GOVERNMENT GAZETTE

OF THE

REPUBLIC OF NAMIBIA

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Government Notice

MINISTRY OF HEALTH AND SOCIAL SERVICES

No. 94 2021

NOTIFICATION OF 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 of the registration of the medicines whose particulars are specified in the Schedule.

J. GAESEB
REGISTRAR OF MEDICINES Windhoek, 21 April 2021

SCHEDULE

S/N	Particulars required under section 23(a)(i) to (v) of the Act				
	Name under which medicine is registered	**Active components of medicine**	**Name of Applicant**	**Name of Manufacturer**	**Registration number allocated to medicine in terms of section 19(9) of Act**
1	CP-Oxytocin 10IU Injection	Oxytocin	Cospharm Investments (Pty) Ltd	Steril-Gene Life Sciences (P) Ltd., India	21/19/0001
2	Biorphen 0,1 mg/ml	Phenylephrine hydrochloride	Umsebe Healthcare	Sintetica S.A., Switzerland	21/7.2/0002
3	Biorphen 10 mg/ml	Phenylephrine hydrochloride	Umsebe Healthcare	Sintetica S.A., Switzerland	21/7.2/0003
4	Eurovin 20	Vinorelbine tartrate	Eurolab (Pty) Ltd	Lotus Pharmaceutical Co., Ltd, Taiwan	21/26/0004
5	Eurovin 30	Vinorelbine tartrate	Eurolab (Pty) Ltd	Lotus Pharmaceutical Co., Ltd, Taiwan	21/26/0005
6	Stalomac 10	Escitalopram Oxalate	Macleods Pharmaceuticals Limited	Macleods Pharmaceuticals Limited, India	21/1.2/0006
7	Stalomac 20	Escitalopram Oxalate	Macleods Pharmaceuticals Limited	Macleods Pharmaceuticals Limited, India	21/1.2/0007
8	Medaxone	Ceftriaxone Sodium	Medochemie Ltd	Medochemie Ltd (Factory C), Cyprus	21/20.1.1/0008
9	Sinutab Sinus Pain Extra Strength	Paracetamol, Chlorphenamine maleate, Pesudoephedrine and Codeine Phosphate	Johnson and Johnson (Pty) Ltd	Johnson & Johnson (Pty) Ltd, South Africa	21/5.8/0009
10	Brimochek Drops	Brimonidine tartrate	Indoco Remedies	Indoco Remedies Limited, Indoco	21/32.2/0010
11	Norflex Gel Forte 3g/100g	Benzydamine hydrochloride	iNova Pharmaceuticals (Pty) Ltd	Ensign Laboratories (Pty) Ltd, Australia	21/3.1/0011
12	Veupolin 75	Pregabalin	N2SA Limited	Sai Mirra Innopharm Pvt. Ltd, India	21/2.5/0012
13	Veupolin 150	Pregabalin	N2SA Limited	Sai Mirra Innopharm Pvt. Ltd, India	21/2.5/0013
14	Dulexa 60	Duloxetine hydrochloride	Forrester Pharma (Pty) Ltd	RA Chem Pharma, India	21/1.2/0014
15	Epicin-RD 10	Epirubicin Hydrochloride	VHB Mediscience Limited	VHB Medi Sciences Ltd, India	21/26/0015
16	Epicin-RD 50	Epirubicin Hydrochloride	VHB Mediscience Limited	VHB Medi Sciences Ltd, India	21/26/0016

17	Urodoxa 1mg	Doxazocin	Aurobindo Pharma (Pty) Ltd	Aurobindo Pharma Limited, India	21/7.1.3/0017
18	Urodoxa 2mg	Doxazocin	Aurobindo Pharma (Pty) Ltd	Aurobindo Pharma Limited, India	21/7.1.3/0018
19	Urodoxa 4mg	Doxazocin	Aurobindo Pharma (Pty) Ltd	Aurobindo Pharma Limited, India	21/7.1.3/0019
20	Urodoxa 8mg	Doxazocin	Aurobindo Pharma (Pty) Ltd	Aurobindo Pharma Limited, India	21/7.1.3/0020
21	Dolutegravir Sodium/ Lamivudine/ Tenofovir Disoproxil Fumarate 50mg/300mg/300mg Tablets	Dolutegravir Sodium, Lamivudine and Tenofovir Disoproxil Fumarate	Cipla Quality Chemical Industries Limited	Cipla Quality Chemical Industries Limited, Uganda	21/20.2.8/0021
22	Linezolid 600 mg Tablets	Linezolid	Lupin Limited	Lupin Limited, India	21/20.1.1/0022
23	Rifampicin, Isoniazid and Ethambutol Hydrochloride Tablets 150/75/275	Rifampicin, Isoniazid and Ethambutol Hydrochloride	Lupin Limited	Lupin Limited, India	21/20.2.3/0023
24	OK pills	Levonorgestrel and Ethinylestradiol	Population Services International	1. Mylan Laboratories Limited (Plot 1606-1609), India 2. Mylan Laboratories Limited (Plot No. 20 & 21), India	21/18.7/0024
25	Abacavir Sulfate and Lamivudine Tablets USP 600mg/300mg	Abacavir Sulfate and Lamivudine	Mylan Laboratories Limited	1. Mylan Laboratories Limited (F-4 & F-12), Maharashtra State, India 2. Mylan Laboratories Limited (Plot No. 11,12 & 13), Madhya Pradesh, India	21/20.2.8/0025
26	Dolutegravir Sodium/Lamivudine/ Tenofovir Disoproxil Fumarate 50mg/ 300mg/ 300mg Tablets	Dolutegravir Sodium, Lamivudine and Tenofovir Disoproxil Fumarate	Ranbaxy Pharmaceutical (Pty) Ltd	Sun Pharmaceutical Industries Limited, India	21.20.2.8/0026
27	Abacavir Sulfate and Lamivudine Tablets	Abacavir Sulfate and Lamivudine	Ranbaxy Pharmaceutical (Pty) Ltd	Sun Pharmaceutical Industries Limited, India	21/20.2.8/0027
28	Emtricitabine and Tenofovir Disoproxil Fumarate 200mg/300mg	Emtricitabine and Tenofovir Disoproxil Fumarate	Laurus Labs Limited	Laurus Labs Ltd, India	21/20.2.8/0028
29	Tivicay 5 mg	Dolutegravir	GlaxoSmithKline South Africa (Pty) Ltd	Glaxo Operations UK Ltd (trading as Glaxo Wellcome Operations), United Kingdom	21/20.2.8/0029

30	Apoquel 3,6mg	Oclacitinib maleate	Zoetis South Africa	1. Pfizer Italia S.r.L, Italy 2. Zoetis LLC, USA	V21/13.3/1465
31	Apoquel 5,4mg	Oclacitinib maleate	Zoetis South Africa	1. Pfizer Italia S.r.L, Italy 2. Zoetis LLC, USA	V21/13.3/1466
32	Apoquel 16mg	Oclacitinib maleate	Zoetis South Africa	1. Pfizer Italia S.r.L, Italy 2. Zoetis LLC, USA	V21/13.3/1467
33	Bovi- Shield	Bovine Rhinotracheitis Virus, Bovine Virus Diarrhoea Type 1, Bovine Virus Diarrhoea Type 2, Parainfluenza3 Virus, Bovine Respiratory Syncytial Virus, Mannheimia haemolytica TYPE A1	Zoetis South Africa	Zoetis Inc, USA	V21.24.4/1468
34	Agramycin	Oxytetracycline	Ascendis Animal Health (Pty) Ltd	Laboratorios Microsules Uruguay S.A, Uruguay	V21/17.1.2/1469
35	Suprelorin	Deslorelin acetate	Virbac RSA (Pty) Ltd	Peptech Animal Health (Pty) Ltd, Australia	V21/11.4/1470
36	Virbacox	Salinomycin sodium	Virbac RSA (Pty) Ltd	Shandong Qilu King- Phar Pharmaceutical Co. Ltd, India	V21/17.4.1/1471

As required under section 23(a)(iv) of the Act, the medicines whose particulars are specified in this Schedule are registered subject to the following conditions:

(a) the manufacture and control of the medicines must be in accordance with the existing good manufacturing practices as required by the World Health Organization;

(b) in order to assess compliance with paragraph (a), an inspection or investigation may be carried out regularly by an inspector authorised in terms of sections 35 of the Act to undertake such inspection or investigation;

(c) every manufacturer of a medicine must, with the approval of the Namibia Medicines Regulatory Council, ensure that the information contained in the medicine package insert is regularly updated and varied so as to provide accurate information to the user of the medicine;

(d) the holder of the certificate of registration which is referred to in section 19(7)(b) of the Act must comply with the provisions of the Act;

(e) the registration of the medicine is subject to regular review regarding its quality, safety and efficacy and the Namibia Medicines Regulatory Council may, if 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 Namibia Medicines Regulatory Council within one month from the date of completion of the validation referred to in paragraph (f); and

(h) the Namibia Medicines Regulatory Council may review the registration dossier at such intervals as the Council may determine.
