



# GOVERNMENT GAZETTE

## OF THE

# REPUBLIC OF NAMIBIA

---

N\$8.00

WINDHOEK - 2 June 2022

No. 7819

---

### CONTENTS

*Page*

#### GOVERNMENT NOTICE

No. 157 Notification of registration of certain medicines: Medicines and Related Substances Control Act, 2003 ..... 1

---

## Government Notice

---

### MINISTRY OF HEALTH AND SOCIAL SERVICES

No. 157

2022

#### 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 set out in the Schedule.

**F. N. NAMBAHU**  
**REGISTRAR OF MEDICINES**

**SCHEDULE**

<b>Particulars required under section 23(a)(i) to (v) of the Act</b>						
<b>S/N</b>	<b>Name under which the medicine is registered</b>	<b>Active components of medicine</b>	<b>Name of Applicant</b>	<b>Name of Manufacturer</b>	<b>Registration number allocated to the medicine in terms of Section 19(9) of the Act.</b>	
1	Priftin	Rifapentine	Sanofi-aventis South Africa (Pty) Ltd	Sanofi S.p.A Via Angelo Titi, 22/26 – Zona Punto Franco, 72100 Brindisi, Italy	22/20.2.3/0001	
2	Azmasol HFA Inhalation Aerosol	Salbutamol Sulphate	Beximco Pharmaceuticals Ltd	Beximco Pharmaceuticals Limited, 126, Kathaldia, Auchpara, Tongi- 1711, Gazipur, Bangladesh	22/10.2.1/0002	
3	Tadalafil Cipla 5mg	Tadalafil	Cipla Medpro (Pty) Ltd	(1) Cipla Limited unit III, Plot No. L-139, S-103 & M-62, Verna Industrial Estate Verna, Salcette, Goa 403722, India  (2) Cipla Medpro Manufacturing (Pty) Ltd 1474 South Coast Road, Mobeni, Durban, 405 2, South Africa	22/21.2/0004	
4	Tadalafil Cipla 20mg	Tadalafil	Cipla Medpro (Pty) Ltd	(1) Cipla Limited unit III, Plot No. L-139, S-103 & M-62, Verna Industrial Estate Verna, Salcette, Goa 403722, India  (2) Cipla Medpro Manufacturing (Pty) Ltd 1474 South Coast Road, Mobeni, Durban, 405 2, South Africa	22/21.2/0005	

5	Envuteg	Dolutegravir Sodium/ Lamivudine/Tenofovir Alafenamide Fumarate	Mylan Laboratories Limited	Mylan Laboratories Limited, Plot No. 11, 12 & 13, Indore Special Economic Zone, Pharma Zone, Phase-II, Sector-III, Pithampur - 454775, Dist. - Dhar, Madhya Pradesh, India.	22/20.2.8/0006
6	Atazanavir sulfate and Ritonavir tablets 300mg and 100mg	Atazanavir sulfate and Ritonavir	Lupin Limited	Lupin Limited, Plot No. 6A1, 6A2, Sector-17, Special Economic Zone, MIHAN Notified Area, Nagpur, Maharashtra-4411 08, India.	22/20.2.8/0008
7	Dexisun	Dexmedetomidine	Ranbaxy Pharmaceuticals (Pty) Ltd	Gland Pharma Limited, Sy.No: 143-148, 150 & 151, Near Gandimaisamma, Cross Roads, D.P. Pally, Dundigal Post, Dundigal-Gandimaisamma Mandal, Medchal-Malkajiri District, Hyderabad – 500043, Telangana, India	22/2.9/0009
8	Rifampicin and Isoniazid Dispersible Tablets 75mg and 50mg	Rifampicin and Isoniazid	Lupin Limited	Lupin Limited, A-28/1, MIDC Area, Chikalhana, Aurangabad, Aurangabad-431210, India	22/20.2.3/0010
9	Trafid	Dolutegravir, Emtricitabine and Tenofovir Alafenamide	Hetero Labs Limited	Hetero Labs Limited, Unit-III, 22-110,IDA, Jeedimetla Hyderabad, Telangana ,India	22/20.2.8/0011
10	Sinora 0,08mg/ml RTU	Noradrenaline	Umsebe Healthcare	Sintetica S.A., Via Penate 5, CH-6850 Mendrisio, Switzerland	22/5.1/0012
11	Sinora 0,16 mg/ml RTU	Noradrenaline	Umsebe Healthcare	Sintetica S.A., Via Penate 5, CH-6850 Mendrisio, Switzerland	22/5.1/0013
12	Abhayrab®	Purified Vero cell rabies vaccine	Cospharm Investments CC	Human Biologicals Institute, (A division of Indian immunologicals), Kozhipannai, Pudumund post, Udhagamandalam-643 007, Tamil Nadu, India	22/30.1/0014
13	Glenstat 5mg	Rosuvastatin Calcium	Glenmark Pharmaceuticals South Africa (Pty) Ltd	Glenmark Pharmaceuticals Limited Plot No. S-7, Colvale Industrial Estate, Colvale, Baredéz – Goa	22/7.5/0015

14	Glenstat 10mg	Rosuvastatin Calcium	Glenmark Pharmaceuticals South Africa (Pty) Ltd	Glenmark Pharmaceuticals Limited, Plot No. S-7, Colvale Industrial Estate, Colvale, Baredéz – Goa	22/7.5/0016
15	Glenstat 20mg	Rosuvastatin Calcium	Glenmark Pharmaceuticals South Africa (Pty) Ltd	Glenmark Pharmaceuticals Limited, Plot No. S-7, Colvale Industrial Estate, Colvale, Baredéz – Goa	22/7.5/0017
16	Glenstat 40mg	Rosuvastatin Calcium	Glenmark Pharmaceuticals South Africa (Pty) Ltd	Glenmark Pharmaceuticals Limited Plot No. S-7, Colvale Industrial Estate, Colvale, Baredéz – Goa	22/7.5/0018
17	Novistig	Glycopyrronium bromide and neostigmine metilsulfate	Umsebe Healthcare	Sintetica S.A Via Penate 5, CH-6850 Mendrisio, Switzerland	22/5.4/0019
18	Tramol	Tramadol Hydrochloride	Varichem Pharmaceuticals (Pvt) Ltd	Varichem Pharmaceuticals (Pvt) Ltd, 194 Gleneagles Road, Willowvale, Harare, Zimbabwe	22/2.10/0020
19	Amlocal 5mg	Amlodipine (as besylate)	N2SA Limited	Sai Mirra InnoPharm pvt.ltd, 288 & 299, Sidco estate, Chennai- 600098, Tamilnadu, India	22/7.1/0021
20	Avacort-BF 100/6	Budesonide/Formoterol fumarate 100mcg/6mcg	Innovata Pharmaceuticals Ltd	ELPEN Pharmaceutical Co. Inc., 95, Marathonos Ave., Pikermi 19009, Attica, Greece	22/10.3/0022
21	Rotasii-Liquid	Live Attenuated Bovine-Human Rotavirus Reassortant (G1, G2, G3, G4 and G9)	Serum Institute of India	Serum Institute of India Pvt. Ltd., 212/2 Hadapsar, Pune – 411 028, India	22/30.1/0023
22	Tecentriq 840mg	Atozolizumab	Roche Products (Pty) Ltd	F. Hoffmann-La Roche Ltd, Wurmisweg, CH-4303 Kaiseraugst, Switzerland	22/30.1/0024

23	Tecentriq 1200mg	Atozolizumab	Roche Products (Pty) Ltd	(1) F. Hoffmann-La Roche Ltd, Wurmisweg, CH-4303 Kaiseraugst, Switzerland (2) Roche Diagnostics GmbH, Sandhofer Straße 116, 68305 Mannheim, Germany	22/30.1/0025
24	Medogen Injection	Medroxyprogesterone acetate	Cospharm Investments CC	Incepta Pharmaceuticals Ltd., Factory: Unit – 1, Injectable Potent Drug (IPD), Krishnapura, Sahabelishor, Dhamrai, Dhaka, Bangladesh	22/21.8.2/0026
25	Lenvima 4	Lenvatinib Mesilate	Equity Pharmaceuticals (Pty) Ltd	Toronto Region Operations, Patheon Inc. 2100 Syntex Court, Mississauga, Ontario, L5N 7K9, Canada	22/26/0027
26	Lenvima 10	Lenvatinib Mesilate	Equity Pharmaceuticals (Pty) Ltd	Toronto Region Operations, Patheon Inc., 2100 Syntex Court, Mississauga, Ontario, L5N 7K9, Canada	22/26/0028
27	Dolutegravir (Sodium)/ Lamivudine/Tenofovir Disoproxil Fumarate 50mg/300mg/300mg Tablets	Dolutegravir (Sodium), Lamivudine and Tenofovir Disoproxil Fumarate	Lupin Limited	Lupin Limited Plot No. 6A1, 6A2, Sector-17, Special Economic Zone, MIHAN Notified Area, Nagpur, Maharashtra-4411 08, India	22/20.2.8/0029
28	Dolutegravir Sodium Tablet for Oral Suspension (Dispersible Tablets) 10mg	Dolutegravir	Macleods Pharmaceuticals Limited	(1) Macleods Pharmaceuticals Limited, Block N2, Village Theda, Post Office Lodhimajra, Tehsil Baddi, Distt. Solan, Himachal Pradesh, 174101, India (2) Macleods Pharmaceuticals Ltd., Macleods Pharmaceuticals Limited, Unit II, Phase II, Plot No. 25 - 27, Survey No. 366, Premier Industrial Estate, Kachigam, Daman, 396210 India	22/20.2.8/0030
29	Monimax	Monensin Sodium and Nicarbazin	HuvePharma SA (Pty) Ltd	Biovet Joint Stock Company, 39 Petar Rakov Street, 4550 Petshera, Bulgaria	V22/17.4.1/1494

30	Coyden 25%	Clopidol	HuvePharma SA (Pty) Ltd	Biovet Joint Stock Company, 39 Petar Rakov Street, 4550 Petshera, Bulgaria	V22/17.4.1/1495
31	Convenia	Cefovecin	Zoetis SA (Pty) Ltd	(1) Pfizer Inc, 801 River Rd, Conshohocken, PA 19428, USA (2) Pfizer Global Manufacturing, 7000 Portage Rd, Kalamazoo, MI 49001, USA	V22/17.1.1.2/1496
32	Posatex	Orbifloxacin (micronized), Mometasone furoate monohydrate (micronized) and Posaconazole (micronized)	Intervet SA (Pty) Ltd	(1) Vet Pharma Friesoythe GmbH, Sedelsberger Str. 2-4, 26169 Friesoythe, Germany (2) Pfizer Inc, 801 River Rd, Conshohocken, PA 19428, USA	V22/14.3/1497
33	Innovax-ND-ILT	Cell-associated live recombinant turkey herpesvirus (strain HVT/NDV/ILT), expressing the fusion protein of Newcastle disease virus and the glycoproteins gD and gI of infectious laryngotracheitis virus	Intervet SA (Pty) Ltd	(1) Intervet International B.V. Ambachtstraat 2, 4, 5a, De Bilt, 3732 CN, Netherlands (2) Intervet Inc. 29160 Intervet Lane, Millsboro, Delaware 19966-0318, USA	V22/24.3/1498
34	Forcyl 16% Solution for injection	Marbofloxacin	Afrivet Business Management (Pty) Ltd	(1) Vetoquinol SA Magny-Vermois, 70200 Lure CEDEX France (2) Vetoquinol Biowet Sp. z o. o St Kosynierów, Gdynskich 13/14, 66-400 Gorzów WLKP, Poland	V22/17.1.6/1499

35	Eradia	Metronidazole	Virbac RSA (Pty) Ltd	<p>1. Virbac SA, 1ère Avenue – 2065 m – L.I.D. – 06516 CARROS France</p> <p>2. Delpharm Huningue, 26 Rue De La Chapelle, 68330 Huningue</p>	V22/17.4/1500
36	Calbro Forte	Calcium gluconate Monohydrate, Magnesium glycerophosphate, Magnesium Chloride hexadrate, anhydrous glucose and anhydrous caffeine	Ascendis Animal Health (Pty) Ltd	Laboratorios Microsules Uruguay S.A, Ruta 101km 28- Cno. Al Paso Escobar s/n Pueblo Capitan Juan A Artigas, Canelones, Uruguay	V22/19.2/1501

**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) above, inspections and investigations may be carried out regularly by inspectors authorised in terms of section 35 of the Act to undertake such inspections and investigations;
  - (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(4) of the Act must comply with the provisions of the Act;
  - (e) the registration of 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 and may determine the intervals when such review will take place.
-