.1.2/0252

Name of medicine/Naam van medisyne: PROMOXIL-125 DT

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH DISPERSIBLE TABLET CONTAINS/
ELKE OPLOSBARE TABLET BEVAT:
AMOXYCILLIN TRIHYDRATE EQUIVALENT TO
AMOXYCILLIN ... 125,0 mg

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

Applicant/Applikant: CIPLA-MEDPRO (PTY) LTD

Manufacturer/Vervaardiger: OKASA PHARMA PVT, SATARA INDIA

Packer/Verpakker: OKASA PHARMA PVT, SATARA INDIA

Laboratory/Laboratorium: OKASA PHARMA PVT, SATARA INDIA
CIPLA-MEDPRO, ROSENPARK RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 13 NOVEMBER 2002
Datum van registrasie 13 NOVEMBER 2002

Registration number/Registrasienommer: 32/20.1.2/0253

Name of medicine/Naam van medisyne: PROMOXIL-250 DT

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH DISPERSIBLE TABLET CONTAINS/
ELKE OPLOSBARE TABLET BEVAT:
AMOXYCILLIN TRIHYDRATE EQUIVALENT TO
AMOXYCILLIN ... 250,0 mg

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

Applicant/Applikant:	CIPLA-MEDPRO (PTY) LTD
Manufacturer/Vervaardiger:	OKASA PHARMA PVT, SATARA INDIA
Packer/Verpakker:	OKASA PHARMA PVT, SATARA INDIA
Laboratory/Laboratorium:	OKASA PHARMA PVT, SATARA INDIA CIPLA-MEDPRO, ROSENPARK RSA
Shelf-life/Rakleeftyd:	24 months/maande
Date of registration: Datum van registrasie	13 NOVEMBER 2002 13 NOVEMBER 2002

Registration number/Registrasienommer: 34/20.2.8/0142

Name of medicine/Naam van medisyne: CIPLA-ZIDOVUDINE

Dosage form/Doseringsvorm: CAPSULES/KAPSULES

Active ingredients/Aktiewe bestanddele:
EACH CAPSULE CONTAINS/ELKE KAPSULE BEVAT:
ZIDOVUDINE ... 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 LTD, VIKHROLI INDIA

Packer/Verpakker: CIPLA LTD, VIKHROLI INDIA

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

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 13 NOVEMBER 2002
Datum van registrasie 13 NOVEMBER 2002

Registration number/Registrasienommer: 32/11.4.3/0196

Name of medicine/Naam van medisyne: MICRO CIMETIDINE INJECTION 200 MG/2 ML

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH 2,0 ml AMPOULE CONTAINS/ELKE 2,0 ml INSPUITING BEVAT :
CIMETIDINE ... 200,0 mg

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

Applicant/Applikant: MICRO HEALTHCARE (PTY) LTD

Manufacturer/Vervaardiger: MICRO HEALTHCARE, BETHLEHEM RSA

Packer/Verpakker: MICRO HEALTHCARE, BETHLEHEM RSA

Laboratory/Laboratorium: MICRO HEALTHCARE, BETHLEHEM RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 13 NOVEMBER 2002
Datum van registrasie 13 NOVEMBER 2002

Registration number/Registrasienommer: 32/34/0744

Name of medicine/Naam van medisyne: BIOGEN WATER FOR INJECTION

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH 1,0 ml SOLUTION CONTAINS/ELKE 1,0 ml OPLOSSING BEVAT :
WATER FOR INJECTIONS ... 1,0 ml

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

Applicant/Applikant: PHARMAPLAN (PTY) LTD

Manufacturer/Vervaardiger: SOLVAY PHARM BV, OLST, NETHERLANDS

Packer/Verpakker: SOLVAY PHARM BV, OLST, NETHERLANDS

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

Shelf-life/Rakleeftyd: 36 months/maande

Date of registration: 13 NOVEMBER 2002
Datum van registrasie 13 NOVEMBER 2002

Registration number/Registrasienommer: 29/34/0700

Name of medicine/Naam van medisyne: MESSER FEDGAS MEDICAL AIR

Dosage form/Doseringsvorm: GAS

Active ingredients/Aktiewe bestanddele:
EACH CONTAINER CONTAINS/ELKE HOUER BEVAT:
NITROGEN ... 79,0 % v/v
OXYGEN ... 21,0 % v/v

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

Applicant/Applikant: FEDGAS (PTY) LTD

Manufacturer/Vervaardiger: FEDGAS, ALRODE RSA

Packer/Verpakker: FEDGAS, ALRODE RSA

Laboratory/Laboratorium: FEDGAS, ALRODE RSA

Shelf-life/Rakleeftyd: 12 months/maande

Date of registration: 14 NOVEMBER 2002
Datum van registrasie 14 NOVEMBER 2002

Registration number/Registrasienommer: 29/34/0701

Name of medicine/Naam van medisyne: MESSER FEDGAS MEDICAL OXYGEN

Dosage form/Doseringsvorm: GAS

Active ingredients/Aktiewe bestanddele:
EACH CONTAINER CONTAINS/ELKE HOUER BEVAT:
OXYGEN ... 99,7% v/v

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

Applicant/Applikant:	FEDGAS (PTY) LTD
Manufacturer/Vervaardiger:	FEDGAS, ALRODE RSA
Packer/Verpakker:	FEDGAS, ALRODE RSA
Laboratory/Laboratorium:	FEDGAS, ALRODE RSA
Shelf-life/Rakleeftyd:	12 months/maande
Date of registration: Datum van registrasie	14 NOVEMBER 2002 14 NOVEMBER 2002

Registration number/Registrasienommer: 29/34/0702

Name of medicine/Naam van medisyne: MESSER FEDGAS MEDICAL CARBON DIOXIDE

Dosage form/Doseringsvorm: GAS

Active ingredients/Aktiewe bestanddele:
EACH CONTAINER CONTAINS/ELKE HOUER BEVAT:
CARBON DIOXIDE ... 99,97 % v/v

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

Applicant/Applikant: FEDGAS (PTY) LTD

Manufacturer/Vervaardiger: FEDGAS, ALRODE RSA

Packer/Verpakker: FEDGAS, ALRODE RSA

Laboratory/Laboratorium: FEDGAS, ALRODE RSA

Shelf-life/Rakleeftyd: 12 months/maande

Date of registration: 14 NOVEMBER 2002
Datum van registrasie 14 NOVEMBER 2002

Registration number/Registrasienommer: 29/34/0703

Name of medicine/Naam van medisyne: MESSER FEDGAS ENTONOX

Dosage form/Doseringsvorm: GAS

Active ingredients/Aktiewe bestanddele:
EACH CONTAINER CONTAINS/ELKE HOUER BEVAT :
NITROGEN ... 50,0 % v/v
OXYGEN ... 50,0 % v/v

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

Applicant/Applikant: FEDGAS (PTY) LTD

Manufacturer/Vervaardiger: FEDGAS, ALRODE RSA

Packer/Verpakker: FEDGAS, ALRODE RSA

Laboratory/Laboratorium: FEDGAS, ALRODE RSA

Shelf-life/Rakleeftyd: 12 months/maande

Date of registration: 14 NOVEMBER 2002
Datum van registrasie 14 NOVEMBER 2002

Registration number/Registrasienommer: 32/21.5.1/0363

Name of medicine/Naam van medisyne: BECLAZON 50 EASI-BREATHE

Dosage form/Doseringsvorm: INHALER/INHALEERDER

Active ingredients/Aktiewe bestanddele:
EACH METERED DOSE CONTAINS/ELKE AFGEMETE DOSIS BEVAT:
BECLOMETHASONE DIPROPIONATE ... 50,0 ug

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

Applicant/Applikant: NORTON HEALTHCARE (PTY) LTD

Manufacturer/Vervaardiger: NORTON (WATERFORD) LTD, WATERFORD IRELAND

Packer/Verpakker: NORTON (WATERFORD) LTD, WATERFORD IRELAND

Laboratory/Laboratorium: NORTON (WATERFORD) LTD, WATERFORD IRELAND
NORTON HEALTHCARE, GREENSIDE RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 14 NOVEMBER 2002
Datum van registrasie 14 NOVEMBER 2002

Registration number/Registrasienommer: 32/10.2.1/0679

Name of medicine/Naam van medisyne: NORTON SALBUTAMOL
BREATH OPERATED INHALER

Dosage form/Doseringsvorm: INHALER/INHALEERDER

Active ingredients/Aktiewe bestanddele:
EACH METERED DOSE CONTAINS/ELKE AFGEMETE DOSIS BEVAT:
SALBUTAMOL ... 100,0 ug

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

Applicant/Applikant: NORTON HEALTHCARE (PTY) LTD

Manufacturer/Vervaardiger: NORTON (WATERFORD) LTD, WATERFORD IRELAND

Packer/Verpakker: NORTON (WATERFORD) LTD, WATERFORD IRELAND

Laboratory/Laboratorium: NORTON (WATERFORD) LTD, WATERFORD IRELAND
NORTON HEALTHCARE, GREENSIDE RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 14 NOVEMBER 2002
Datum van registrasie 14 NOVEMBER 2002

Registration number/Registrasienommer: 33/2.7/0203

Name of medicine/Naam van medisyne: MEDI-PARACETAMOL T TABLETS

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, 8a, 9

Applicant/Applikant: PHARMADYNE HEALTHCARE (PTY) LTD

Manufacturer/Vervaardiger: BE-TABS PHARMACEUTICALS, ROODEPOORT RSA

Packer/Verpakker: BE-TABS PHARMACEUTICALS, ROODEPOORT RSA

Laboratory/Laboratorium: BE-TABS PHARMACEUTICALS, ROODEPOORT RSA
PHARMADYNE, DURBAN NORTH, RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 14 NOVEMBER 2002
Datum van registrasie 14 NOVEMBER 2002

Registration number/Registrasienommer: 33/2.8/0430

Name of medicine/Naam van medisyne: IBUCOD

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
CODEINE PHOSPHATE ... 10,0 mg
IBUPROFEN ... 200,0 mg

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

Applicant/Applikant:	COLUMBIA PHARMACEUTICALS (PTY) LTD
Manufacturer/Vervaardiger:	COLUMBIA PHARMACEUTICALS, BOKSBURG RSA
Packer/Verpakker:	COLUMBIA PHARMACEUTICALS, BOKSBURG RSA
Laboratory/Laboratorium:	COLUMBIA PHARMACEUTICALS, BOKSBURG RSA
Shelf-life/Rakleeftyd:	24 months/maande
Date of registration: Datum van registrasie	14 NOVEMBER 2002 14 NOVEMBER 2002

Registration number/Registrasienommer: 33/20.1.1/0300

Name of medicine/Naam van medisyne: CEC 250 TABLETS

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
CEFACLOR (MONOHYDRATE) EQUIVALENT TO
CEFACLOR ... 250,0 mg

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

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

Manufacturer/Vervaardiger: ALLPHAMED, GOTTINGEN GERMANY

Packer/Verpakker: ALLPHAMED, GOTTINGEN GERMANY
DIVPHARM MANUFACTURING AND PACKAGING, LONGDALE RSA

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

Shelf-life/Rakleeftyd: 36 months/maande

Date of registration: 14 NOVEMBER 2002
Datum van registrasie 14 NOVEMBER 2002

Registration number/Registrasienommer: 28/20.1.1/0446

Name of medicine/Naam van medisyne: ROLAB-CEPHALEXIN 250C

Dosage form/Doseringsvorm: CAPSULES/KAPSULES

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

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

Applicant/Applikant: ROLAB (PTY) LTD

Manufacturer/Vervaardiger: BIOCHEMIE GmbH, KUNDL TIROL AUSTRIA

Packer/Verpakker: BIOCHEMIE GmbH, KUNDL TIROL AUSTRIA
DIVPHARM MANUFACTURING AND PACKAGING, LONGDALE RSA

Laboratory/Laboratorium: BIOCHEMIE GmbH, KUNDL TIROL AUSTRIA
SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA RSA
NOVARTIS, SPARTAN KEMPTON PARK RSA

Shelf-life/Rakleeftyd: 48 months/maande

Date of registration: 14 NOVEMBER 2002
Datum van registrasie 14 NOVEMBER 2002

Registration number/Registrasienommer: 33/34/0377

Name of medicine/Naam van medisyne: SUBUTEX SUBLINGUAL 0,4 MG

Dosage form/Doseringsvorm: TABLET

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

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

Applicant/Applikant: SCHERING-PLOUGH (PTY) LTD

Manufacturer/Vervaardiger: RECKITT & COLMAN PRODUCTS, HULL UK

Packer/Verpakker: RECKITT & COLMAN PRODUCTS, HULL UK
SCHERING-PLOUGH, ISANDO RSA

Laboratory/Laboratorium: RECKITT & COLMAN PRODUCTS, HULL UK
SCHERING-PLOUGH, ISANDO RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 15 NOVEMBER 2002
Datum van registrasie 15 NOVEMBER 2002

Registration number/Registrasienommer: 33/34/0378

Name of medicine/Naam van medisyne: SUBUTEX SUBLINGUAL 2,0 MG

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT :
BUPRENORPHINE HYDROCHLORIDE EQUIVALENT TO
BUPRENORPHINE ... 2,0 mg

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

Applicant/Applikant: SCHERING-PLOUGH (PTY) LTD

Manufacturer/Vervaardiger: RECKITT & COLMAN PRODUCTS, HULL UK

Packer/Verpakker: RECKITT & COLMAN PRODUCTS, HULL UK
SCHERING-PLOUGH, ISANDO RSA

Laboratory/Laboratorium: RECKITT & COLMAN PRODUCTS, HULL UK
SCHERING-PLOUGH, ISANDO RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 15 NOVEMBER 2002
Datum van registrasie 15 NOVEMBER 2002

Registration number/Registrasienommer: 33/34/0379

Name of medicine/Naam van medisyne: SUBUTEX SUBLINGUAL 8,0 MG

Dosage form/Doseringsvorm: TABLET

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

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

Applicant/Applikant: SCHERING-PLOUGH (PTY) LTD

Manufacturer/Vervaardiger: RECKITT & COLMAN PRODUCTS, HULL UK

Packer/Verpakker: RECKITT & COLMAN PRODUCTS, HULL UK
SCHERING-PLOUGH, ISANDO RSA

Laboratory/Laboratorium: RECKITT & COLMAN PRODUCTS, HULL UK
SCHERING-PLOUGH, ISANDO RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 15 NOVEMBER 2002
Datum van registrasie 15 NOVEMBER 2002

Registration number/Registrasienommer: 34/5.3/0162

Name of medicine/Naam van medisyne: EXELON 2 mg/ml ORAL SOLUTION

Dosage form/Doseringsvorm: SOLUTION/OPLOSSING

Active ingredients/Aktiewe bestanddele:
EACH 1,0 ml SOLUTION CONTAINS/ELKE 1,0 ml OPLOSSING BEVAT:
RIVASTIGMINE HYDROGEN TARTRATE EQUIVALENT TO
RIVASTIGMINE ... 2,0 mg

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

Applicant/Applikant: NOVARTIS SOUTH AFRICA (PTY) LTD

Manufacturer/Vervaardiger: NOVARTIS, ORLEANS CEDEX, FRANCE

Packer/Verpakker: NOVARTIS, ORLEANS CEDEX, FRANCE
NOVARTIS, SPARTAN KEMPTON PARK RSA

Laboratory/Laboratorium: NOVARTIS, ORLEANS CEDEX, FRANCE
NOVARTIS, SPARTAN KEMPTON PARK RSA

Shelf-life/Rakleeftyd: 36 months/maande

Date of registration: 15 NOVEMBER 2002
Datum van registrasie 15 NOVEMBER 2002

Registration number/Registrasienommer: 34/11.4.1/0238

Name of medicine/Naam van medisyne: RESMED MIST MAG HYDROXIDE

Dosage form/Doseringsvorm: SUSPENSION/SUSPENSIE

Active ingredients/Aktiewe bestanddele:
EACH 5,0 ml SUSPENSION CONTAINS/
ELKE 5,0 ml SUSPENSIE BEVAT :
MAGNESIUM OXIDE EQUIVALENT TO
MAGNESIUM HYDROXIDE ... 425,0 mg

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

Applicant/Applikant: RESMED PHARMACEUTICALS

Manufacturer/Vervaardiger: RESMED PHARMACEUTICALS PINETOWN, RSA

Packer/Verpakker: RESMED PHARMACEUTICALS PINETOWN, RSA

Laboratory/Laboratorium: RESMED PHARMACEUTICALS PINETOWN, RSA

Shelf-life/Rakleeftyd: 36 months/maande

Date of registration: 15 NOVEMBER 2002
Datum van registrasie 15 NOVEMBER 2002

Registration number/Registrasienommer: 34/21.8.1/0289

Name of medicine/Naam van medisyne: DIVIGEL 0,1 %

Dosage form/Doseringsvorm: GEL/JEL

Active ingredients/Aktiewe bestanddele:
EACH 1,0 g GEL CONTAINS/ELKE 1,0 g JEL BEVAT:
OESTRADIOL HEMIHYDRATE EQUIVALENT TO
OESTRADIOL ... 1,0 mg

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

Applicant/Applikant: PHARMACARE LIMITED

Manufacturer/Vervaardiger: ORION-FARMOS, TURKU FINLAND

Packer/Verpakker: ORION-FARMOS, TURKU FINLAND
LENNON LTD, PORT ELIZABETH RSA
SAD SELF MEDICATION, EAST LONDON RSA

Laboratory/Laboratorium: ORION-FARMOS, TURKU FINLAND
PHARMACARE LTD, PORT ELIZABETH RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 15 NOVEMBER 2002
Datum van registrasie 15 NOVEMBER 2002

Registration number/Registrasienommer: 34/2.8/0489

Name of medicine/Naam van medisyne: CODOXOL

Dosage form/Doseringsvorm: TABLET

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

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

Applicant/Applikant: 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: 15 NOVEMBER 2002
Datum van registrasie 15 NOVEMBER 2002

Registration number/Registrasienommer: 34/16.4/0502

Name of medicine/Naam van medisyne: STREPSILS SUGAR-FREE

Dosage form/Doseringsvorm: LOZENGES/SUIGTABLETTE

Active ingredients/Aktiewe bestanddele:
EACH LOZENGE CONTAINS/ELKE SUIGTABLET BEVAT:
AMYLMETACRESOL ... 0,6 mg
DICHLOROBENZYL ALCOHOL ... 1,2 mg

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

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

Manufacturer/Vervaardiger: BOOTS, NOTTINGHAM UK

Packer/Verpakker: BOOTS, NOTTINGHAM UK

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

Shelf-life/Rakleeftyd: 36 months/maande

Date of registration: 15 NOVEMBER 2002
Datum van registrasie 15 NOVEMBER 2002

Registration number/Registrasienommer: 34/20.1.1/0503

Name of medicine/Naam van medisyne: MERCK-ROXITHROMYCIN

Dosage form/Doseringsvorm: TABLET

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

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

Applicant/Applikant: MERCK GENERICS RSA (PTY) LTD

Manufacturer/Vervaardiger: MERCK PHARMACEUTICALS MANUFACTURING, WADEVILLE GERMISTON RSA
PACIFIC PHARMACEUTICALS LIMITED, AUCKLAND, NEW ZEALAND

Packer/Verpakker: MERCK PHARMACEUTICALS MANUFACTURING, WADEVILLE GERMISTON RSA

Laboratory/Laboratorium: PACIFIC PHARMACEUTICALS LIMITED, AUCKLAND, NEW ZEALAND
MERCK PHARMACEUTICALS MANUFACTURING, WADEVILLE GERMISTON RSA
RESEARCH INSTITUTE FOR IND. PHARMACY, POTCHEFSTROOM
MERCK GENERICS RSA (PTY) LTD RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 15 NOVEMBER 2002
Datum van registrasie 15 NOVEMBER 2002

Registration number/Registrasienommer: 35/10.2.1/ 0004

Name of medicine/Naam van medisyne: SABAX NEBRAFEN

Dosage form/Doseringsvorm: SOLUTION

Active ingredients/Aktiewe bestanddele:
EACH 4,0 ml SOLUTION CONTAINS
FENOTEROL HYDROBROMIDE ... 1,25 mg
IPRATROPIUM BROMIDE ... 0,5 mg

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

Applicant/Applikant: ADCOCK INGRAM LTD (CRITICAL CARE)

Manufacturer/Vervaardiger: ADCOCK INGRAM LTD, 1 SABAX RD JHB

Packer/Verpakker: ADCOCK INGRAM LTD, 1 SABAX RD JHB

Laboratory/Laboratorium: ADCOCK INGRAM LTD, 1 SABAX RD JHB

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 15 NOVEMBER 2002
Datum van registrasie 15 NOVEMBER 2002

Registration number/Registrasienommer: 35/8.2/0025

Name of medicine/Naam van medisyne: FENWAL SECONDARY CONTAINER WITH SALINE ADENINE GLUCOSE MANNITOL (SAG-M)

Dosage form/Doseringsvorm: SOLUTION/OPLOSSING

Active ingredients/Aktiewe bestanddele:
EACH 1 000,0 ml SOLUTION CONTAINS/
ELKE 1 000,0 ml OPLOSSING BEVAT:
ADENINE ... 0,169 g
GLUCOSE ... 9,0 g
MANNITOL ... 5,25 g
SODIUM CHLORIDE ... 8,77 g

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: ADCOCK INGRAM CRITICAL CARE (PTY) LTD

Manufacturer/Vervaardiger: ADCOCK INGRAM CRITICAL CARE, JOHANNESBURG

Packer/Verpakker: ADCOCK INGRAM CRITICAL CARE, JOHANNESBURG

Laboratory/Laboratorium: ADCOCK INGRAM CRITICAL CARE, JOHANNESBUR
BIOMEDICAL RESOURCE CENTRE, WESTVILLE RSA
WICKHAM LABORATORY, WICKHAM HAMPSHIRE UK

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 15 NOVEMBER 2002
Datum van registrasie 15 NOVEMBER 2002

Registration number/Registrasienommer: 35/7.1.3/0051

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

Dosage form/Doseringsvorm: TABLET

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

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

Applicant/Applikant: MERCK GENERICS RSA (PTY) LTD

Manufacturer/Vervaardiger: MERCK, BARCELONA SPAIN
MERCK PHARMACEUTICALS MANUFACTURING ,
WADEVILLE GERMISTON RSA

Packer/Verpakker: MERCK, BARCELONA SPAIN
MERCK PHARMACEUTICALS MANUFACTURING ,
WADEVILLE GERMISTON RSA

Laboratory/Laboratorium: MERCK GENERICS RSA (PTY) LTD RSA
MERCK, BARCELONA SPAIN
MERCK PHARMACEUTICALS MANUFACTURING ,
WADEVILLE GERMISTON RSA
RESEARCH INSTITUTE FOR IND. PHARMACY,
POTCHEFSTROOM

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 15 NOVEMBER 2002
Datum van registrasie 15 NOVEMBER 2002

Registration number/Registrasienommer: 35/7.1.3/0052

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

Dosage form/Doseringsvorm: TABLET

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

Conditions of registration/Voorwaardes vir registrasie:

Applicant/Applikant: MERCK GENERICS RSA (PTY) LTD

Manufacturer/Vervaardiger: MERCK, BARCELONA SPAIN
MERCK PHARMACEUTICALS MANUFACTURING,
WADEVILLE GERMISTON RSA

Packer/Verpakker: MERCK, BARCELONA SPAIN
MERCK PHARMACEUTICALS MANUFACTURING,
WADEVILLE GERMISTON RSA

Laboratory/Laboratorium: MERCK GENERICS RSA (PTY) LTD RSA
MERCK, BARCELONA SPAIN
MERCK PHARMACEUTICALS MANUFACTURING ,
WADEVILLE GERMISTON RSA
RESEARCH INSTITUTE FOR IND. PHARMACY,
POTCHEFSTROOM

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 15 NOVEMBER 2002
Datum van registrasie 15 NOVEMBER 2002

Registration number/Registrasienommer: 35/7.1.3/0053

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

Dosage form/Doseringsvorm: TABLET

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

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

Applicant/Applikant: MERCK GENERICS RSA (PTY) LTD

Manufacturer/Vervaardiger: MERCK, BARCELONA SPAIN
MERCK PHARMACEUTICALS MANUFACTURING ,
WADEVILLE GERMISTON

Packer/Verpakker: MERCK, BARCELONA SPAIN
MERCK PHARMACEUTICALS MANUFACTURING ,
WADEVILLE GERMISTON RSA

Laboratory/Laboratorium: MERCK, BARCELONA SPAIN
MERCK PHARMACEUTICALS MANUFACTURING ,
WADEVILLE GERMISTON RSA
MERCK, MIDRAND RSA RSA FPRR
RESEARCH INSTITUTE FOR IND. PHARMACY,
POTCHEFSTROOM FPRC

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 15 NOVEMBER 2002
Datum van registrasie 15 NOVEMBER 2002

Registration number/Registrasienommer: 35/7.1.3/0054

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

Dosage form/Doseringsvorm: TABLET

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

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

Applicant/Applikant: MERCK GENERICS RSA (PTY) LTD

Manufacturer/Vervaardiger: MERCK, BARCELONA SPAIN
MERCK PHARMACEUTICALS MANUFACTURING,
WADEVILLE GERMISTON RSA

Packer/Verpakker: MERCK, BARCELONA SPAIN
MERCK PHARMACEUTICALS MANUFACTURING,
WADEVILLE GERMISTON RSA

Laboratory/Laboratorium: MERCK, BARCELONA SPAIN
MERCK, MIDRAND RSA
MERCK PHARMACEUTICALS MANUFACTURING,
WADEVILLE GERMISTON RSA
RESEARCH INSTITUTE FOR IND. PHARMACY,
POTCHEFSTROOM

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 15 NOVEMBER 2002
Datum van registrasie 15 NOVEMBER 2002

Registration number/Registrasienommer: 35/10.2/0142

Name of medicine/Naam van medisyne: VARI-SALBUTAMOL 2 MG/ML SYRUP

Dosage form/Doseringsvorm: SYRUP/STROOP

Active ingredients/Aktiewe bestanddele:
EACH 5,0 ml SYRUP CONTAINS/ELKE 5,0 ml STROOP BEVAT:
SALBUTAMOL SULPHATE EQUIVALENT TO
SALBUTAMOL ... 2,00 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 IND. PHARMACY, POTCHEFSTROOM
SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA RSA
DANENE PHARMACEUTICALS, PTA RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 15 NOVEMBER 2002
Datum van registrasie 15 NOVEMBER 2002

Registration number/Registrasienommer: 35/26/0195

Name of medicine/Naam van medisyne: ETOPOPHOS 1 G

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH VIAL CONTAINS/ELKE FLESSIE BEVAT:
ETOPOSIDE PHOSPHATE EQUIVALENT TO ETOPOSIDE ... 1 000,0 mg

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

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

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

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

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

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 15 NOVEMBER 2002
Datum van registrasie 15 NOVEMBER 2002

Registration number/Registrasienommer: 35/20.1.1/0330

Name of medicine/Naam van medisyne: KETEK

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS
TELITHROMYCIN ... 400,0 mg

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

Applicant/Applikant:	AVENTIS PHARMA (PTY) LTD
Manufacturer/Vervaardiger	AVENTIS PHARMA, MISSOURI
Packer/Verpakker:	AVENTIS PHARMA, SCOPPITO, ITALY
Laboratory/Laboratorium:	AVENTIS PHARMA, SCOPPITO, ITALY GRUPPO LEPITIT SPA, ANAGNI ITALY AVENTIS PHARMA, WALTLOO RSA FPRC, FPRR
Shelf-life/Rakleeftyd:	36 months/maande
Date of registration: Datum van registrasie	15 NOVEMBER 2002 15 NOVEMBER 2002

Registration number/Registrasienommer: 35/28/0380

Name of medicine/Naam van medisyne: OMNIPAQUE 300 MG I/ML - 200 ML

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH 1,0 ml SOLUTION CONTAINS/ELKE 1,0 ml OPLOSSING BEVAT:
IOHEXOL EQUIVALENT TO IODINE ... 300,0 mg

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

Applicant/Applikant: NYCOMED (PTY) LTD

Manufacturer/Vervaardiger: NYCOMED, OSLO NORWAY
NYCOMED, CORK IRELAND

Packer/Verpakker: NYCOMED, OSLO NORWAY
NYCOMED, CORK IRELAND

Laboratory/Laboratorium: NYCOMED, OSLO NORWAY
NYCOMED, CORK IRELAND
INSPECTORATE M & L, ORMONDE RSA
NYCOMED, WELTEVREDEN PARK RSA

Shelf-life/Rakleeftyd: 36 months/maande

Date of registration: 15 NOVEMBER 2002
Datum van registrasie 15 NOVEMBER 2002

Registration number/Registrasienommer: 35/28/0381

Name of medicine/Naam van medisyne: OMNIPAQUE 300 MG I/ML 200 ML (POLYPROPYLENE BOTTLE)

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH 1,0 ml SOLUTION CONTAINS/ELKE 1,0 ml OPLOSSING BEVAT:
IOHEXOL EQUIVALENT TO IODINE ... 300,0 mg

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

Applicant/Applikant: NYCOMED (PTY) LTD

Manufacturer/Vervaardiger: NYCOMED, CORK IRELAND

Packer/Verpakker: NYCOMED, CORK IRELAND

Laboratory/Laboratorium: NYCOMED, CORK IRELAND
INSPECTORATE M & L, ORMONDE RSA
NYCOMED, OSLO NORWAY
NYCOMED, WELTEVREDEN PARK RSA

Shelf-life/Rakleeftyd: 36 months/maande

Date of registration: 15 NOVEMBER 2002
Datum van registrasie: 15 NOVEMBER 2002

Registration number/Registrasienommer: 35/28/0382

Name of medicine/Naam van medisyne: OMNIPAQUE 350 MG I/ML 200 ML

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH 1,0 ml SOLUTION CONTAINS/ELKE 1,0 ml OPLOSSING BEVAT:
IOHEXOL EQUIVALENT TO IODINE ... 350,0 mg

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

Applicant/Applikant: NYCOMED (PTY) LTD

Manufacturer/Vervaardiger: NYCOMED, OSLO NORWAY
NYCOMED, CORK IRELAND

Packer/Verpakker: NYCOMED, OSLO NORWAY
NYCOMED, CORK IRELAND

Laboratory/Laboratorium: NYCOMED, OSLO NORWAY
NYCOMED, CORK IRELAND
INSPECTORATE M & L, ORMONDE RSA
NYCOMED, WELTEVREDEN PARK RSA

Shelf-life/Rakleeftyd: 36 months/maande

Date of registration: 15 NOVEMBER 2002
Datum van registrasie 15 NOVEMBER 2002

Registration number/Registrasienommer: 35/28/0383

Name of medicine/Naam van medisyne: OMNIPAQUE 350 MG I/ML 200 ML (POLYPROPYLENE BOTTLE)

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH 1,0 ml SOLUTION CONTAINS/ELKE 1,0 ml OPLOSSING BEVAT:
IOHEXOL EQUIVALENT TO IODINE ... 350,0 mg

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

Applicant/Applikant: NYCOMED (PTY) LTD

Manufacturer/Vervaardiger: NYCOMED, CORK IRELAND

Packer/Verpakker: NYCOMED, CORK IRELAND

Laboratory/Laboratorium: NYCOMED, CORK IRELAND
INSPECTORATE M & L, ORMONDE RSA
NYCOMED, OSLO NORWAY
NYCOMED, WELTEVREDEN PARK RSA

Shelf-life/Rakleeftyd: 36 months/maande

Date of registration: 15 NOVEMBER 2002
Datum van registrasie 15 NOVEMBER 2002

Registration number/Registrasienommer: 35/13.4.1/0384

Name of medicine/Naam van medisyne: VARI-HYDROCORTISONE 1% CREAM

Dosage form/Doseringsvorm: CREAM/ROOM

Active ingredients/Aktiewe bestanddele:
EACH 1,0 g CREAM CONTAINS/ELKE 1,0 g ROOM BEVAT :
HYDROCORTISONE ... 10,0 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 IND. PHARMACY, POTCHEFSTROOM
SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA
DANENE PHARMACEUTICALS, PTA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 15 NOVEMBER 2002
Datum van registrasie 15 NOVEMBER 2002

Registration number/Registrasienommer: 35/28/0388

Name of medicine/Naam van medisyne: OMNIPAQUE 300 MG I/ML 500 ML

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

Active ingredients/Aktiewe bestanddele:
EACH 1,0 ml SOLUTION CONTAINS/ELKE 1,0 ml OPLOSSING BEVAT:
IOHEXOL EQUIVALENT TO IODINE ... 300,0 mg

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

Applicant/Applikant: NYCOMED (PTY) LTD

Manufacturer/Vervaardiger: NYCOMED, OSLO NORWAY
NYCOMED, CORK IRELAND

Packer/Verpakker: NYCOMED, OSLO NORWAY
NYCOMED, CORK IRELAND

Laboratory/Laboratorium: NYCOMED, OSLO NORWAY
NYCOMED, CORK IRELAND
INSPECTORATE M & L, ORMONDE RSA
NYCOMED, WELTEVREDEN PARK RSA

Shelf-life/Rakleeftyd: 36 months/maande

Date of registration: 15 NOVEMBER 2002
Datum van registrasie 15 NOVEMBER 2002

Registration number/Registrasienommer: 35/28/0389

Name of medicine/Naam van medisyne: OMNIPAQUE 300 MG I/ML 500 ML (POLYPROPYLENE BOTTLE)

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

Active ingredients/Aktiewe bestanddele:
EACH 1,0 ml SOLUTION CONTAINS/ELKE 1,0 ml OPLOSSING BEVAT:
IOHEXOL EQUIVALENT TO IODINE ... 300,0 g

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

Applicant/Applikant: NYCOMED (PTY) LTD

Manufacturer/Vervaardiger: NYCOMED, CORK IRELAND

Packer/Verpakker: NYCOMED, CORK IRELAND

Laboratory/Laboratorium: NYCOMED, CORK IRELAND
INSPECTORATE M & L, ORMONDE RSA
NYCOMED, OSLO NORWAY
NYCOMED, WELTEVREDEN PARK RSA

Shelf-life/Rakleeftyd: 36 months/maande

Date of registration: 15 NOVEMBER 2002
Datum van registrasie 15 NOVEMBER 2002

Registration number/Registrasienommer: 35/28/0390

Name of medicine/Naam van medisyne: OMNIPAQUE 350 MG I/ML 500 ML

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

Active ingredients/Aktiewe bestanddele:
EACH 1,0 ml SOLUTION CONTAINS/ELKE 1,0 ml OPLOSSING BEVAT:
IOHEXOL EQUIVALENT TO IODINE ... 350,0 mg

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

Applicant/Applikant: NYCOMED (PTY) LTD

Manufacturer/Vervaardiger: NYCOMED, OSLO NORWAY
NYCOMED, CORK IRELAND

Packer/Verpakker: NYCOMED, OSLO NORWAY
NYCOMED, CORK IRELAND

Laboratory/Laboratorium: NYCOMED, OSLO NORWAY
NYCOMED, CORK IRELAND
INSPECTORATE M & L, ORMONDE RSA
NYCOMED, WELTEVREDEN PARK RSA

Shelf-life/Rakleeftyd: 36 months/maande

Date of registration: 15 NOVEMBER 2002
Datum van registrasie 15 NOVEMBER 2002

Registration number/Registrasienommer: 35/28/0391

Name of medicine/Naam van medisyne: OMNIPAQUE 350 MG I/ML 500 ML (POLYPROPYLENE BOTTLE)

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

Active ingredients/Aktiewe bestanddele:
EACH 1,0 ml SOLUTION CONTAINS/ELKE 1,0 ml OPLOSSING BEVAT:
IOHEXOL EQUIVALENT TO IODINE ... 350,0 mg

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

Applicant/Applikant: NYCOMED (PTY) LTD

Manufacturer/Vervaardiger: NYCOMED, CORK IRELAND

Packer/Verpakker: NYCOMED, CORK IRELAND

Laboratory/Laboratorium: NYCOMED, CORK IRELAND
INSPECTORATE M & L, ORMONDE RSA
NYCOMED, OSLO NORWAY
NYCOMED, WELTEVREDEN PARK RSA

Shelf-life/Rakleeftyd: 36 months/maande

Date of registration: 15 NOVEMBER 2002
Datum van registrasie 15 NOVEMBER 2002

Registration number/Registrasienommer: 35/4/0409

Name of medicine/Naam van medisyne: NAROPIN 5 MG/ML POLYAMP

Dosage form/Doseringsvorm: INJECTION/INSPUITING

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

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

Applicant/Applikant: ASTRAZENECA PHARMACEUTICALS (PTY) LTD

Manufacturer/Vervaardiger: ASTRAZENECA AB, GARTUNAVAGEN, SODERTALJE SWEDEN

Packer/Verpakker: ASTRAZENECA AB, GARTUNAVAGEN, SODERTALJE SWEDEN

Laboratory/Laboratorium: ASTRAZENECA AB, GARTUNAVAGEN, SODERTALJE SWEDEN
JANSSEN PHARMACEUTICA, HALFWAY HOUSE RSA
ANALYTICON, KEMPTON PARK RSA
ASTRAZENECA, ALRODE, ALBERTON RSA

Shelf-life/Rakleeftyd: 36 months/maande

Date of registration: 15 NOVEMBER 2002
Datum van registrasie 15 NOVEMBER 2002

Registration number/Registrasienommer: 36/28/0027

Name of medicine/Naam van medisyne: MAGNEVIST 100 ML

Dosage form/Doseringsvorm: SOLUTION/OPLOSSING

Active ingredients/Aktiewe bestanddele:
EACH 1,0 ml SOLUTION CONTAINS/ELKE 1,0 ml OPLOSSING BEVAT:
GADOPENTETATE DIMEGLUMINE ... 469,01 mg

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

Applicant/Applikant: SCHERING (PTY) LTD

Manufacturer/Vervaardiger: SCHERING, BERLIN GERMANY

Packer/Verpakker: SCHERING, BERLIN GERMANY

Laboratory/Laboratorium: SCHERING, BERLIN GERMANY
SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA
SCHERING, MIDRAND RSA

Shelf-life/Rakleeftyd: 60 months/maande

Date of registration: 15 NOVEMBER 2002
Datum van registrasie 15 NOVEMBER 2002

Registration number/Registrasienommer: 36/28/0026

Name of medicine/Naam van medisyne: MAGNEVIST 30 ML

Dosage form/Doseringsvorm: SOLUTION/OPLOSSING

Active ingredients/Aktiewe bestanddele:
EACH 1,0 ml SOLUTION CONTAINS/ELKE 1,0 ml OPLOSSING BEVAT:
GADOPENTETATE DIMEGLUMINE 469,01 mg

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

Applicant/Applikant: SCHERING (PTY) LTD

Manufacturer/Vervaardiger: SCHERING, BERLIN GERMANY

Packer/Verpakker: SCHERING, BERLIN GERMANY

Laboratory/Laboratorium: SCHERING, BERLIN GERMANY
SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA RSA
SCHERING, MIDRAND RSA

Shelf-life/Rakleeftyd: 60 months/maande

Date of registration: 15 NOVEMBER 2002
Datum van registrasie 15 NOVEMBER 2002

Registration number/Registrasienommer: 36/3.1/0041

Name of medicine/Naam van medisyne: BREN-400

Dosage form/Doseringsvorm: TABLET

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

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

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

Manufacturer/Vervaardiger: KOPRAN LIMITED, RAIGAD INDIA

Packer/Verpakker: KOPRAN LIMITED, RAIGAD INDIA

Laboratory/Laboratorium: KOPRAN LIMITED, RAIGAD INDIA
BE-TABS PHARMACEUTICALS, ROODEPOORT RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 15 NOVEMBER 2002
Datum van registrasie 15 NOVEMBER 2002

Registration number/Registrasienommer: 36/3.1/0042

Name of medicine/Naam van medisyne: BETAPROFEN 400 FC

Dosage form/Doseringsvorm: TABLET

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

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

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

Manufacturer/Vervaardiger: KOPRAN LIMITED, RAIGAD INDIA

Packer/Verpakker: KOPRAN LIMITED, RAIGAD INDIA

Laboratory/Laboratorium: KOPRAN LIMITED, RAIGAD INDIA
BE-TABS PHARMACEUTICALS, ROODEPOORT RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 15 NOVEMBER 2002
Datum van registrasie 15 NOVEMBER 2002

Registration number/Registrasienommer: 36/15.4/0043

Name of medicine/Naam van medisyne: XALACOM

Dosage form/Doseringsvorm: DROPS/DRUPPELS

Active ingredients/Aktiewe bestanddele:
EACH 1,0 ml SOLUTION CONTAINS/ELKE 1,0 ml OPLOSSING BEVAT :
LATANOPROST ... 50,0 ug
TIMOLOL MALEATE EQUIVALENT TO TIMOLOL ... 5,0 mg

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

Applicant/Applikant: PHARMACIA SOUTH AFRICA (PTY) LTD

Manufacturer/Vervaardiger: AUTOMATIC LIQUID PACK., ILLINOIS, USA
PHARMACIA & UPJOHN, RIJKSWEG, PUURS, BELGIUM

Packer/Verpakker: AUTOMATIC LIQUID PACK., ILLINOIS, USA
PHARMACIA & UPJOHN, RIJKSWEG, PUURS, BELGIUM

Laboratory/Laboratorium: AUTOMATIC LIQUID PACK., ILLINOIS, USA
PHARMACIA & UPJOHN, RIJKSWEG, PUURS, BELGIUM
KHULULEKANI LABORATORY SERVICES, MIDRAND RSA
SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA RSA
PHARMACIA SOUTH AFRICA, MIDRAND RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 15 NOVEMBER 2002
Datum van registrasie 15 NOVEMBER 2002

Registration number/Registrasienommer: 36/10.2.1/0044

Name of medicine/Naam van medisyne: SPIRIVA

Dosage form/Doseringsvorm: CAPSULES/KAPSULES

Active ingredients/Aktiewe bestanddele:
EACH CAPSULE FOR INHALATION CONTAINS/
ELKE INHALASIE KAPSULE BEVAT:
TIOTROPIUM BROMIDE EQUIVALENT TO TIOTROPIUM ... 18,0 ug

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

Applicant/Applikant: INGELHEIM PHARMACEUTICALS (PTY) LTD

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

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

Laboratory/Laboratorium: BOEHRINGER INGELHEIM, INGELHEIM AM RHEIN, GERMANY
AVENTIS PHARMA, WALTLOO RSA
INSTITUT FRESENIUS GmbH, TAUNUSSTEIN GERMANY
INGELHEIM PHARMACEUTICALS, RANDBURG RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 15 NOVEMBER 2002
Datum van registrasie 15 NOVEMBER 2002

Registration number/Registrasienommer: 36/10.1/0053

Name of medicine/Naam van medisyne: CHIEF LINCTUS - HONEY FLAVOUR

Dosage form/Doseringsvorm: SYRUP/STROOP

Active ingredients/Aktiewe bestanddele:
EACH 10,0 ml SYRUP CONTAINS/
ELKE 10,0 ml STROOP BEVAT :
GUAIFENESIN ... 200,0 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
ADCOCK INGRAM HEALTHCARE, CLAYVILLE RSA

Shelf-life/Rakleeftyd: 48 months/maande

Date of registration: 15 NOVEMBER 2002
Datum van registrasie 15 NOVEMBER 2002

Registration number/Registrasienommer: 36/7.1.3/0020

Name of medicine/Naam van medisyne: PREXUM

Dosage form/Doseringsvorm: TABLET

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

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

Applicant/Applikant: TEMA MEDICAL (PTY) LTD

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

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

Laboratory/Laboratorium: EGIS PHARMACEUTICALS,BUDAPEST,HUNGARY
LES LABORATOIRES SERVIER IND.
FLEURY-LES-AUBRAIS FRANCE
SERVIER, WICKLOW, IRELAND
INSPECTORATE M & L, ORMONDE RSA
TECHNIKON LABORATORIES, FLORIDA RSA
TEMA MEDICAL, SANDTON, RSA

Shelf-life/Rakleeftyd: 48 months/maande

Date of registration: 15 NOVEMBER 2002
Datum van registrasie 15 NOVEMBER 2002

Registration number/Registrasienommer: 36/5.4/0019

Name of medicine/Naam van medisyne: DETRUNORM

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT :
PROPIVERINE HYDROCHLORIDE 15,0 mg

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

Applicant/Applikant: SCHERING-PLOUGH (PTY) LTD

Manufacturer/Vervaardiger: APOGEPHA ARZNEIMITTEL, DRESDEN GERMANY

Packer/Verpakker: APOGEPHA ARZNEIMITTEL, DRESDEN GERMANY
SCHERING-PLOUGH, ISANDO RSA

Laboratory/Laboratorium: APOGEPHA ARZNEIMITTEL, DRESDEN GERMANY
SCHERING-PLOUGH, ISANDO RSA

Shelf-life/Rakleeftyd: 36 months/maande

Date of registration: 15 NOVEMBER 2002
Datum van registrasie 15 NOVEMBER 2002

Registration number/Registrasienommer: 32/20.1.1/0515

Name of medicine/Naam van medisyne: SAFELINE-AMIKACIN SULPHATE 250

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH 2,0 ml SOLUTION CONTAINS/
ELKE 2,0 ml OPLOSSING BEVAT:
AMIKACIN SULPHATE ... 250,0 mg

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

Applicant/Applikant: SAFELINE PHARMACEUTICALS (PTY) LTD

Manufacturer/Vervaardiger: LISAPHARMA S.P.A., ERBA, ITALY

Packer/Verpakker: LISAPHARMA S.P.A., ERBA, ITALY

Laboratory/Laboratorium: LISAPHARMA S.P.A., ERBA, ITALY
ANALYTICON, KEMPTON PARK RSA
SAFELINE PHARMACEUTICALS, FLORIDA, RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 15 NOVEMBER 2002
Datum van registrasie 15 NOVEMBER 2002

Registration number/Registrasienommer: 32/20.1.1/0516

Name of medicine/Naam van medisyne: SAFELINE - AMIKACIN SULPHATE 500

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH 2,0 ml SOLUTION CONTAINS/
ELKE 2,0 ml OPLOSSING BEVAT:
AMIKACIN SULPHATE ... 500,0 mg

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

Applicant/Applikant: SAFELINE PHARMACEUTICALS (PTY) LTD

Manufacturer/Vervaardiger: LISAPHARMA S.P.A., ERBA, ITALY

Packer/Verpakker: LISAPHARMA S.P.A., ERBA, ITALY

Laboratory/Laboratorium: LISAPHARMA S.P.A., ERBA, ITALY
ANALYTICON, KEMPTON PARK RSA
SAFELINE PHARMACEUTICALS, FLORIDA, RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 15 NOVEMBER 2002
Datum van registrasie 15 NOVEMBER 2002

Registration number/Registrasienommer: 35/7.1.3/0051

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

Dosage form/Doseringsvorm: TABLET

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

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

Applicant/Applikant: MERCK GENERICS RSA (PTY) LTD

Manufacturer/Vervaardiger: MERCK, BARCELONA SPAIN
MERCK PHARMACEUTICALS MANUFACTURING ,
WADEVILLE GERMISTON RSA

Packer/Verpakker: MERCK, BARCELONA SPAIN
MERCK PHARMACEUTICALS MANUFACTURING ,
WADEVILLE GERMISTON RSA

Laboratory/Laboratorium: MERCK GENERICS RSA , MODDERFONTEIN, RSA
MERCK, BARCELONA SPAIN
MERCK PHARMACEUTICALS MANUFACTURING ,
WADEVILLE GERMISTON RSA
RESEARCH INSTITUTE FOR IND. PHARMACY,
POTCHEFSTROOM

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 15 NOVEMBER 2002
Datum van registrasie: 15 NOVEMBER 2002

Registration number/Registrasienommer: 35/7.1.3/0052

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

Dosage form/Doseringsvorm: TABLET

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

Conditions of registration/Voorwaardes vir registrasie:

Applicant/Applikant: MERCK GENERICS RSA (PTY) LTD

Manufacturer/Vervaardiger: MERCK, BARCELONA SPAIN
MERCK PHARMACEUTICALS MANUFACTURING,
WADEVILLE GERMISTON RSA

Packer/Verpakker: MERCK, BARCELONA SPAIN
MERCK PHARMACEUTICALS MANUFACTURING,
WADEVILLE GERMISTON RSA

Laboratory/Laboratorium: MERCK GENERICS RSA, MODDERFONTEIN
MERCK, BARCELONA SPAIN
MERCK PHARMACEUTICALS MANUFACTURING ,
WADEVILLE GERMISTON RSA
RESEARCH INSTITUTE FOR IND. PHARMACY,
POTCHEFSTROOM

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 15 NOVEMBER 2002
Datum van registrasie 15 NOVEMBER 2002

Registration number/Registrasienommer: 35/7.1.3/0053

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

Dosage form/Doseringsvorm: TABLET

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

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

Applicant/Applikant:	MERCK GENERICS RSA (PTY) LTD
Manufacturer/Vervaardiger:	MERCK, BARCELONA SPAIN MERCK PHARMACEUTICALS MANUFACTURING , WADEVILLE GERMISTON RSA
Packer/Verpakker:	MERCK, BARCELONA SPAIN MERCK PHARMACEUTICALS MANUFACTURING , WADEVILLE GERMISTON RSA
Laboratory/Laboratorium:	MERCK, BARCELONA SPAIN MERCK PHARMACEUTICALS MANUFACTURING , WADEVILLE GERMISTON RSA MERCK GENERICS RSA, MODDERFONTEIN FPRR RESEARCH INSTITUTE FOR IND. PHARMACY, POTCHEFSTROOM
Shelf-life/Rakleeftyd:	24 months/maande
Date of registration: Datum van registrasie:	15 NOVEMBER 2002 15 NOVEMBER 2002

Registration number/Registrasienommer: 35/7.1.3/0054

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

Dosage form/Doseringsvorm: TABLET

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

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

Applicant/Applikant: MERCK GENERICS RSA (PTY) LTD

Manufacturer/Vervaardiger: MERCK, BARCELONA SPAIN
MERCK PHARMACEUTICALS MANUFACTURING ,
WADEVILLE GERMISTON RSA

Packer/Verpakker: MERCK, BARCELONA SPAIN
MERCK PHARMACEUTICALS MANUFACTURING ,
WADEVILLE GERMISTON RSA

Laboratory/Laboratorium: MERCK, BARCELONA SPAIN
MERCK GENERICS RSA, MODDERFONTEIN
MERCK PHARMACEUTICALS MANUFACTURING
WADEVILLE GERMISTON RSA
RESEARCH INSTITUTE FOR IND. PHARMACY,
POTCHEFSTROOM

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 15 NOVEMBER 2002
Datum van registrasie: 15 NOVEMBER 2002

Registration number/Registrasienommer: 35/5.7.1/0354

Name of medicine/Naam van medisyne: LORANO 10

Dosage form/Doseringsvorm: TABLET

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

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

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

Manufacturer/Vervaardiger: SALUTAS PHARMA, BARLEBEN GERMANY

Packer/Verpakker: DIVPHARM MANUFACTURING AND PACKAGING, LONGDALE RSA

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

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 15 NOVEMBER 2002
Datum van registrasie 15 NOVEMBER 2002

Registration number/Registrasienommer: 35/5.7.1/0355

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

Dosage form/Doseringsvorm: TABLET

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

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

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

Manufacturer/Vervaardiger: HEXAL AG, HOLZKIRCHEN GERMANY

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

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

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 15 NOVEMBER 2002
Datum van registrasie 15 NOVEMBER 2002

Registration number/Registrasienommer: 35/26/0394

Name of medicine/Naam van medisyne: PHARM-AZATHIOPRINE

Dosage form/Doseringsvorm: TABLET

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

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

Applicant/Applikant: PHARMACARE LIMITED

Manufacturer/Vervaardiger: LENNON LTD, PORT ELIZABETH RSA

Packer/Verpakker: LENNON LTD, PORT ELIZABETH RSA

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

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 15 NOVEMBER 2002
Datum van registrasie 15 NOVEMBER 2002

Registration number/Registrasienommer: 36/15.4/0333

Name of medicine/Naam van medisyne: TRAVATAN

Dosage form/Doseringsvorm: EYEDROPS/OOGDRUPPELS

Active ingredients/Aktiewe bestanddele:
EACH 1,0 ml CONTAINS/ELKE 1,0 ml BEVAT:
TRAVOPROST ... 40,0 ug

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

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

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

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

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

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 15 NOVEMBER 2002
Datum van registrasie 15 NOVEMBER 2002

Registration number/Registrasienommer: 98/22.6.1/10

Name of medicine/Naam van medisyne: INCURIN

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS
OESTRIOL ... 1.0 mg

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

Applicant/Applikant:	INTERVET SA (PTY) LTD
Manufacturer/Vervaardiger:	NV ORGANON, OSS NETHERLANDS
Packer/Verpakker:	NV ORGANON, OSS NETHERLANDS
Laboratory/Laboratorium:	NV ORGANON, OSS NETHERLANDS INTERVET S.A., EDENVALE RSA SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA, RSA
Shelf-life/Rakleeftyd:	36 months/maande
Date of registration: Datum van registrasie	15 NOVEMBER 2002 15 NOVEMBER 2002

Registration number/Registrasienommer: 33/3/0182

Name of medicine/Naam van medisyne: DUOVISC INTRAOCULAR VISCOELASTIC SYSTEM

Dosage form/Doseringsvorm: SOLUTION/OPLOSSING

Active ingredients/Aktiewe bestanddele:
EACH 1,0 ml PROVISC CONTAINS:
SODIUM HYALURONATE ... 10,0 mg

EACH 1,0 ml VISCOAT CONTAINS:
SODIUM CHONDROITIN SULPHATE ... 40,0 mg
SODIUM HYALURONATE ... 30,0 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: 36 months/maande

Date of registration: 15 NOVEMBER 2002
Datum van registrasie 15 NOVEMBER 2002

Registration number/Registrasienommer: 35/5.7.1/0288

Name of medicine/Naam van medisyne: CLARINESE 10 MG TABLETS

Dosage form/Doseringsvorm: TABLET

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

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

Applicant/Applikant: PHARMACARE LIMITED

Manufacturer/Vervaardiger: LENNON LTD, PORT ELIZABETH RSA

Packer/Verpakker: LENNON LTD, PORT ELIZABETH RSA

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

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 15 NOVEMBER 2002
Datum van registrasie 15 NOVEMBER 2002

Registration number/Registrasienommer: 35/34/0182

Name of medicine/Naam van medisyne: ZOMETA

Dosage form/Doseringsvorm: INJECTION/INJECTION

Active ingredients/Aktiewe bestanddele:
EACH VIAL CONTAINS/ELKE FLESSIE BEVAT :
ZOLEDRONATE TRISODIUM ... 4,0 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
Laboratory/Laboratorium:	NOVARTIS, STEIN SWITZERLAND INSPECTORATE M & L, ORMONDE RSA NOVARTIS, SPARTAN KEMPTON PARK RSA
Shelf-life/Rakleeftyd:	24 months/maande
Date of registration: Datum van registrasie	15 NOVEMBER 2002 15 NOVEMBER 2002

Registration number/Registrasienommer: 35/34/0183

Name of medicine/Naam van medisyne: ZOMERIL

Dosage form/Doseringsvorm: INJECTION/INJECTION

Active ingredients/Aktiewe bestanddele:
EACH VIAL CONTAINS/ELKE FLESSIE BEVAT:
ZOLEDRONATE TRISODIUM ... 4,0 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

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

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 15 NOVEMBER 2002
Datum van registrasie 15 NOVEMBER 2002

Registration number/Registrasienommer: 35/7.5/0237

Name of medicine/Naam van medisyne: SIMVACOR 10 MG

Dosage form/Doseringsvorm: TABLET

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

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

Applicant/Applikant: WARNER-LAMBERT SA (PTY) LTD

Manufacturer/Vervaardiger: KRKA, NOVO MESTO, SLOVENIA

Packer/Verpakker: KRKA, NOVO MESTO, SLOVENIA
WARNER-LAMBERT, RETREAT RSA

Laboratory/Laboratorium: KRKA, NOVO MESTO, SLOVENIA
WARNER-LAMBERT, RETREAT RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 15 NOVEMBER 2002
Datum van registrasie 15 NOVEMBER 2002

Registration number/Registrasienommer: 35/7.5/0238

Name of medicine/Naam van medisyne: SIMVACOR 20 MG

Dosage form/Doseringsvorm: TABLET

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

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

Applicant/Applikant: WARNER-LAMBERT SA (PTY) LTD

Manufacturer/Vervaardiger: KRKA, NOVO MESTO, SLOVENIA

Packer/Verpakker: KRKA, NOVO MESTO, SLOVENIA
WARNER-LAMBERT, RETREAT RSA

Laboratory/Laboratorium: KRKA, NOVO MESTO, SLOVENIA
WARNER-LAMBERT, RETREAT RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 15 NOVEMBER 2002
Datum van registrasie 15 NOVEMBER 2002

Registration number/Registrasienommer: 35/5.7.1/0289

Name of medicine/Naam van medisyne: LESS-SPORE 10 MG TABLETS

Dosage form/Doseringsvorm: TABLET

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

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

Applicant/Applikant:	PHARMACARE LIMITED
Manufacturer/Vervaardiger:	LENNON LTD, PORT ELIZABETH RSA
Packer/Verpakker:	LENNON LTD, PORT ELIZABETH RSA
Laboratory/Laboratorium:	LENNON LTD, PORT ELIZABETH RSA PHARMACARE LTD, PORT ELIZABETH RSA
Shelf-life/Rakleeftyd:	24 months/maande
Date of registration: Datum van registrasie	15 NOVEMBER 2002 15 NOVEMBER 2002

Registration number/Registrasienommer:35/21.8/0020

Name of medicine/Naam van medisyne: ESTASURE

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele: EACH PACK CONTAINS:
14 WHITE TABLETS EACH CONTAINING:
17 BETA-ESTRADIOL ... 2,0 mg

14 REDDISH-BROWN TABLETS EACH CONTAINING:
17 BETA-ESTRADIOL ... 2,0 mg
TRIMESGESTONE ... 0,5 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: WYETH S.A. (PTY) LTD

Manufacturer/Vervaardiger: WYETH MEDICA IRELAND, KILDARE IRELAND

Packer/Verpakker: WYETH MEDICA IRELAND, KILDARE IRELAND
PHARMA-Q, INDUSTRIA

Laboratory/Laboratorium: WYETH MEDICA IRELAND, KILDARE IRELAND
SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA
PHARMA-Q, INDUSTRIA

Shelf-life/Rakleeftyd: 36 months/maande

Date of registration: 15 NOVEMBER 2002
Datum van registrasie 15 NOVEMBER 2002

Registration number/Registrasienommer: 35/5.7.1/314

Name of medicine/Naam van medisyne: TEXA 10 MG

Dosage form/Doseringsvorm: TABLET

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

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

Applicant/Applikant: PHARMA DYNAMICS (PTY) LTD

Manufacturer/Vervaardiger: DELTA LIMITED,HAFNARFJOROUR,ICELAND

Packer/Verpakker: DELTA LIMITED,HAFNARFJOROUR,ICELAND
DIVPHARM MANUFACTURING AND PACKAGING,
LONGDALE RSA

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

Shelf-life/Rakleeftyd: 36 Months/Maande In PVCA/Blisters
24 Months/Maande In Securitainers

Date of registration: 15 NOVEMBER 2002
Datum van registrasie 15 NOVEMBER 2002

Registration number/Registrasienommer: 35/7.1.3/0357

Name of medicine/Naam van medisyne: LISINOHEXAL 5

Dosage form/Doseringsvorm: TABLET

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

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

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

Manufacturer/Vervaardiger: SALUTAS PHARMA, BARLEBEN GERMANY

Packer/Verpakker: DIVPHARM MANUFACTURING AND PACKAGING, LONGDALE RSA

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

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 15 NOVEMBER 2002
Datum van registrasie 15 NOVEMBER 2002

Registration number/Registrasienommer: 35/7.1.3/0358

Name of medicine/Naam van medisyne: LISINOHEXAL 10

Dosage form/Doseringsvorm: TABLET

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

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

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

Manufacturer/Vervaardiger: SALUTAS PHARMA, BARLEBEN GERMANY

Packer/Verpakker: DIVPHARM MANUFACTURING AND PACKAGING, LONGDALE RSA

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

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 15 NOVEMBER 2002
Datum van registrasie 15 NOVEMBER 2002

Registration number/Registrasienommer: 35/7.1.3/0359

Name of medicine/Naam van medisyne: LISINOHEXAL 20

Dosage form/Doseringsvorm: TABLET

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

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

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

Manufacturer/Vervaardiger: SALUTAS PHARMA, BARLEBEN GERMANY

Packer/Verpakker: DIVPHARM MANUFACTURING AND PACKAGING, LONGDALE RSA

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

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 15 NOVEMBER 2002
Datum van registrasie 15 NOVEMBER 2002

Registration number/Registrasienommer: 35/21.5.1/0363

Name of medicine/Naam van medisyne: PULMISON 5 MG/5 ML

Dosage form/Doseringsvorm: SOLUTION/OPLOSSING

Active ingredients/Aktiewe bestanddele:
EACH 5,0 ml ORAL SOLUTION CONTAINS/
ELKE 5,0 ml OPLOSSING BEVAT:
PREDNISONE ... 5,00 mg

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

Applicant/Applikant: INGELHEIM PHARMACEUTICALS (PTY) LTD

Manufacturer/Vervaardiger: AVENTIS PHARMA, PORT ELIZABETH RSA
AVENTIS PHARMA, WALTLOO RSA

Packer/Verpakker: AVENTIS PHARMA, PORT ELIZABETH RSA
AVENTIS PHARMA, WALTLOO RSA

Laboratory/Laboratorium: AVENTIS PHARMA, PORT ELIZABETH RSA
AVENTIS PHARMA, WALTLOO RSA
INGELHEIM PHARMACEUTICALS, RANDBURG RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 15 NOVEMBER 2002
Datum van registrasie 15 NOVEMBER 2002

Registration number/Registrasienommer: 35/21.5.1/0364

Name of medicine/Naam van medisyne: PULMISON 5 MG/ML

Dosage form/Doseringsvorm: SOLUTION/OPLOSSING

Active ingredients/Aktiewe bestanddele:
EACH 1,0 ml CONCENTRATED ORAL SOLUTION CONTAINS/
ELKE 1,0 ml OPLOSSING BEVAT :
PREDNISONE ... 5,0 mg

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

Applicant/Applikant: INGELHEIM PHARMACEUTICALS (PTY) LTD

Manufacturer/Vervaardiger: AVENTIS PHARMA, PORT ELIZABETH RSA
AVENTIS PHARMA, WALTLOO RSA

Packer/Verpakker: AVENTIS PHARMA, PORT ELIZABETH RSA
AVENTIS PHARMA, WALTLOO RSA

Laboratory/Laboratorium: AVENTIS PHARMA, PORT ELIZABETH RSA
AVENTIS PHARMA, WALTLOO RSA
INGELHEIM PHARMACEUTICALS, RANDBURG RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 15 NOVEMBER 2002
Datum van registrasie 15 NOVEMBER 2002

Registration number/Registrasienommer: 36/26/0001

Name of medicine/Naam van medisyne: BLEOLEM

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH VIAL CONTAINS/ELKE FLESSIE BEVAT :
BLEOMYCIN SULPHATE ... 8,57 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: KEY ONCOLOGICS (PTY) LTD

Manufacturer/Vervaardiger: LEMERY SA de CV, MEXICO

Packer/Verpakker: LEMERY SA de CV, MEXICO

Laboratory/Laboratorium: LEMERY SA de CV, MEXICO
KEY ONCOLOGICS, SANDTON RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 15 NOVEMBER 2002
Datum van registrasie 15 NOVEMBER 2002

Registration number/Registrasienommer: 36/10.2.1/0045

Name of medicine/Naam van medisyne: IP-TIOTROPIUM

Dosage form/Doseringsvorm: CAPSULES/KAPSULES

Active ingredients/Aktiewe bestanddele:
EACH CAPSULE FOR INHALATION CONTAINS/ELKE INHALASIE KAPSULE BEVAT :
TIOTROPIUM BROMIDE EQUIVALENT TO TIOTROPIUM ... 18,0 ug

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

Applicant/Applikant: INGELHEIM PHARMACEUTICALS (PTY) LTD

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

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

Laboratory/Laboratorium: BOEHRINGER INGELHEIM, INGELHEIM AM RHEIN, GERMANY
AVENTIS PHARMA, WALTLOO RSA
INSTITUT FRESENIUS GmbH, TAUNUSSTEIN GERMANY
INGELHEIM PHARMACEUTICALS, RANDBURG RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 15 NOVEMBER 2002
Datum van registrasie 15 NOVEMBER 2002

Registration number/Registrasienommer: 36/2.6.5/0070

Name of medicine/Naam van medisyne: SEROQUEL 300

Dosage form/Doseringsvorm: TABLET

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

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

Applicant/Applikant: ASTRAZENECA PHARMACEUTICALS (PTY) LTD

Manufacturer/Vervaardiger: ASTRAZENECA, CHESHIRE UK
ASTRAZENECA, NEWARK, DELAWARE, USA

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

Laboratory/Laboratorium: ASTRAZENECA, CHESHIRE UK
ASTRAZENECA, NEWARK, DELAWARE, USA
JANSSEN PHARMACEUTICA, HALFWAY HOUSE RSA
ANALYTICON, KEMPTON PARK RSA
CONSULTING CHEMICAL LAB, STAR STREET
BOKSBURG RSA
ASTRAZENECA, ALRODE, ALBERTON RSA

Shelf-life/Rakleeftyd: 36 months/maande

Date of registration: 15 NOVEMBER 2002
Datum van registrasie 15 NOVEMBER 2002

Registration number/Registrasienommer: 33/13.3/0467

Name of medicine/Naam van medisyne: CATHEJELL WITH LIDOCAINE

Dosage form/Doseringsvorm: GEL/JEL

Active ingredients/Aktiewe bestanddele:
EACH 100,0 g GEL CONTAINS/ELKE 100,0 g JEL BEVAT :
CHLORHEXIDIN-HYDROCHLORID ... 0,05 g
LIDOCAINE HYDROCHLORIDE ... 2,0 g

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

Applicant/Applikant: PHARMAPLAN (PTY) LTD

Manufacturer/Vervaardiger: MONTAVIT GmbH, TIROL,AUSTRIA

Packer/Verpakker: MONTAVIT GmbH, TIROL,AUSTRIA

Laboratory/Laboratorium: MONTAVIT GmbH, TIROL,AUSTRIA
CONSULTING CHEMICAL LAB, STAR STREET
BOKSBURG RSA
MPL MIKROBIOLOGISCHES,INNSBRUCK,AUSTRIA
PHARMAPLAN, MIDRAND RSA

Shelf-life/Rakleeftyd: 24 months/maande

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

Registration number/Registrasienommer: 32/30.1/0745

Name of medicine/Naam van medisyne: BCG CULTURE SSI

Dosage form/Doseringsvorm: SUSPENSION/SUSPENSIE

Active ingredients/Aktiewe bestanddele:
EACH VIAL CONTAINS/ELKE FLESSIE BEVAT :
MYCOBACTERIUM BOVIS ... 30,0 mg

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

Applicant/Applikant: VACCINA (PTY) LTD

Manufacturer/Vervaardiger: STATENS SERUMINSTITUT, COPENHAGEN DENMARK

Packer/Verpakker: STATENS SERUMINSTITUT, COPENHAGEN DENMARK
VACCINA CC, WADEVILLE

Laboratory/Laboratorium: STATENS SERUMINSTITUT, COPENHAGEN DENMARK
NATIONAL CONTROL LAB (NCL) BLOEMFONTEIN

Shelf-life/Rakleeftyd: 24 months/maande

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

Registration number/Registrasienommer: 33/30.1/0072

Name of medicine/Naam van medisyne: TYPHERIX

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH 0,5 ml DOSE CONTAINS/ELKE 0,5 ml DOSIS BEVAT:
SALMONELLA TYPHI ... 25,0 ug

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

Applicant/Applikant: GLAXOSMITHKLINE SOUTH AFRICA (PTY) LIMITED

Manufacturer/Vervaardiger: GLAXOSMITHKLINE, (BIO MAN) RIXENSART BELGIUM

Packer/Verpakker: GLAXOSMITHKLINE, (BIO MAN) WAVRE BELGIUM

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

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 19 DECEMBER 2002
Datum van registrasie 19 DESEMBER 2002

Registration number/Registrasienommer: 33/21.5.1/0512

Name of medicine/Naam van medisyne: MICRO DEXAMETHASONE PHOSPHATE INJECTION 4 mg/1 ml C/A

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH 1,0 ml SOLUTION CONTAINS/ELKE 1,0 ml OPLOSSING BEVAT:
DEXAMETHASONE SODIUM PHOSPHATE EQUIVALENT TO
DEXAMETHASONE PHOSPHATE ... 4,0 mg

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

Applicant/Applikant: MICRO HEALTHCARE (PTY) LTD

Manufacturer/Vervaardiger: MICRO HEALTHCARE, BETHLEHEM RSA

Packer/Verpakker: MICRO HEALTHCARE, BETHLEHEM RSA

Laboratory/Laboratorium: MICRO HEALTHCARE, BETHLEHEM RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 19 DECEMBER 2002
Datum van registrasie 19 DESEMBER 2002

Registration number/Registrasienommer: 33/2.7/0426

Name of medicine/Naam van medisyne: MICRO SUFENTANIL FORTE INJECTION 250 ug/5 ml

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH 5,0 ml SOLUTION CONTAINS/ELKE 5,0 ml OPLOSSING BEVAT :
SUFENTANIL CITRATE EQUIVALENT TO
SUFENTANIL ... 250,0 ug

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

Applicant/Applikant: MICRO HEALTHCARE (PTY) LTD

Manufacturer/Vervaardiger: MICRO HEALTHCARE, BETHLEHEM RSA

Packer/Verpakker: MICRO HEALTHCARE, BETHLEHEM RSA

Laboratory/Laboratorium: MICRO HEALTHCARE, BETHLEHEM RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 19 DECEMBER 2002
Datum van registrasie 19 DESEMBER 2002

Registration number/Registrasienommer: 34/13.12/0026

Name of medicine/Naam van medisyne: DERMA-T

Dosage form/Doseringsvorm: GEL/JEL

Active ingredients/Aktiewe bestanddele:
EACH 1,0 g GEL CONTAINS/ELKE 1,0 g JEL BEVAT :
TRETINOIN ... 0,25 mg

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

Applicant/Applikant: ALCHEMY PHARMACEUTICALS CC

Manufacturer/Vervaardiger: BEIGE PHARMACEUTICALS, EDENVALE RSA

Packer/Verpakker: BEIGE PHARMACEUTICALS, EDENVALE RSA

Laboratory/Laboratorium: BEIGE PHARMACEUTICALS, EDENVALE RSA
ALCHEMY PHARMACEUTICALS, NIGEL RSA

Shelf-life/Rakleeftyd: 24 months/maande

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

Registration number/Registrasienommer: 98/22.6.1/3

Name of medicine/Naam van medisyne: MESALIN

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH 1,0 ml SOLUTION CONTAINS/ELKE 1,0 ml OPLOSSING BEVAT:
ESTRADIOL BENZOATE ... 0,2 mg

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

Applicant/Applikant: INTERVET SA (PTY) LTD

Manufacturer/Vervaardiger: INTERVET INTERNATIONAL, BOXMEER
NETHERLANDS

Packer/Verpakker: INTERVET INTERNATIONAL, BOXMEER
NETHERLANDS

Laboratory/Laboratorium: INTERVET INTERNATIONAL, BOXMEER
NETHERLANDS
SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA
RSA
INTERVET S.A., EDENVALE RSA

Shelf-life/Rakleeftyd: 60 months/maande

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

Registration number/Registrasienommer: 29/7.1/0590

Name of medicine/Naam van medisyne: MERCK-INDAPAMIDE 2,5 mg

Dosage form/Doseringsvorm: TABLET

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

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

Applicant/Applikant: MERCK GENERICS RSA (PTY) LTD

Manufacturer/Vervaardiger: GERARD LABORATORIES, DUBLIN IRELAND

Packer/Verpakker: GERARD LABORATORIES, DUBLIN IRELAND

Laboratory/Laboratorium: GERARD LABORATORIES, DUBLIN IRELAND
RESEARCH INSTITUTE FOR IND. PHARMACY, POTCHEFSTROOM RSA
MERCK GENERICS RSA, MODDERFONTEIN RSA

Shelf-life/Rakleeftyd: 24 months/maande

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

Registration number/Registrasienommer: 34/8.1/0464

Name of medicine/Naam van medisyne: COLLATAMP FASCIA

Dosage form/Doseringsvorm: DRESSING/VERBAND

Active ingredients/Aktiewe bestanddele:
EACH 1,0 cm3 DRESSING CONTAINS/ELKE 1,0 cm3 VERBAND BEVAT:
BOVINE COLLAGEN ... 8,0 mg

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

Applicant/Applikant: SYNTACOLL (PTY) LTD

Manufacturer/Vervaardiger: INNOCOLL GmbH, DONAU, GERMANY

Packer/Verpakker: INNOCOLL GmbH, DONAU, GERMANY

Laboratory/Laboratorium: INNOCOLL GmbH, DONAU, GERMANY
SYNTACOLL, MIDRAND RSA

Shelf-life/Rakleeftyd: 24 months/maande

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