



GOVERNMENT GAZETTE

OF THE

REPUBLIC OF NAMIBIA

N\$8.00

WINDHOEK - 10 February 2022

No. 7744

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Government Notices

MINISTRY OF HEALTH AND SOCIAL SERVICES

No. 19

2022

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

J. GAESEB
REGISTRAR OF MEDICINES

Windhoek, 26 January 2022

SCHEDULE

Particulars required under section 23(b) of the Act			
S/N	Name under which that medicine was registered	Name of the holder of the certificate of registration issued in respect of that medicine	Registration number which was allocated to that medicine in terms of section 19(9)
1	Thrombophob Gel	Sanofi-Aventis South Africa (Pty) Ltd	03 1002403
2	Maalox Plus Suspension	Sanofi-Aventis South Africa (Pty) Ltd	90/11.4.3/00323
3	Maalox Plus Tablets	Sanofi-Aventis South Africa (Pty) Ltd	90/11.4.3/00324
4	Maalox Pocket Pack Suspension	Sanofi-Aventis South Africa (Pty) Ltd	15/11.4.1/0083
5	Maalox Suspension	Sanofi-Aventis South Africa (Pty) Ltd	15/11.4.1/0082
6	Maalox Tablets	Sanofi-Aventis South Africa (Pty) Ltd	04/11.4.1/1388
7	CIPROBAY 250	Bayer (Pty) Ltd	04/20.1.1/0350
8	Nicorette Patch 5mg	Johnson & Johnson (Pty) Ltd	07/34/0052
9	Nicorette Patch 10mg	Johnson & Johnson (Pty) Ltd	07/34/0053
10	Nicorette Patch 15mg	Johnson & Johnson (Pty) Ltd	07/34/0054
11	Caladryl Lotion	Johnson & Johnson (Pty) Ltd	14/13.4/0366
12	Chamberlain's Traditional Colic Remedy	Johnson & Johnson (Pty) Ltd	14/11.2/0200
13	Choats Extract of Lettuce	Johnson & Johnson (Pty) Ltd	90/10.1/00760
14	Combantrin Oral Suspension	Johnson & Johnson (Pty) Ltd	90/12/00761
15	Combantrin Tablets	Johnson & Johnson (Pty) Ltd	90/12/00762
16	Flemeze Bronchodilatory Syrup	Johnson & Johnson (Pty) Ltd	04/10.1/1526
17	Gelusil Peppermint	Johnson & Johnson (Pty) Ltd	04/11.4.1/1515
18	Gelusil-S	Johnson & Johnson (Pty) Ltd	04/11.4.1/1519
19	Johnson's Antiseptic Powder	Johnson & Johnson (Pty) Ltd	90/13.1/00663
20	Listerfluor Fluoride Dental Rinse	Johnson & Johnson (Pty) Ltd	90/24/001642
21	Polysporin Ointment	Johnson & Johnson (Pty) Ltd	14/14/0522
22	Sinutab Original	Johnson & Johnson (Pty) Ltd	90/5.8/001645
23	Sinutab with Codeine	Johnson & Johnson (Pty) Ltd	90/5.8/001646
24	Acatak	Eli Lilly	V98/18.3.8/1213
25	AviPro 101 Coryza	Eli Lilly	V11/24.3/1089
26	AviPro 304 ND-IB-MG	Eli Lilly	V11/24.3/1023
27	AviPro AE POX	Eli Lilly	V11/24.3/1014
28	AviPro Gumboro	Eli Lilly	V08/24.3/1130
29	AviPro ILT	Eli Lilly	V08/24.3/1133
30	AviPro MD Bivac	Eli Lilly	V11/24.3/1001
31	AviPro MD Rispens RL	Eli Lilly	V11/24.3/1002
32	AviPro ND C131	Eli Lilly	V11/24.3/1016
33	AviPro ND HB1	Eli Lilly	V08/24.3/1131
34	AviPro ND-IB Lasota	Eli Lilly	V11/24.3/974
35	Capstar Tablets for Cats and Small Dogs	Eli Lilly	V03/18.3/411
36	Capstar Tablets for Large Dogs	Eli Lilly	V03/18.3/412
37	Comfortis 140 mg Chewable Tablets	Eli Lilly	V18/18.3.10/1430

38	Comfortis 1620 mg Chewable Tablets	Eli Lilly	V18/18.3.10/1434
39	Comfortis 270 mg Chewable Tablets	Eli Lilly	V18/18.3.10/1431
40	Comfortis 560 mg Chewable Tablets	Eli Lilly	V18/18.3.10/1432
41	Comfortis 810 mg Chewable Tablets	Eli Lilly	V18/18.3.10/1433
42	Elancoban 200	Eli Lilly	V14/25.1/1227
43	Extinosad	Eli Lilly	V09/29/202
44	Multispect	Eli Lilly	V95/18.1.1/369
45	Program for Dogs weighing 20 kg	Eli Lilly	V90/18.3.8/1212
46	Program for Dogs weighing 6 kg	Eli Lilly	V90/18.3.8/1211
47	Program 40 kg	Eli Lilly	V93/18.3.8/837
48	Program Suspension	Eli Lilly	V90/18.3.8/1214
49	Pulmotil 200	Eli Lilly	V15/17.1.4/1292
50	Pulmotil AC	Eli Lilly	V15/17.1.4/1291
51	Quadrozole	Eli Lilly	V95/18.1.1/371
52	Ripercol Pour-On	Eli Lilly	V95/18.1.4/384
53	Seponver Injectable	Eli Lilly	V95/18.1.1/379
54	Seponver Oral Suspension	Eli Lilly	V95/18.1.1/377
55	Telmin Granules	Eli Lilly	V95/18.1.1/400
56	Tylan 100 Premix	Eli Lilly	V14/17.1.4/1232
57	Tylan 200	Eli Lilly	V15/17.1.4/1290
58	Tylan Soluble Powder	Eli Lilly	V14/17.1.4/1233
59	Tylosin 100 Plus Sulpha	Eli Lilly	V15/17.1.10/1293
60	Alphamune	Zoetis	V16/29/1360
61	Cydectin 0,1 % Oral Solution	Zoetis	V01/18.1.2/578
62	Cydectin plus Tape Oral Drench	Zoetis	V04/18.1.8/545
63	Excenel	Zoetis	V16/17.1.1.1/1325
64	Linco-Spectin Sterile Solution	Zoetis	V16/17.1.4/1340
65	Poulvac IBMM	Zoetis	V97/24.3/597
66	Terramycin Animal Formula Soluble Powder	Zoetis	V16/17.1.2/1354
67	Terramycin Eye Powder	Zoetis	V16/14.1/1350
68	Terravit Soluble Powder with Vitamins	Zoetis	V16/17.1.10/1355
69	Tikgard	Zoetis	V92/18.1.8/401

MINISTRY OF HEALTH AND SOCIAL SERVICES

No. 20

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 specified in the Schedule.

J. GAESEB
REGISTRAR OF MEDICINES

Windhoek, 26 January 2022

SCHEDULE

Particulars required under section 23(a)(i) to (v) of the Act					
S/N	Name under which the medicine is registered	Active components of medicine	Name of Applicant	Name of Manufacturer	Registration number allocated to a medicine in terms of Section 19(9) of the Act.
1	Copalia 5/160	Valsartan/ Amlodipine besylate	Novartis South Africa (Pty) Ltd	1. NOVARTIS PHARMA STEIN AG Schaffhauserstrasse, CH-4332, Stein, Switzerland 2. NOVARTIS FARMACEUTICA SA Ronda de Santa Maria, 158, 08210 Barberà del Vallés, Barcelona, Spain	21/7.1.3/0091
2	Copalia 10/160	Valsartan/ Amlodipine besylate	Novartis South Africa (Pty) Ltd	1. NOVARTIS PHARMA STEIN AG Schaffhauserstrasse, CH-4332, Stein, Switzerland 2. NOVARTIS FARMACEUTICA SA Ronda de Santa Maria, 158, 08210 Barberà del Vallés, Barcelona, Spain	21/7.1.3/0092
3	Copalia 5/320	Valsartan/ Amlodipine besylate	Novartis South Africa (Pty) Ltd	1. NOVARTIS PHARMA STEIN AG Schaffhauserstrasse, CH-4332, Stein, Switzerland 2. NOVARTIS FARMACEUTICA SA Ronda de Santa Maria, 158, 08210 Barberà del Vallés, Barcelona, Spain	21/7.1.3/0093
4	Copalia 10/320	Valsartan/ Amlodipine besylate	Novartis South Africa (Pty) Ltd	1. NOVARTIS PHARMA STEIN AG Schaffhauserstrasse, CH-4332, Stein, Switzerland 2. NOVARTIS FARMACEUTICA SA Ronda de Santa Maria, 158, 08210 Barberà del Vallés, Barcelona, Spain	21/7.1.3/0094

5	Kadcyla® 100	Trastuzumab emtansine	Roche Products (Pty) Ltd	F. Hoffmann – La Roche Ltd, Wurmisweg CH-4303, Kaiseraugst Switzerland	21/26/0095
6	Kadcyla® 160	Trastuzumab emtansine	Roche Products (Pty) Ltd	F. Hoffmann – La Roche Ltd, Wurmisweg CH-4303, Kaiseraugst Switzerland	21/26/0096
7	Histacet	Cetirizine hydrochloride	Varichem Pharmaceuticals (PVT) Ltd	Varichem Pharmaceuticals (Pvt) Ltd, 194 Gleneagles Road, Willowvale, Harare, Zimbabwe	21/5.7.1/0097
8	Ibucet	Paracetamol/Ibuprofen	Varichem Pharmaceuticals (PVT) Ltd	Varichem Pharmaceuticals (Pvt) Ltd, 194 Gleneagles Road, Willowvale, Harare, Zimbabwe	21/2.8/0098
9	Telstan 20	Telmisartan	Glenmark Pharmaceuticals South Africa (Pty) Ltd	Glenmark Pharmaceuticals Limited Plot No. S-7, Colvale Industrial Estate, Colvale, Baredéz – Goa	21/7.1.3/0100
10	Telstan 40	Telmisartan	Glenmark Pharmaceuticals South Africa (Pty) Ltd	Glenmark Pharmaceuticals Limited Plot No. S-7, Colvale Industrial Estate, Colvale, Baredéz – Goa	21/7.1.3/0101
11	Telstan 80	Telmisartan	Glenmark Pharmaceuticals South Africa (Pty) Ltd	Glenmark Pharmaceuticals Limited Plot No. S-7, Colvale Industrial Estate, Colvale, Baredéz – Goa	21/7.1.3/0102
12	Penthop	Methoxyflurane	Equity Pharmaceuticals (Pty) Ltd	Medical Developments International Limited Buildings 8 & 10, 56 Smith Road, Springvale, Victoria 3171, Australia	21/2.10/0103
13	Pamta 100	Pemetrexed disodium hemipentahydrate	Innovata Pharmaceuticals (Pty) Ltd	Sichuan Huiyu Pharmaceutical Company Limited Address: Buidling 3, No. 333 Hanyang Road, Shizhong district, Neijiang CN-641000, China	21/26/0104
14	Pamta 500	Pemetrexed disodium hemipentahydrate	Innovata Pharmaceuticals (Pty) Ltd	Sichuan Huiyu Pharmaceutical Company Limited Address: Buidling 3, No. 333 Hanyang Road, Shizhong district, Neijiang CN-641000, China	21/26/0105
15	Hivuslr 100/25	Lopinavir and Ritonavir	Aurobindo Pharma Limited	Aurobindo Pharma Limited, Unit-III, Survey No: 313 & 314, Bachupally, Bachupally Mandal, Medchal-Malkajgiri District, Telangana, 500090, India	21/20.2.8/0106
16	Hivuslr 200/50	Lopinavir and Ritonavir	Aurobindo Pharma Limited	Aurobindo Pharma Limited, Unit-III, Survey No: 313 & 314, Bachupally, Bachupally Mandal, Medchal-Malkajgiri District, Telangana, 500090, India	21/20.2.8/0107
17	Zylet Ophthalmic suspension	Loteprednol etabonate and Tobramycin	Soflens (Pty) Ltd	Bausch & Lomb Incorporated, 8500 Hidden River Parkway, Tampa, Florida 33637, USA	21/15.3/0108

18	Aprepitant Cipla 80	Aprepitant	Cipla Medpro (Pty) Ltd	Pharmathen International S.A Industrial Park Sapes, Rodopi Prefecture, Block No. 5, Rodopi 69300, Greece	21/5.7.2/0109
19	Aprepitant Cipla 125	Aprepitant	Cipla Medpro (Pty) Ltd	Pharmathen International S.A Industrial Park Sapes, Rodopi Prefecture, Block No. 5, Rodopi 69300, Greece	21/5.7.2/0110
20	Aprepitant Cipla Combipack	Aprepitant	Cipla Medpro (Pty) Ltd	Pharmathen International S.A Industrial Park Sapes, Rodopi Prefecture, Block No. 5, Rodopi 69300, Greece	21/5.7.2/0111
21	Vitadion	Phyto- menadione	Swiss Parenterals Pvt. Ltd	Swiss Parenterals Pvt. Ltd. Manufacturing site: 809, Kerala Industrial Estate, No. Bavla, Dist. Ahmedabad - 382 220 Gujarat, (INDIA)	21/8.2/0112
22	Revolution Plus	Selamectin and Sarolaner	Zoetis South Africa (Pty) Ltd	Zoetis LLC. 2605 East Kilgore Road, Kalamazoo, MI, USA	V21/18.3.9/1487
23	Exitel Plus XL	Praziquantel and Pyrantel	Intervet SA (Pty) Ltd	Chanelle Pharmaceuticals Manufacturing Limited, Dublin Road, Loughrea, Co Galway, H62 FH90, Ireland.	V21/18.3.9/1488
24	Exitel Plus	Praziquantel and Pyrantel	Intervet SA (Pty) Ltd	Chanelle Pharmaceuticals Manufacturing Limited, Dublin Road, Loughrea, Co Galway, H62 FH90, Ireland.	V21/18.3.9/1489
25	Nobivac solvent	Diluent used for the recon- stitution of freeze- dried small animal Nobivac vaccines for dogs and cats.	Intervet SA (Pty) Ltd	1. Intervet International BV, Wim de Körverstraat 35, 5831 AN Boxmeer, The Netherlands 2. Intervet International GmbH, Feldstrasse La, 85716 Unterschleibheim, Germany 3. Bela Pharm GmbH & Co. KG, Lohner Strasse 19, 49377 Vechta, Germany	V21/29/1490
26	Innovax ILT	2 248 PFU of live Herpes virus of turkey strain HVT/ILT- 138	Intervet SA (Pty) Ltd	Intervet Inc, 29160 Intervet Lane, Millsboro, Delaware, USA	V21/24.3/1491
27	Cyflor injection for cattle and swine	Florfenicol	Biotech Laboratories (Pty) Ltd	Norbrook Laboratories Limited, 105 Armagh Road, Newry, Co. Down, BT 35 6PU, Northern Ireland	V21/17.1/1492

28	Noroseal	Bismuth subnitrate	Biotech Laboratories (Pty) Ltd	<ol style="list-style-type: none"> 1. Norbrook Laboratories Limited, Station Works, Camlough Road, Newry, Co. Down, BT 35 6JP, Northern Ireland 2. Norbrook Laboratories Limited, 105 Armagh Road, Newry, Co. Down, BT 35 6PU, Northern Ireland 	V21/16.1/1493
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As required under section 23(a)(iv) of the Act, the medicines whose particulars are specified in these Schedules 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 sections 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 determine the intervals when such review will take place.