



# GOVERNMENT GAZETTE

## OF THE

# REPUBLIC OF NAMIBIA

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WINDHOEK - 10 April 2018

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## Government Notices

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### MINISTRY OF HEALTH AND SOCIAL SERVICES

No. 63

2018

#### REGISTRATION OF CERTAIN VETERINARY 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 veterinary medicines set out in the Schedule have been registered in terms of that Act, subject to the following conditions:

- (a) the applicant must ensure that the medicine is manufactured and controlled in terms of existing good manufacturing practices as determined by the Namibia Medicines Regulatory Council (hereinafter referred to as “the Council”);
- (b) inspections and investigations of the medicine may be carried out regularly by inspectors authorised in terms of section 35 of the Act to assess compliance with existing good manufacturing practices;
- (c) the applicant must ensure that the information in the package insert is regularly updated so as to provide accurate information to the user of the medicine;

- (d) the applicant must comply with all the legal requirements of the Medicines and Related Substances Control Act, 2003 (Act No. 11 of 2003);
- (e) the registration of this medicine is subject to regular review by the Council regarding quality, safety and efficacy and the Council may vary the registration of this medicine, if it considers it necessary;
- (f) the applicant must validate the first two production batches in terms of the detailed process validation protocol submitted at the time of application for registration and the validation report must be submitted to the Council within 30 days after completion of the validation; and
- (g) the Council may review the registration dossier and may determine the intervals when reviews will take place.

**J. GAESEB**  
**REGISTRAR OF MEDICINES**

Windhoek, 22 March 2018

**SCHEDULE**

S/N	Applicant	Proprietary Name	Approved Name of Active(s)	Dosage Form	Species	Registration Number	Registration Date	Scheduling Status
1	Cipla Agrimed	DIB 1g Implant	Each intravaginal device contains progesterone 1 g	Intravaginal device	Cattle	V1 8/11.2.3/1396	15/02/2018	NS2
2	Bayer	Baytril 100	Per ml: 100 mg Enrofloxacin	Injectable solution	Cattle	V18/17.1.6/1397	15/02/2018	NS2
3	Boehringer Ingelheim Animal Health South Africa	Semintra	Telmisartan 4 mg/ml	Oral solution	Cats	V18/5.3.2/1398	15/02/2018	NS2

**MINISTRY OF HEALTH AND SOCIAL SERVICES**

No. 64

2018

**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 Schedule have been registered in terms of that Act, subject to the following conditions:

- (a) the applicant must ensure that medicine is manufactured and controlled in terms of existing good manufacturing practices as determined by the Namibia Medicines Regulatory Council (hereinafter referred to as “the Council”);
- (b) inspections and investigations of the medicine may be carried out regularly by inspectors authorised in terms of section 35 of the Act to assess compliance with existing good manufacturing practices;
- (c) the applicant must ensure that the information in the package insert is regularly updated so as to provide accurate information to the user of the medicine;
- (d) the applicant must comply with the provisions of the Medicines and Related Substance Control Act, 2003(Act No. 11 of 2003);
- (e) the registration of medicine is subject to regular review by the Council regarding its quality, safety and efficacy and the Council may vary the registration of the medicine, if it considers it necessary;
- (f) the applicant must validate the first two production batches in terms of the detailed process validation protocol which was submitted by the applicant at the time of the application for registration and the validation report must be submitted to the Council within 30 days from the date of completion of the validation; and
- (g) the Council may review the registration dossier and may determine the intervals when reviews will take place.

**J. GAESEB**  
**REGISTRAR OF MEDICINES**

Windhoek, 22 March 2018

**SCHEDULE**

S/N	Applicant	Proprietary Name	Dosage Form	Approved Name Of Active(S) & Strength/ Dose Unit	Registration Number	Registration Date	Scheduling Status
1	Innovata Pharmaceuticals (Pty) Ltd	Irocan 40	Solution for infusion	Each 2m1 contains Irinotecan hydrochloride 40 mg	18/26/0001	2018.02.15	NS2
2	Innovata Pharmaceuticals (Pty) Ltd	Irocan 100	Solution for infusion	Each 5m1 contains Irinotecan hydrochloride 40 mg	18/26/0002	2018.02.15	NS2
3	Innovata Pharmaceuticals (Pty) Ltd	Irocan 300	Solution for infusion	Each 15m1 contains Irinotecan hydrochloride 40 mg	18/26/0003	2018.02.15	NS2
4	Innovata Pharmaceuticals (Pty) Ltd	Irocan 500	Solution for infusion	Each 25ml contains Irinotecan hydrochloride 40 mg	18/26/0004	2018.02.15	NS2
5	Forrester Pharma (Pty) Ltd	Neubalin 25	Capsules	Each capsule contains Pregabalin 25 mg	18/2.5/0005	2018.02.15	NS3
6	Forrester Pharma (Pty) Ltd	Neubalin 75	Capsules	Each capsule contains Pregabalin 75 mg	18/2.5/0006	2018.02.15	NS3
7	Forrester Pharma (Pty) Ltd	Neubalin 150	Capsules	Each capsule contains Pregabalin 150 mg	18/2.5/0007	2018.02.15	NS3
8	Sigma-Tau Industrie Farmaceutiche Riunite S.p.A	Eurartesim 320 mg/40 mg	Tablet	Each film coated tablet contains Piperazine Tetraphosphate (as Tetrahydrate) 320,0 mg, Arteminol 40,0 mg	18/20.2.6/0008	2018.02.15	NS2
9	Sigma-Tau Industrie Farmaceutiche Riunite S.p.A	Eurartesim 160 mg/20 mg	Tablet	Each film coated tablet contains Piperazine Tetraphosphate (as Tetrahydrate) 160,0 mg, Arteminol 20,0 mg	18/20.2.6/0009	2018.02.15	NS2
10	Mylan Laboratories Limited	Avonza	BFC Tablet	Each bilayered film coated tablet contains Tenovofir DSF 300mg, Lamivudine 300mg, Efavirenz 400 mg	18/20.2.8/0010	2018.02.15	NS2
11	Cospharm Investments	Goutseal-80	FC tablet	Each film coated tablet contains Febuxostat 80 mg	18/3.3/0011	2018.02.15	NS2
12	Cospharm Investments	Goutseal-40	FC tablet	Each film coated tablet contains Febuxostat 40 mg	18/3.3/0012	2018.02.15	NS2
13	Cospharm Investments	Prostar 200	Injection	Each 1ml oily solution contains; Progesterone 100 mg	18/21.8.2/0013	2018.02.15	NS2

14	Cospharm Investments	Prostar 100	Injection	Each lml oily solution contains; Progesterone 100 mg	18/21.8.2/0014	2018.02.15	NS2
15	Pharma Dynamics (Pty) Ltd	Acyrax IV	Solution for infusion	Each ml of infusion contains Aciclovir 25mg	18/20.2.8/0015	2018.02.15	NS2
16	Litha Pharma (Pty) Ltd	Oratane 40mg	Soft Gelatin Capsule	Each soft gelatin capsule contains Isotretinoin 40mg	18/13.4.3/0016	2018.02.15	NS3
17	Galentic Pharma (India) Pvt Ltd	Silvadex cream	Cream	Each ml of topical cream contains Silver sulphadiazine 1mg	18/14.2/0017	2018.02.15	NS1
18	Merck (Pty) Ltd	Ziabeta 10/6.25mg	Tablets	Each tablet contains Bisoprolol fumarate 10mg and Hydrochlorthiazide 6.25mg	18/7.1.3/0018	2018.02.15	NS2
19	Merck (Pty) Ltd	Ziabeta 2.5/6.25mg	Tablets	Each tablet contains Bisoprolol fumarate 2.5mg and Hydrochlorthiazide 6.25mg	18/7.1.3/0019	2018.02.15	NS2
20	Merck (Pty) Ltd	Ziabeta 5/6.25mg	Tablets	Each tablet contains Bisoprolol fumarate 5mg and Hydrochlorthiazide 6.25mg	18/7.1.3/0020	2018.02.15	NS2
21	Novo Nordisk A/S	Ryzodeg Flextouch	Subcutaneous	Each ml contains Insulin Degludec and Insulin Aspart 100IU	18/21.1/0021	2018.02.15	NS2
22	Novo Nordisk A/S	Flextouch Tresiba	Subcutaneous	Each ml contains Insulin Degludec 100IU	18/22.2/0022	2018.02.15	NS2
23	Roche Products (Pty) Ltd	MabThera SC 1400	Injection	Each vial contains Rituximab 1400mg/11.7ml	18/26/0023	2018.02.15	NS2
24	Roche Products (Pty) Ltd	MabThera SC 1600	Injection	Each via contains Rituximab 1600mg/13.4ml	18/26/0024	2018.02.15	NS2
25	Roche Products (Pty) Ltd	Herceptin SC 600	Injection	Each vial contains Trastuzumab 600mg/5ml	18/26/0025	2018.02.15	NS2
26	Innovata Pharmaceuticals (Pty) Ltd	Amlotel 40/5	Tablets	Each uncoated tablet contains Telmisartan 40mg and Amlodipine 5mg	18/7.1.3/0026	2018.02.15	NS2
27	Innovata Pharmaceuticals (Pty) Ltd	Amlotel 40/10	Tablets	Each uncoated tablet contains Telmisartan 40mg and Amlodipine 10mg	18/7.1.3/0027	2018.02.15	NS2
28	Innovata Pharmaceuticals (Pty) Ltd	Amlotel 80/5	Tablets	Each uncoated tablet contains Telmisartan 80mg and Amlodipine 5mg	18/7.1.3/0028	2018.02.15	NS2
29	Innovata Pharmaceuticals (Pty) Ltd	Amlotel 80/10	Tablets	Each uncoated tablet contains Telmisartan 80mg and Amlodipine 10mg	18/7.1.3/0029	2018.02.15	NS2
30	Claris Injectables Limited	Acyzox	Solution for infusion	Each ml of infusion contains Aciclovir 25mg	18/20.2.8/0030	2018.02.15	NS2