



GOVERNMENT GAZETTE

OF THE

REPUBLIC OF NAMIBIA

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WINDHOEK - 26 July 2011

No. 4761

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Government Notice

MINISTRY OF HEALTH AND SOCIAL SERVICES

No. 122 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 Schedule 1 and 2 have been registered in terms of that Act, subject to the following conditions -

- (a) the manufacturer and control of the medicines must be in accordance with the existing current Good Manufacturing Practices as required by the World Health Organisation;
- (b) in order to assess compliance with paragraph (a) inspections and investigations may be carried out regularly by inspectors authorized in terms of section 35 of the Act;
- (c) the information in the package insert must, on a regular basis, be updated to conform with the package insert approved by the Council;
- (d) the holder of the certificate of registration which is referred to in subsection (7) of section 19 of the Act, must comply with the Act;
- (e) 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;

- (f) 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;
- (g) a validation report must be submitted to the Council within one month from the date of completion of the validation referred to in paragraph (1); and
- (h) the Council may review the registration dossier at such intervals as the Council may determine.

J. GAESEB
REGISTRAR OF MEDICINES

Windhoek, 11 July 2011

**VETERINARY MEDICINES LOT 2
SCHEDULE**

APPLICANT	REGISTERED NAME	APPROVED NAME OF ACTIVE(S)	DOSSAGE FORM	STRENGTH/DOSE UNIT	REG. NO. OTHER	REG. DATE	SCHED. STATUS
1 Merial South Africa (Pty) Ltd	Intraval Sodium Injection 1 g	Thiopentone Sodium	Injection	Each 20 ml vial contains Thiopentone Sodium for injection 1,0 g	11/2.1/0146	6/16/2011	NS3
2 Merial South Africa (Pty) Ltd	Intraval Sodium Injection 5 g	Thiopentone Sodium	Injection	Each 100 ml vial contains Thiopentone Sodium for injection 5 g	11/2.1/0147	6/16/2011	NS3
3 Merial South Africa (Pty) Ltd	Ketofen Tablets 5 mg	Ketoprofen	Tablet	Each tablet contains Ketoprofen 5,0 mg	11/3.1/0148	6/16/2011	NS2
4 Merial South Africa (Pty) Ltd	Ketofen Tablets 10 mg	Ketoprofen	Tablet	Each tablet contains Ketoprofen 10,0 mg	11/3.1/0149	6/16/2011	NS2
5 Merial South Africa (Pty) Ltd	Ketofen Tablets 20 mg	Ketoprofen	Tablet	Each tablet contains Ketoprofen 20,0 mg	11/3.1/0150	6/16/2011	NS2
6 Merial South Africa (Pty) Ltd	Ketofen 10 %	Ketoprofen	Injection	Each 100 ml solution contains Ketoprofen 10,0 g	11/3.1/0151	6/16/2011	NS2
7 Merial South Africa (Pty) Ltd	Ketofen 1 %	Ketoprofen	Injection	Each 1 ml solution contains Ketoprofen 10,0 mg	11/3.1/0152	6/16/2011	NS2
8 Novartis South Africa (Pty) Ltd	Denagard 10 % Feed Premix	Tiamulin Hydrogen Fumarate	Premix	Each 1 kg Denagard Feed Premix contains Tiamulin Hydrogen Fumarate 100,0 g	11/21.9/0153	6/16/2011	NS1
9 Merial South Africa (Pty) Ltd	Enacard 2.5 mg Tablets	Enalapril Maleate	Tablet	Each tablet contains Enalapril Maleate 2,5 mg	11/8/0154	6/16/2011	NS2
10 Merial South Africa (Pty) Ltd	Enacard 5 mg Tablets	Enalapril Maleate	Tablet	Each tablet contains Enalapril Maleate 5 mg	11/8/0155	6/16/2011	NS2
11 Merial South Africa (Pty) Ltd	Enacard 10 mg Tablets	Enalapril Maleate	Tablet	Each tablet contains Enalapril Maleate 10 mg	11/8/0156	6/16/2011	NS2
12 Merial South Africa (Pty) Ltd	Previcox 57 mg Tablets	Firocoxib	Tablet	Each tablet contains Firocoxib 57,0 mg	11/3.1.2/0157	6/16/2011	NS2
13 Merial South Africa (Pty) Ltd	Previcox 227 mg Tablets	Firocoxib	Tablet	Each tablet contains Firocoxib 227,0 mg	11/3/1.2/0158	6/16/2011	NS2
14 Merial South Africa (Pty) Ltd	Bomathal Injection	Thiopentone Sodium	Injection	Each 250 ml vial contains Thiopentone Sodium equivalent to Thiopentone 5,0 g	11/2.1/0159	6/16/2011	NS3

SCHEDULE

S/N	APPLICANT	PROPRIETARY NAME	APPROVED NAME OF ACTIVE(S)	DOSAGE FORM	STRENGTH/DOSE UNIT	REG. NO. NAMIBIA	REGIST. DATE	SCHED. STATUS
1	Hoffman - La Roche Ltd	Recormon 2000	Epoetin Beta	solution for injection (pre-filled syringe)	Each syringe contains Epoetin Beta 2000	11/30.4/0100	6/16/2011	NS2
2	Hoffman - La Roche Ltd	Recormon 4000	Epoetin Beta	solution for injection (pre-filled syringe)	Each syringe contains Epoetin Beta 4000	11/30.4/0101	6/16/2011	NS2
3	Hoffman - La Roche Ltd	Recormon 6000	Epoetin Beta	solution for injection (pre-filled syringe)	Each syringe contains Epoetin Beta 6000	11/30.4/0102	6/16/2011	NS2
4	Ranbaxy (S.A.) (Pty) Ltd	Atolip 10	Atorvastatin Calcium	tablet	Each tablet contains Atorvastatin Calcium equivalent to Atorvastatin 10,0mg	11/7.5/0103	6/16/2011	NS2
5	Ranbaxy (S.A.) (Pty) Ltd	Atolip 20	Atorvastatin Calcium	tablet	Each tablet contains Atorvastatin Calcium equivalent to Atorvastatin 20,0 mg	11/7.5/0104	6/16/2011	NS2
6	Ranbaxy (S.A.) (Pty) Ltd	Atolip 40	Atorvastatin Calcium	tablet	Each tablet contains Atorvastatin Calcium equivalent to Atorvastatin 40,0 mg	11/7.5/0105	6/16/2011	NS2
7	Ranbaxy (S.A.) (Pty) Ltd	Atolip 80	Atorvastatin Calcium	tablet	Each tablet contains Atorvastatin Calcium equivalent to Atorvastatin 80,0 mg	11/7.5/0106	6/16/2011	NS2
8	Cipla Medpro (Pty) Ltd	Rheugesic	Piroxicam	tablet	Each tablet contains Piroxicam 20 mg	11/3.1/0107	6/16/2011	NS1
9	Cipla Medpro (Pty) Ltd	Fertomid-50	Clomiphene Citrate	tablet	Each tablet contains Clomiphene Citrate 50,0 mg	11/18.8/0108	6/16/2011	NS2
10	Cipla Medpro (Pty) Ltd	Cefasyn - 500	Cefuroxime Axetil	tablet	Each tablet contains Cefuroxime Axetil equivalent to Cefuroxime 500,0 mg	11/20.1.1/0109	6/16/2011	NS2
11	Cipla Medpro (Pty) Ltd	Cefasyn - 250	Cefuroxime Axetil	tablet	Each tablet contains Cefuroxime Axetil equivalent to Cefuroxime 250,0 mg	11/20.1.1/0110	6/16/2011	NS2
12	Cipla Medpro (Pty) Ltd	Ultak - 150	Ranitidine Hydrochloride	tablet	Each tablet contains Ranitidine Hydrochloride equivalent to Ranitidine 150,0 mg	1/11.4.3/0111	6/16/2011	NS2
13	Cipla Medpro (Pty) Ltd	Ultak - 300	Ranitidine Hydrochloride	tablet	Each tablet contains Ranitidine Hydrochloride equivalent to Ranitidine 300,0 mg	11/11.4.3/0112	6/16/2011	NS2

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14	Medpro Pharmaceutica (Pty) Ltd	Pymmed	Caffeine anhydrous; Meprobamate; Codeine Phosphate Paracetamol	tablet	Each tablet contains Caffeine Anhydrous 32 mg, Meprobamate 150 mg, Codeine Phosphate 8 mg and Paracetamol 320 mg	11/2.8/0113	6/16/2011	NS1
15	Cipla Medpro (Pty) Ltd	Ciplatec 5.0	Enalapril Maleate	tablet	Each tablet contains Enalapril Maleate 5,0 mg	11/7.1.3/0114	6/16/2011	NS2
16	Cipla Medpro (Pty) Ltd	Abflex - 4	Caffeine; Codeine Phosphate; Doxylamine Succinate, Paracetamol	tablet	Each tablet contains Caffeine 30,0 mg, Codeine Phosphate 10,0 mg, Doxylamine Succinate 5,0 mg and Paracetamol 450,0 mg	11/2.8/0115	6/16/2011	NS1
17	Cipla Medpro (Pty) Ltd	Carloc 6,25	Carvedilol	tablet	Each tablet contains Carvedilol 6,25 mg	11/7.1.3/0116	6/16/2011	NS2
18	Cipla Medpro (Pty) Ltd	Roxxibid 150	Roxithromycin	tablet	Each tablet contains Roxithromycin 150,0 mg	11/20.1.1/0117	6/16/2011	NS2
19	Cipla Medpro (Pty) Ltd	Acitab - 200 DT	Acyclovir	tablet	Each tablet contains Acyclovir 200,0 mg	11/20.2.8/0118	6/16/2011	NS2
20	Cipla Medpro (Pty) Ltd	Tensodol	Caffeine; Codeine Phosphate; Doxylamine Succinate, Paracetamol	tablet	Each tablet contains Caffeine 30,0 mg, Codeine Phosphate 10,0 mg, Doxylamine Succinate 5,0 mg and Paracetamol 450,0 mg	11/2.1/0119	6/16/2011	NS1
21	Cipla Medpro (Pty) Ltd	Cipla Indapamide	Indapamide	tablet	Each tablet contains Indapamide 2,5 mg	11/71/0120	6/16/2011	NS2
22	Cipla Medpro (Pty) Ltd	Co-Codamol	Codeine Phosphate; Paracetamol	effervescent tablet	Each effervescent tablet contains Codeine Phosphate 8,0 mg and Paracetamol 500,0 mg	11/2.8/0121	6/16/2011	NS1
23	Cipla Medpro (Pty) Ltd	Ibugesic Oral Suspension	Ibuprofen	oral suspension	Each 5,0 ml suspension contains Ibuprofen 100,0 mg	11/3.1/0122	6/16/2011	NS1
24	Cipla Medpro (Pty) Ltd	Repivate	Betamethasone Valerate	cream	Each 15,0 g cream contains Betamethasone Valerate equivalent to Betamethasone 15,0 mg	11/13.4.1/0123	6/16/2011	NS2
25	Cipla Medpro (Pty) Ltd	Acitab - 400 DT	Acyclovir	tablet	Each tablet contains Acyclovir 400,0 mg	11/20.2.8/0124	6/16/2011	NS2

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26	Cipla-Medpro (Pty) Ltd	Optilol 0,25% Ophthalmic Solution	Timolol Maleate	ophthalmic solution	Each vial solution contains Timolol Maleate equivalent to Timolol 0,25 % w/v (2,5 mg/ml)	11/15.4/0125	6/16/2011	NS2
27	Cipla-Medpro (Pty) Ltd	Optilol 0,5% Ophthalmic Solutio	Timolol Maleate	ophthalmic solution	Each vial solution contains Timolol Maleate equivalent to Timolol 0,5%w/v (5mg/ml)	11/15.4/0126	6/16/2011	NS2
28	Cipla-Medpro (Pty) Ltd	Prazoloc 40 IV	Pantoprazole Sodium Sesquihydrate	Injection	Each vial contains 42,3 mg Pantoprazole Sodium Sesquihydrate equivalent to Pantoprazole 40,0 mg	11/11.4.3/0127	6/16/2011	NS2
29	Ranbaxy (SA) (Pty) Ltd	Conoran IV	Pantoprazole Sodium Sesquihydrate	Injection	Each ml contains Pantoprazole Sodium Sesquihydrate equivalent to Pantoprazole 40 mg	11/11.4.3/0128	6/16/2011	NS2
30	Ranbaxy (SA) (Pty) Ltd	Tazogen	Piperacillin Sodium	Injection	Each vial contains Piperacillin Sodium equivalent to Piperacillin 4g Tazobactam Sodium equivalent to Tazobactam 500 mg	11/201.2/0129	6/16/2011	NS2
31	Ranbaxy (SA) Pty Limited	Dilair 4	Montelukast Sodium	tablet	Each tablet contains Montelukast Sodium equivalent to Montelukast 4mg	11/10.2.2/0130	6/16/2011	NS2
32	Ranbaxy (SA) Pty Limited	Dilair 5	Montelukast Sodium	tablet	Each tablet contains Montelukast Sodium equivalent to Montelukast 5 mg	11/10.2.2/0131	6/16/2011	NS2
33	Ranbaxy (SA) Pty Limited	Dilair 10	Montelukast Sodium	tablet	Each tablet contains Montelukast Sodium equivalent to Montelukast 10 mg	11/10.2.2/0132	6/16/2011	NS2
34	The Biovac Institute	TetaBio	Tetanus Toxoid	Injection	Each 0.5 ml dose contains purified Tetanus Toxoid 40 IU	11/30.1/0133	6/16/2011	NS1
35	The Biovac Institute	MeasBio	Measles Attenuated Virus	Injection	Each 0.5 ml dose contains not less than 1000 CCID50 CAM 70 strain of Measles live, attenuated virus	11/30.1/0134	6/16/2011	NS1
36	Merek SA (Pty) Ltd	Euthyrox 25 µg	Levothyroxine	tablet	Each tablet contains Levothyroxine Sodium 25 µg	11/21.3/0135	6/16/2011	NS2
37	Merek SA (Pty) Ltd	Euthyrox 50 µg	Levothyroxine	tablet	Each tablet contains Levothyroxine Sodium 50 µg	11/21.3/0136	6/16/2011	NS2
38	Merek SA (Pty) Ltd	Euthyrox 100 µg	Levothyroxine	tablet	Each tablet contains Levothyroxine Sodium 100 µg	11/21.3/0137	6/16/2011	NS2
39	Pharmacare Limited	Aspen Cetirizine 1 mg/ml	Cetirizine Dihydrochloride	oral solution	Each 1 ml solution contains Cetirizine Dihydrochloride 1,0 mg	11/5.7.1/0138	6/16/2011	NS1

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40	Sanofi-Aventis South Africa (Pty) Ltd	Rifinah 150/75	Rifampicin, Isoniazid	tablet	Each tablet contains Rifampicin 150,0 mg and Isoniazid 75,0 mg	11/20.2.3/0139	6/16/2011	NS2
41	Pharmacare Limited	Avirez	Efavirenz	tablet	Each tablet contains Efavirenz 600,0 mg	11/20.2.8/0140	6/16/2011	NS2
42	Pharmacare Limited	Aspen Levofloxacin 250 mg	Levofloxacin Hemihydrate	tablet	Each tablet contains Levofloxacin Hemihydrate equivalent to Levofloxacin 250,0 mg	11/20.1.1/0141	6/16/2011	NS2
43	Pharmacare Limited	Aspen Levofloxacin 500 mg	Levofloxacin Hemihydrate	tablet	Each tablet contains Levofloxacin Hemihydrate equivalent to Levofloxacin 500,0 mg	11/20.1.1/0142	6/16/2011	NS2
44	Cipla-Medpro (Pty) Ltd	Duolin HFA Inhaler	Ipratropium Bromide, Salbutamol Sulphate	Inhaler	Each Actuation delivers Ipratropium Bromide 21 µg equiv. to Ipratropium 20.0 µg. Salbutamol Sulphate equiv. to Salbutamol 100 µg	11/20.2.1/0143	6/16/2011	NS2
45	Cipla-Medpro (Pty) Ltd	Budeflam Respules 0.25	Budesonide	Respules	Each 1ml suspension contains Budesonide 0,25mg	11/21.5.1/0144	6/16/2011	NS2
46	Cipla-Medpro (Pty) Ltd	Budeflam Respules 0.5	Budesonide	Respules	Each 1 ml suspension contains Budesonide 0,5 mg	11/21.5.1/0145	6/16/2011	NS2