



GOVERNMENT GAZETTE

OF THE

REPUBLIC OF NAMIBIA

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Government Notice

MINISTRY OF HEALTH AND SOCIAL SERVICES

No. 197

2011

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 give notice that the medicines set out in the attached schedule have been registered in terms of that Act, subject to the following conditions:

1. The manufacture and control of the medicines must be in accordance with the existing current Good Manufacturing Practices as required by the World Health Organization;
2. In order to assess compliance with paragraph (1), inspections and investigations may be carried out regularly by inspectors authorized in terms of sections 35 of the Act;
3. The information in the package insert must, on a regular basis, be updated to conform with the package insert approved by the Council;
4. The holder of the certificate of registration which is referred to in section 19(7) of the Act, must comply with the Act;
5. The registration of medicine is subject to regular review regarding its quality, safety and efficacy, and the Council may, as it considers necessary, vary the registration of the medicine;

6. The first two production batches must be validated in accordance with the detailed process validation protocol which was submitted at the time of the application for registration;
7. A validation report must be submitted to the Council within one month from the date of completion of the validation referred to in paragraph (6); and
8. The Council may review the registration dossier at such intervals as the Council may determine.

L. INDONGO
ACTING REGISTRAR OF MEDICINES

Windhoek, 29 September 2011

NOTIFICATION OF REGISTRATION OF CERTAIN MEDICINES

SCHEDULE

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	10/10.2.1/0351	4/15/2010	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	4/15/2010	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	4/15/2010	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	4/15/2010	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	4/15/2010	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	4/15/2010	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	4/15/2010	NS2
8	Ranbaxy (SA) (Pty) Ltd	Zelivire 500	Valaciclovir hydrochloride	tablet	Each film-coated tablet contains Valaciclovir Hydrochloride to equivalent to Valaciclovir 500 mg	10/20.2.8/0358	4/15/2010	NS2

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9	Be-Tabs Pharmaceuticals (Pty) Ltd	Be-Tabs Diclofenac Injection	Diclofenac Sodium	injection	Each 3 ml ampoule contains Diclofenac Sodium 75 mg	10/3.1/0359	4/15/2010	NS2
10	Be-Tabs Pharmaceuticals (Pty) Ltd	Cimlok 400 mg	Cimetidine	tablet	Each tablet contains Cimetidine 400,0 mg	10/11.4.3/0360	4/15/2010	NS2
11	Be-Tabs Pharmaceuticals (Pty) Ltd	Diacare Tablets	Glibenclamide	tablet	Each tablet contains Glibenclamide 5,0 mg	10/21.2/0361	4/15/2010	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	4/15/2010	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	4/15/2010	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	4/15/2010	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	4/15/2010	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	4/15/2010	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	4/15/2010	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	4/15/2010	NS2

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19	GlaxoSmithKline South Africa (Pty) Ltd	Arepanrix	antigen; A/Californial-7/2009(H1N1)v-like virus	injection	Each dose (0,5 ml) contains split Influenza Virus, inactivated, containing antigen equivalent to A/Californial/7/2009(H1N1)v-like virus 3,75 micrograms	10/30.1/0369	4/15/2010	NS1
20	Aurobindo Pharma (Pty) Ltd	Auro-Amoxiclav 125-31.25 mg/5ml	Potassium Clavulanate Amoxicillin Trihydrate;	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	4/15/2010	NS2
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	4/15/2010	NS2
22	Ranbaxy (SA) (Pty) Ltd	Contiflo SR	Tamsulosin Hydrochloride	capsule	Each capsule contains Tamsulosin Hydrochloride 0,4 mg	10/34/0372	4/15/2010	NS2
23	GlaxoSmithKline South Africa (Pty) Ltd	Zentel 400	Albendazole	tablet	Each tablet contains Albendazole 400 mg	10/12/0373	4/15/2010	NS2
24	Adcock Ingram Ltd	Plagrol	Clopidogrel Bisulfate	tablet	Each tablet contains Clopidogrel Bisulfate equivalent to Clopidogrel 75,0 mg	10/8.2/0374	4/15/2010	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	4/15/2010	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	4/15/2010	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	4/15/2010	NS2

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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	4/15/2010	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	4/15/2010	NS1
30	Adcock Ingram Ltd	Bioplus Syrup Strawberry	Calcium Gluconate, Caffeine, Calcium Citrate, Thiamine Hydrochloride, Riboflavin Pyridoxine, Nicotinamide, d-Pantothanol 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-Pantothanol 11,0 mg and Cyanocobalamin 26,0 mg	10/33/0380	4/15/2010	NS1
50	Cipla - Medpro (Pty) Ltd	Donecept 10	Donepezil Hydrochloride	tablet	Each film-coated tablet contains Donepezil Hydrochloride equivalent to Donepezil 10,0 mg	10/5.3/0400	4/15/2010	NS3
51	Cipla - Medpro (Pty) Ltd	Imavec	Imatinib Mesylate	capsule	Each capsule contains Imatinib Mesylate equivalent to Imatinib 100,0 mg	10/34/0401	4/15/2010	NS2
52	Cipla - Medpro (Pty) Ltd	Omeprazole 40mg IV Injection	Omeprazole Sodium	injection	Each 10 ml vial contains Omeprazole Sodium equivalent to Omeprazole 40,0mg	10/11.4.3/0402	4/15/2010	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	4/15/2010	NS1
54	Cipla - Medpro (Pty) Ltd	Cipla-Topotecan I mg	Topotecan hydrochloride	injection	Each 5 ml injection vial contains Topotecan Hydrochloride equivalent to Topotecan 1,0 mg	10/26/0404	4/15/2010	NS2

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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	4/15/2010	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	4/15/2010	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	4/15/2010	NS3
58	Cipla - Medpro (Pty) Ltd	Zomedros	Zoledronic Acid Monohydrate	injection	Each vial contains Zoledronic Acid Monohydrate equivalent to Zoledronic Acid Anhydrous 4,0 mg	10/34/0408	4/15/2010	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	4/15/2010	NS2
60	Cipla - Medpro (Pty) Ltd	Deslora	Desloratadine	tablet	Each tablet contains Desloratadine 5,0 mg	10/5.7.1/0410	4/15/2010	NS1
61	Cipla - Medpro (Pty) Ltd	Cromal	Cromolyn Sodium	ophthalmic solution	Each vial of ophthalmic solution contains Cromolyn Sodium 2% w/v (20mg/ml)	10/15.5/0411	4/15/2010	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	4/15/2010	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	4/15/2010	NS2

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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	4/15/2010	NS2
65	Cipla - Medpro (Pty) Ltd	Gelacid tablets	Hydroxide; Alginic Acid; Magnesium Trisilicate; Aluminium Sodium Bicarbonate	chewable tablet	Each chewable tablet contains Alginic acid 500 mg, Magnesium Trisilicate 25 mg, Aluminium Hydroxide gel 100 mg, Sodium Bicarbonate 170 mg	10/11.4/0415	4/15/2010	NS1
66	Cipla - Medpro (Pty) Ltd	Epileve 250 mg	Levetiracetam	tablet	Each film-coated tablet contains Levetiracetam 250,0 mg	10/2.5/0416	4/15/2010	NS2
67	Cipla - Medpro (Pty) Ltd	Epileve 500 mg	Levetiracetam	tablet	Each film-coated tablet contains Levetiracetam 500,0 mg	10/2.5/0417	4/15/2010	NS2
68	Cipla - Medpro (Pty) Ltd	Epileve 750 mg	Levetiracetam	tablet	Each film-coated tablet contains Levetiracetam 750,0 mg	10/2.5/0418	4/15/2010	NS2
69	Cipla - Medpro (Pty) Ltd	Epileve 1000mg	Levetiracetam	tablet	Each film-coated tablet contains Levetiracetam 1000,0 mg	10/2.5/0419	4/15/2010	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	4/15/2010	NS2
71	Hetero Drugs Ltd	Tenof	Tenofovir Disoproxil Fumarate	tablet	Each film-coated tablet contains Tenofovir Disoproxil Fumarate 300 mg equivalent to Tenofovir Disoproxil 245,0 mg	10/20.2.8/0421	4/15/2010	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	4/15/2010	NS2

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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 rag and Caffeine anhydrous 8,0 rag	10/2.7/0423	4/15/2010	NS1