



GOVERNMENT GAZETTE

OF THE

REPUBLIC OF NAMIBIA

N\$2.00

WINDHOEK - 17 June 2010

No. 4505

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Government Notice

MINISTRY OF HEALTH AND SOCIAL SERVICES

No. 128

2010

REGISTRATION OF CERTAIN MEDICINES: MEDICINES AND RELATED SUBSTANCES CONTROL ACT, 2003

In terms of section 23 of the Medicines and Related Substances Control Act, 2003 (Act No. 13 of 2003) I make known that the medicines set out in Part I of the Schedule have been registered -

- (a) in terms of that Act; and
- (b) subject to the conditions set out in Part II of the Schedule.

J. GAESEB
REGISTRAR OF MEDICINES

Windhoek, 28 May 2010

SCHEDULE

PART I

S/N	APPLICANT	PROPRIETARY NAME	APPROVED NAME OF ACTIVE(S)	DOSAGE FORM	STRENGTH/DOSE UNIT	REGIST. NO NAMIBIA	REGISTRATION DATE	SCHED. STATUS
1	Ingelheim Pharmaceuticals (Pty) Ltd	Forvent	Tiotropium Bromide	capsules for inhalation	Each capsule for inhalation contains Tiotropium Bromide equivalent to Tiotropium 18,0 µg	10.2.1/0351	2010/04/15	NS2
2	Ranbaxy (SA) (Pty) Ltd	Lipogen 10	Atorvastatin Calcium	tablet	Each tablet contains atorvastatin calcium equivalent to atorvastatin 10,0 mg	10/7.5/0352	2010/04/15	NS2
3	Ranbaxy (SA) (Pty) Ltd	Lipogen 20	Atorvastatin Calcium	tablet	Each tablet contains atorvastatin calcium equivalent to atorvastatin 20,0 mg	10/7.5/0353	2010/04/15	NS2
4	Ranbaxy (SA) (Pty) Ltd	Lipogen 40	Atorvastatin Calcium	tablet	Each tablet contains atorvastatin calcium equivalent to atorvastatin 40,0 mg	10/7.5/0354	2010/04/15	NS2
5	Ranbaxy (SA) (Pty) Ltd	Lipogen 80	Atorvastatin Calcium	tablet	Each tablet contains atorvastatin calcium equivalent to atorvastatin 80,0 mg	10/7.5/0355	2010/04/15	NS2
6	Ranbaxy (SA) (Pty) Ltd	Lescogen 20	Fluvastatin sodium	capsule	Each capsule contains Fluvastatin Sodium equivalent to Fluvastatin 20,0 mg	10/7.5/0356	2010/04/15	NS2
7	Ranbaxy (SA) (Pty) Ltd	Lescogen 40	Fluvastatin sodium	capsule	Each capsule contains Fluvastatin Sodium equivalent to fluvastatin 40,0 mg	10/7.5/0357	2010/04/15	NS2
8	Ranbaxy (SA) (Pty) Ltd	Zelivire 500	Valaciclovir hydrochloride	tablet	Each film-coated tablet contains Valaciclovir Hydrochloride equivalent to Valaciclovir 500 mg	10/20.2.8/0358	2010/04/15	NS2
9	Be-Tab Pharmaceuticals (Pty) Ltd	Be-Tab Diclofenac Injection	Diclofenac Sodium	injection	Each 3 ml ampoule contains Diclofenac Sodium 75 mg	10/3.1/0359	2010/04/15	NS2
10	Be-Tab Pharmaceuticals (Pty) Ltd	Cimlok 400 mg	Cimetidine	tablet	Each tablet contains Cimetidine 400,0 mg	10/11.4.3/0360	2010/04/15	NS2

11	Be-Tab Pharmaceuticals (Pty) Ltd	Diacare Tablets	Glibenclamide	tablet	Each tablet contains Glibenclamide 5,0 mg	10/21.2/0361	2010/04/15	NS2
12	Bayer (Pty) Ltd	Yaz	Drospirenone; Ethinylestradiol	tablet	Each tablet contains Drospirenone 3,0 mg and Ethinylestradiol 0,02 mg	10/21.8.2/0362	2010/04/15	NS1
13	MSD (Pty) Ltd	Tredaptive	Niacin; Laropiprant	tablet	Each tablet contains 1 g extended - release (ER) Niacin (nicotinic acid), immediate-release Laropiprant 20,0 mg	10/7.5/0363	2010/04/15	NS2
14	MSD (Pty) Ltd	MSD- Niacin/ Laropiprant	Niacin; Laropiprant	tablet	Each tablet contains 1 g extended - release (ER) Niacin (nicotinic acid), immediate-release Laropiprant 20,0 mg	10/7.5/0364	2010/04/15	NS2
15	Wyeth (Pty) Ltd	Prevenar 13	13 saccharide serotypes combination	suspension for injection	Each 0,5 ml dose contains 2,2 µg of Saccharide for serotypes 1, 3, 4, 5, 6A, 7F, 9V, 14, 18C, 19A, 19F, and 23F and 4,4 µg of saccharide for serotype 6B	10/30.1/0365	2010/04/15	NS1
16	Allergan Pharmaceuticals (Pty) Ltd	Ganfort	Bimaprost; Timolol Maleate	eye drops	Each 1,0 ml solution contains Bimaprost 0,3 mg, Timolol Maleate equivalent to Timolol 5,0 mg	10/15.4/0366	2010/04/15	NS2
17	Novartis South Africa (Pty) Ltd	Excedrin	Paracetamol; Aspirin; Caffeine	tablet	Each tablet contains Paracetamol 250,0 mg, Aspirin 250,0 mg and Caffeine 65,0 mg	10/2.8/0367	2010/04/15	NS1
18	MSD (Pty) Ltd	Ivemend	Fosaprepitant	iv injection	Each vial of Emend for injection contains Fosaprepitant Dimeglumine 115 mg	10/5.7.2/0368	2010/04/15	NS2
19	GlaxoSmithKline South Africa (Pty) Ltd	Arepanrix	antigen: A/Cali- formia/7/2009 (H N1)v-like virus	injection	Each dose (0,5 ml) contains split Influenza Virus, inactivated, containing antigen equivalent to A/California/7/2009(H1N1)v-like virus 3,75 micrograms	10/30.1/0369	2010/04/15	NS1
20	Aurobindo Pharma (Pty) Ltd	Auro-Amoxiclav 125-31.25 mg/5ml	Amoxicillin Trihydrate; Potassium Clavulanate	powder for suspension	Each 5,0 ml suspension contains Amoxicillin Trihydrate equivalent to Amoxicillin 125,0 mg and Potassium Clavulanate equivalent to Clavulanic Acid 31,25 mg	10/20.1.2/0370	2010/04/15	NS 2
21	Aurobindo Pharma (Pty) Ltd	Auro-Amoxiclav 250-62.50 mg/5ml	Amoxicillin Trihydrate; Potassium Clavulanate	powder for suspension	Each 5,0 ml suspension contains Amoxicillin Trihydrate equivalent to Amoxicillin 250,0 mg and Potassium Clavulanate equivalent to Clavulanic Acid 62,50 mg	10/20.1.2/0371	2010/04/15	NS2

22	Ranbaxy (SA) (Pty) Ltd	Contiflo SR	Tamsulosin Hydrochloride	capsule	Each capsule contains Tamsulosin Hydrochloride 0,4 mg	10/34/0372	2010/04/15	NS2
23	GlaxoSmithKline South Africa (Pty) Ltd	Zentel 400	Albendazole	tablet	Each tablet contains Albendazole 400 mg	10/12/0373	2010/04/15	NS2
24	Adcock Ingram Ltd	Plagrol	Clopidogrel Bisulfate	tablet	Each tablet contains Clopidogrel Bisulfate equivalent to Clopidogrel 75,0 mg	10/8.2/0374	2010/04/15	NS2
25	Orthomedics Pharmaceuticals (Pty) Ltd	SmartSet GHV Gentamicin Bone Cement	Gentamicin Sulphate	bone cement	Each 40,0 g contains Gentamicin Sulphate equivalent to Gentamicin 1,0 g	10/20.1.1/0375	2010/04/15	NS2
26	Pharma Dynamics (Pty) Ltd	Carzin XL	Doxazosin Mesylate	tablet	Each tablet contains Doxazosin Mesylate equivalent to Doxazosin 4,0 mg	10/34/0376	2010/04/15	NS2
27	Pharma Dynamics (Pty) Ltd	Pharma Dynamics Clopidogrel 75 mg	Clopidogrel Hydrogen Sulphate	tablet	Each film-coated tablet contains Clopidogrel Hydrogen Sulphate equivalent to Clopidogrel 75,0 mg	10/7.1/0377	2010/04/15	NS2
28	Specpharm (Pty) Ltd	Spec-Co-Amiloride	Amiloride HCl; Hydrochlorothiazide	tablet	Each tablet contains Amiloride Hydrochloride 5 mg and Hydrochlorothiazide 50 mg	10/18.1/0378	2010/04/15	NS2
29	Adcock Ingram Ltd	Corenza Cold and Flu Syrup	Pseudoephedrine HCl, Chlorpheniramine Maleate, Paracetamol	syrup	Each 5,0 ml syrup contains Pseudoephedrine HCl 15,0 mg, Chlorpheniramine Maleate 2,0 mg and Paracetamol 120,0 mg	10/5.8/0379	2010/04/15	NS1
30	Adcock Ingram Ltd	Bioplus Syrup Strawberry	Calcium Gluconate, Caffeine, Calcium Citrate, Thiamine Hydrochloride, Riboflavin Pyridoxine, Pantothenol and Cyanocobalamin	syrup	Each 30,0 ml syrup contains Calcium Gluconate 900,0 mg, Caffeine 270,0 mg, Calcium Citrate 180,0 mg, Thiamine Hydrochloride 16,0 mg, Riboflavin 11,0 mg, Pyridoxine 9,0 mg, Nicotinamide 42,0 mg d- Pantothenol 11,0 mg and Cyanocobalamin 26,0 mg	10/33/0380	2010/04/15	NS1

31	Sanofi-Aventis South Africa (Pty) Ltd	Adacel Quadra	Pertussis toxoid, Filamentous haemagglutinin, Fimbriae types 2+3, 2 Lf Diphtheria Toxoid, 5 Lf Tetanus Toxoid and Inactivated Poliomyelitis Type 3	suspension for injection	Each 0,5 ml contains 2,5 mg Pertussis Toxoid, 5mcg Filamentous haemagglutinin, 5 mcg, Fimbriae types 2+3, 3 mcg Pertactin, 2 Lf Diphtheria Toxoid,, 5 Lf Tetanus Toxoid and Inactivated Poliomyelitis 40 D units Type 1, 8 Dunits Type 3	10/30.1/0381	2010/04/15	NS1
32	Cipla - Medpro (Pty) Ltd	Trozodex	Anastrozole	tablet	Each film-coated tablet contains Anastrozole 1 mg	10/21.12/0382	2010/04/15	NS2
33	Cipla - Medpro (Pty) Ltd	Cipla-Pamidronic Acid 90	Pamidrone disodium	injection	Each 10 ml of injection vial contains Pamidronate Disodium equivalent to Pamidronic Acid 90 mg	10/34/0383	2010/04/15	NS2
34	Cipla - Medpro (Pty) Ltd	Cipla-Pamidronic Acid 60	Pamidrone disodium	injection	Each 10 ml of injection vial contains Pamidronate Disodium equivalent to Pamidronic Acid 60 mg	10/34/0384	2010/04/15	NS2
35	Cipla - Medpro (Pty) Ltd	Cipla-Pamidronic Acid 30	Pamidrone disodium	injection	Each 10 ml of injection vial contains Pamidronate Disodium equivalent to Pamidronic Acid 30 mg	10/34/0385	2010/04/15	NS2
36	Cipla - Medpro (Pty) Ltd	Cipla-Oxaliplatin 100	Oxaliplatin	injection	Each 50 ml vial contains Oxaliplatin 100,0 mg	10/26/0386	2010/04/15	NS2
37	Cipla - Medpro (Pty) Ltd	Cipla-Oxaliplatin 50	Oxaliplatin	injection	Each 50 ml vial contains Oxaliplatin 50,0 mg	10/26/0387	2010/04/15	NS2
38	Cipla - Medpro (Pty) Ltd	Parafizz	Paracetamol	tablet	Each effervescent tablet contains Paracetamol 500,0 mg	10/2.7/0388	2010/04/15	NS1
39	Cipla - Medpro (Pty) Ltd	Ipvent 20 HFA	Ipratropium Bromide	metered dose inhaler	Each actuation delivers Ipratropium Bromide 20 µg	10/10.2.1/0389	2010/04/15	NS1
40	Cipla - Medpro (Pty) Ltd	Co-Zartan 25/100	Losartan Potassium; Hydrochlorothiazide	tablet	Each film-coated tablet contains Losartan Potassium 100,0 mg and Hydrochlorothiazide 25,0 mg	10/7.1.3/0390	2010/04/15	NS2

41	Cipla - Medpro (Pty) Ltd	Co-Zartan 12.5/50	Losartan Potassium; Hydrochlorothiazide	tablet	Each film-coated tablet contains Losartan Potassium 50,0 mg and Hydrochlorothiazide 12,5 mg	10/7.1.3/0391	2010/04/15	NS2
42	Cipla - Medpro (Pty) Ltd	Cipla - Pravastatin 10	Pravastatin sodium	tablet	Each tablet contains Pravastatin Sodium 10,0 mg	10/7.5/0392	2010/04/15	NS2
43	Cipla - Medpro (Pty) Ltd	Cipla - Pravastatin 20	Pravastatin sodium	tablet	Each tablet contains Pravastatin Sodium 20,0 mg	10/7.5/0393	2010/04/15	NS2
44	Cipla - Medpro (Pty) Ltd	Cipla - Pravastatin 40	Pravastatin sodium	tablet	Each tablet contains Pravastatin Sodium 40,0 mg	10/7.5/0394	2010/04/15	NS2
45	Cipla - Medpro (Pty) Ltd	Cipla - Pravastatin 80	Pravastatin sodium	tablet	Each tablet contains Pravastatin Sodium 80,0 mg	10/7.5/0395	2010/04/15	NS2
46	Cipla - Medpro (Pty) Ltd	Virafam 125	Famciclovir	tablet	Each film-coated tablet contains Famciclovir 125 mg	10/20.2.8/0396	2010/04/15	NS2
47	Cipla - Medpro (Pty) Ltd	Virafam 250	Famciclovir	tablet	Each film-coated tablet contains Famciclovir 250 mg	10/20.2.8/0397	2010/04/15	NS2
48	Cipla - Medpro (Pty) Ltd	Virafam 500	Famciclovir	tablet	Each film-coated tablet contains Famciclovir 500 mg	10/20.2.8/0398	2010/04/15	NS2
49	Cipla - Medpro (Pty) Ltd	Donocept 5	Donepezil Hydrochloride	tablet	Each film-coated tablet contains Donepezil Hydrochloride equivalent to Donepezil 5,0 mg	10/5.3/0399	2010/04/15	NS3
50	Cipla - Medpro (Pty) Ltd	Donocept 10	Donepezil Hydrochloride	tablet	Each film-coated tablet contains Donepezil Hydrochloride equivalent to Donepezil 10,0 mg	10/5.3/0400	2010/04/15	NS3
51	Cipla - Medpro (Pty) Ltd	Imavec	Imatinib Mesylate	capsule	Each capsule contains Imatinib Mesylate equivalent to Imatinib 100,0 mg	10/34/0401	2010/04/15	NS2
52	Cipla - Medpro (Pty) Ltd	Omeprazole IV Injection	Omeprazole Sodium	injection	Each 10 ml vial contains Omeprazole Sodium equivalent to Omeprazole 40,0 mg	10/11.4.3/0402	2010/04/15	NS2
53	Cipla - Medpro (Pty) Ltd	Cipla-Cof	Codeine Phosphate; Pseudoephedrine Hydrochloride	syrup	Each 10 ml syrup contains Codeine Phosphate 19,2 mg and Pseudoephedrine Hydrochloride 60,0 mg	10/10.1/0403	2010/04/15	NS1

54	Cipla - Medpro (Pty) Ltd	Cipla-Topotecan 1 mg	Topotecan hydrochloride	injection	Each 5 ml injection vial contains Topotecan Hydrochloride equivalent to Topotecan 1,0 mg	10/26/0404	2010/04/15	NS2
55	Cipla - Medpro (Pty) Ltd	Cipla-Topotecan 4 mg	Topotecan Hydrochloride	injection	Each 10 ml injection vial contains Topotecan hydrochloride equivalent to Topotecan 4,0 mg	10/26/0405	2010/04/15	NS2
56	Cipla - Medpro (Pty) Ltd	Prazoloc 20	Pantoprazole Sodium Sesquihydrate	tablet	Each enteric coated tablet contains 22,6 mg Pantoprazole Sodium Sesquihydrate equivalent to Pantoprazole 20,0 mg	10/11.4.3/0406	2010/04/15	NS2
57	Cipla - Medpro (Pty) Ltd	Prazoloc 40	Pantoprazole Sodium Sesquihydrate	tablet	Each enteric coated tablet contains 45,1 mg Pantoprazole Sodium Sesquihydrate equivalent to Pantoprazole 40,0 mg	10/11.4.3/0407	2010/04/15	NS3
58	Cipla - Medpro (Pty) Ltd	Zomedron	Zoledronic Acid Monohydrate	injection	Each vial contains Zoledronic Acid Monohydrate equivalent to Zoledronic Acid Anhydrous 4,0 mg	10/34/0408	2010/04/15	NS2
59	Cipla - Medpro (Pty) Ltd	Vancomax 500	Vancomycin hydrochloride	injection	Each vial contains Vancomycin Hydrochloride equivalent to Vancomycin 500,0 mg	10/20.1.1/0409	2010/04/15	NS2
60	Cipla - Medpro (Pty) Ltd	Deslora	Desloratadine	tablet	Each tablet contains Desloratadine 5,0 mg	10/5.7.1/0410	2010/04/15	NS1
61	Cipla - Medpro (Pty) Ltd	Cromal	Cromolyn Sodium	ophthalmic solution	Each vial of ophthalmic solution contains Cromolyn Sodium 2% w/v	10/15.5/0411	2010/04/15	NS1
62	Cipla - Medpro (Pty) Ltd	Letrofeme 2.5 mg tablets	Letrozole	tablet	Each film-coated tablet contains Letrozole 2,5 mg	10/21.12/0412	2010/04/15	NS2
63	Cipla - Medpro (Pty) Ltd	Enoclex 40	Enoxaparin Sodium	pre-filled syringe	Each 0,4 ml pre-filled syringe contains Enoxaparin Sodium 40,0 mg equivalent to 4000 IU anti-Xa activity	10/8.2/0413	2010/04/15	NS2
64	Cipla - Medpro (Pty) Ltd	Enoclex 60	Enoxaparin Sodium	pre-filled syringe	Each 0,6 ml pre-filled syringe contains Enoxaparin Sodium 60,0 mg equivalent to 6000 IU anti-Xa activity	10/8.2/0414	2010/04/15	NS2
65	Cipla - Medpro (Pty) Ltd	Gelacid tablets	Alginate Acid; Magnesium Trisilicate; Aluminium Hydroxide; Sodium Bicarbonate	chewable tablet	Each chewable tablet contains Alginate acid 500 mg, Magnesium Trisilicate 25 mg, Aluminium Hydroxide gel 100 mg, Sodium Bicarbonate 170 mg	10/11.4/0415	2010/04/15	NS1

66	Cipla - Medpro (Pty) Ltd	Epileve 250 mg	Levetiracetam	tablet	Each film-coated tablet contains Levetiracetam 250,0 mg	10/2.5/0416	2010/04/15	NS2
67	Cipla - Medpro (Pty) Ltd	Epileve 500 mg	Levetiracetam	tablet	Each film-coated tablet contains Levetiracetam 500,0 mg	10/2.5/0417	2010/04/15	NS2
68	Cipla - Medpro (Pty) Ltd	Epileve 750 mg	Levetiracetam	tablet	Each film-coated tablet contains Levetiracetam 750,0 mg	10/2.5/0418	2010/04/15	NS2
69	Cipla - Medpro (Pty) Ltd	Epileve 1000 mg	Levetiracetam	tablet	Each film-coated tablet contains Levetiracetam 1000,0 mg	10/2.5/0419	2010/04/15	NS2
70	Cipla - Medpro (Pty) Ltd	Urofin	Finasteride; Tamsulosin hydrochloride	co-packaged tablet; capsule	Each co-packaged tablet and capsule contains Fincar 5 (Each film-coated tablet contains 5,0 mg Finasteride) and Uromax (Each modified release capsule contains 0,4 mg Tamsulosin hydrochloride)	10/21.12/0420	2010/04/15	NS2
71	Hetero Drugs Ltd	Tenof	Tenofovir Disoproxil Fumarate	tablet	Each film-coated tablet contains 300,0 mg Tenofovir Disoproxil Fumarate equivalent to 245,0 mg Tenofovir Disoproxil	10/20.2.8/0421	2010/04/15	NS2
72	Svizera Europe BV	Ripe	Rifampicin; Isoniazid; Pyrazinamide; Ethambutol	tablet	Each tablet contains Rifampicin 150 mg, Isoniazid 75 mg, Pyrazinamide 400 mg and Ethambutol 275 mg	10/20.2.3/0422	2010/04/15	NS2
73	Novartis South Africa (Pty) Ltd	Excedrin Powders	Aspirin; Paracetamol, Caffeine Citrate, Caffeine anhydrous	powder	Each powder contains Aspirin 553 mg, Paracetamol 276 mg, Caffeine Citrate 33,0 mg and Caffeine anhydrous 8,0 mg	10/2.7/0423	2010/04/15	NS1

PART II

The Medicines set out in Part I of the Schedule have been registered subject to the following conditions:

1. The manufacture and control of the medicines must -
 - (a) comply with the requirements of the Current Good Manufacturing Practices;
 - (b) regularly be inspected and investigated by the inspectors authorised under section 35 of the Medicines and Related Substances Control Act, 2003 (Act No. 13 of 2003).
 2. The information in the package insert must be -
 - (a) updated regularly;
 - (b) approved by the Namibia Medicines Regulatory Council.
 3. The Namibia Medicines Regulatory Council may as it deem fit review the registration dossier.
 4. The first two production batches of the medicines must comply with the Validation Protocol which was submitted at the time of the application for the registration of the medicine and the report of validation which is in conformity with the Validation Protocol must be submitted to the Namibia Medicines Regulatory Council within one month starting from the date of the completion of the validation.
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