



GOVERNMENT GAZETTE

OF THE

REPUBLIC OF NAMIBIA

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WINDHOEK - 30 August 2021

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Government Notices

MINISTRY OF HEALTH AND SOCIAL SERVICES

No. 180 2021

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, ?? August 2021

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	Accupril 10mg	Pfizer Laboratories (Pty) Ltd	90/7.1.3/00756
2	Accupril 20mg	Pfizer Laboratories (Pty) Ltd	90/7.1.3/00757
3	Accupril 40mg	Pfizer Laboratories (Pty) Ltd	90/7.1.3/00758
4	Accupril 5mg	Pfizer Laboratories (Pty) Ltd	90/7.1.3/00759
5	Actamax 5	Pharma Dynamics (Pty) Ltd	12/7.5/0034
6	Actos 15	Eli Lilly SA (Pty) Ltd	04/21.2/0640
7	Actos 30	Eli Lilly SA (Pty) Ltd	04/21.2/0641
8	Bravelle 75 IU Powder for Solution for Injection	Ferring Pharmaceuticals (Pty) Ltd	14/32.2/0651
9	Bravelle Solvent for Solution for Injection	Ferring Pharmaceuticals (Pty) Ltd	14/32.2/0652
10	Cellufresh	Allergan Pharmaceuticals (Pty) Ltd	04/15.4/1168
11	Ciavor 20	Eli Lilly SA (Pty) Ltd	15/7.1.5/0173
12	Cymgen 30	Eli Lilly SA (Pty) Ltd	16/1.2/0201
13	Cymgen 60	Eli Lilly SA (Pty) Ltd	16/1.2/0202
14	Dacin 100	Key Oncologics (Pty) Ltd	19/26/0048
15	Diluent for Humatrope 12/24 mg	Eli Lilly SA (Pty) Ltd	04/34/0650
16	Diluent for Humatrope 3.25 ml	Eli Lilly SA (Pty) Ltd	04/34/0648
17	Dyna Bezafibrate SR 400mg	Pharma Dynamics (Pty) Ltd	08/7.5/0182
18	Dynafil 25mg	Pharma Dynamics (Pty) Ltd	13/7.1.5/0085
19	Dynarb 75mg	Pharma Dynamics (Pty) Ltd	12/7.1.3/0222
20	Dynaval 160mg	Pharma Dynamics (Pty) Ltd	18/7.1.3/0043
21	Dynaval 80mg	Pharma Dynamics (Pty) Ltd	18/7.1.3/0042
22	Elantan 20	GlaxoSmithKline South Africa (Pty) Ltd	04/7.1.4/0687
23	Evista 60mg	Eli Lilly SA (Pty) Ltd	04/34/0442
24	Flixonase Aqueous Nasal Spray	GlaxoSmithKline South Africa (Pty) Ltd	12/21.5.1/0241
25	Flixonase Nasules	GlaxoSmithKline South Africa (Pty) Ltd	04/21.5.1/0860
26	Flixotide 250 Accuhaler	GlaxoSmithKline South Africa (Pty) Ltd	04/21.5.1/0875
27	Flixotide 250 CFC-Free Inhaler	GlaxoSmithKline South Africa (Pty) Ltd	04/21.5.1/0855
28	Flixotide 50 Accuhaler	GlaxoSmithKline South Africa (Pty) Ltd	04/21.5.1/0877
29	Flixotide 50 CFC-Free Inhaler	GlaxoSmithKline South Africa (Pty) Ltd	04/21.5.1/0857
30	Humatrope 12 mg	Eli Lilly SA (Pty) Ltd	04/21.10/0649
31	Humatrope 6 mg	Eli Lilly SA (Pty) Ltd	04/21.10/0647
32	Lecrolyn 20/40	Alliance Pharma (Pty) Ltd	04/15.4/0496
33	Lecrolyn 20/40 SDU	Alliance Pharma (Pty) Ltd	04/15.4/0501
34	Levoniv IV	Pharma Dynamics (Pty) Ltd	15/20.1.1/0135
35	Macrodex	Alliance Pharma (Pty) Ltd	04/8.4/0505
36	Medopam 10	Alliance Pharma (Pty) Ltd	04/2.6/0506
37	Medopam 15	Alliance Pharma (Pty) Ltd	04/2.6/0507
38	Nictrocine	GlaxoSmithKline South Africa (Pty) Ltd	04/7.1/0685
39	Niz Shampoo	Johnson & Johnson (Pty) Ltd	90/20.2.2/00632
40	Oftan Timolol 0.25%	Alliance Pharma (Pty) Ltd	04/15.4/0513

41	Oftan Timolol 0.25% SDU	Alliance Pharma (Pty) Ltd	04/15.4/0514
42	Paxil 20	GlaxoSmithKline South Africa (Pty) Ltd	12/1.2/0003
43	Pearinda 2	Pharma Dynamics (Pty) Ltd	10/7.1.3/0475
44	Pearinda Plus 2	Pharma Dynamics (Pty) Ltd	10/7.1.3/0610
45	Penvir 750	Hetero Labs Limited	15/20.2.8/0015
46	Scholl Corn Removers	Alliance Pharma (Pty) Ltd	14/13.7/0257
47	Scholl Corn Removers Washproof	Alliance Pharma (Pty) Ltd	14/13.7/0258
48	Scholl Medicated Callous Removal Pads	Alliance Pharma (Pty) Ltd	04/3.8/0520
49	Scholl Original Corn Removers – Plasters	Alliance Pharma (Pty) Ltd	04/3.8/0521
50	Serevent Accuhaler	GlaxoSmithKline South Africa (Pty) Ltd	04/10.2.1/0934
51	Sofgen	Hetero Labs Limited	18/20.2.8/0038
52	Spectracil S 125	Alliance Pharma (Pty) Ltd	04/20.1.2/0525
53	Spectracil C 250	Alliance Pharma (Pty) Ltd	04/20.1.2/0524
54	Spectracil SF 250	Alliance Pharma (Pty) Ltd	04/20.1.2/0526
55	Stalanev 30 tablets	Varichem Pharmaceutical (Pvt) Ltd	10/20.2.8/0171
56	Telmilo 40	Hetero Labs Limited	17/7.1.3/0065
57	Telmilo 80	Hetero Labs Limited	17/7.1.3/0066
58	Temtero 20	Hetero Labs Limited	17/26/0036
59	Temtero 250	Hetero Labs Limited	17/26/0037
60	Tesar 20mg	Pharma Dynamics (Pty) Ltd	17/7.1.3/0022
61	Vari-Zidovudine tablets	Varichem Pharmaceutical (Pvt) Ltd	10/20.2.8/0317
62	Ventolin Accuhaler	GlaxoSmithKline South Africa (Pty) Ltd	04/10.2.1/0924
63	Ventolin Respirator Solution	GlaxoSmithKline South Africa (Pty) Ltd	04/10.2.1/0922
64	Zovirax Ophthalmic Ointment	GlaxoSmithKline South Africa (Pty) Ltd	90/15.4/00603
65	Zovirax Suspension	GlaxoSmithKline South Africa (Pty) Ltd	04/20.2.8/0907
66	Zoxadon 3mg	Pharma Dynamics (Pty) Ltd	10/2.6.5/0024
67	Zoxadon 4mg	Pharma Dynamics (Pty) Ltd	10/2.6.5/0025
68	Zoxadon 6mg	Pharma Dynamics (Pty) Ltd	10/2.6.5/0026
69	Zyprexa IM	Eli Lilly SA (Pty) Ltd	04/2.6.5/2044
70	Zytomil 15mg	Pharma Dynamics (Pty) Ltd	10/1.2/0480
71	Zytomil 5mg	Pharma Dynamics (Pty) Ltd	10/1.2/0478
72	Endotape	Bayer (Pty) Ltd, Animal Health Division	V01/18.1.8/313
73	Cylence	Bayer (Pty) Ltd, Animal Health Division	V01/18.3.3/317
74	Oxfen	Bayer (Pty) Ltd, Animal Health Division	V01/18.1.1/318
75	Zapp	Bayer (Pty) Ltd, Animal Health Division	V01/18.3.8/324
76	Brutel	Bayer (Pty) Ltd, Animal Health Division	V01/18.1/326
77	Necrospray NF	Bayer (Pty) Ltd, Animal Health Division	V01/17.1.10/327
78	PAB-N.F.	Bayer (Pty) Ltd, Animal Health Division	V03/18.3.2/338
79	Ocean Gold	Bayer (Pty) Ltd, Animal Health Division	V99/19.1/339
80	Maxispec	Bayer (Pty) Ltd, Animal Health Division	V95/18.1.8/370
81	Ripercol-L Oral	Bayer (Pty) Ltd, Animal Health Division	V95/18.1.4/372
82	Seponver Plus	Bayer (Pty) Ltd, Animal Health Division	V95/18.1.8/378
83	Flukiver	Bayer (Pty) Ltd, Animal Health Division	V95/18.1.3/380
84	Ripercol-L Soluble Powder	Bayer (Pty) Ltd, Animal Health Division	V95/18.1.4/381
85	Bayopet Tick and Flea Collar for Cats	Bayer (Pty) Ltd, Animal Health Division	V88/18.3.2/464

86	Bayopet Tick and Flea Collar for small Dogs	Bayer (Pty) Ltd, Animal Health Division	V88/18.3.2/465
87	Bayopet Tick and Flea Dog Collar	Bayer (Pty) Ltd, Animal Health Division	V88/18.3.2/466
88	Wormol	Bayer (Pty) Ltd, Animal Health Division	V99/18.1.6/798
89	Milborrow Wound Oil NF	Bayer (Pty) Ltd, Animal Health Division	V99/13.2/799
90	Tick Dressing "S"	Bayer (Pty) Ltd, Animal Health Division	V99/18.3.2/805
91	Advantage for Cats	Bayer (Pty) Ltd, Animal Health Division	V05/18.3.9/820
92	Advantage for Dogs	Bayer (Pty) Ltd, Animal Health Division	V05/18.3.9/821
93	Advocate for dogs	Bayer (Pty) Ltd, Animal Health Division	V12/18.2/992
94	Advocate for cats	Bayer (Pty) Ltd, Animal Health Division	V12/18.2/993
95	Vit-A-Dex	Bayer (Pty) Ltd, Animal Health Division	V14/19/1271
96	Vit-A-Plus	Bayer (Pty) Ltd, Animal Health Division	V14/19/1272
97	Hi-Tet Aerosol	Bayer (Pty) Ltd, Animal Health Division	V14/17.1.10/1273
98	Lintex-L	Bayer (Pty) Ltd, Animal Health Division	V14/18.1.3/1278
99	Levicon	Bayer (Pty) Ltd, Animal Health Division	V14/18.1.4/1280
100	Tick Grease / Bosluisghries	Bayer (Pty) Ltd, Animal Health Division	V14/18.3.3/1284
101	Baycox 2,5 %	Bayer (Pty) Ltd, Animal Health Division	V14/17.4.1/1286

MINISTRY OF HEALTH AND SOCIAL SERVICES

No. 181

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, ?? August 2021

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	Celdaz 200	Dacarbazine	Cospharm Investments (Pty) Ltd	Celon Laboratories Private Limited, India	21/26/0030	
2	Capexa 150	Capecitabine	Ingwe Lifescience (Pty) Ltd	1. Intas Pharmaceuticals Ltd (Plot No.457, 458), India 2. Intas Pharmaceuticals Ltd (Plot No. 5-14), India	21/26/0031	
3	Capexa 500	Capecitabine	Ingwe Lifescience (Pty) Ltd	1. Intas Pharmaceuticals Ltd (Plot No.457, 458), India 2. Intas Pharmaceuticals Ltd (Plot No. 5-14), India	21/26/0032	
4	Lignox 2%	Lignocaine hydrochloride	Indoco Remedies Limited	Indoco Remedies Limited, India	21/4/0033	
5	Repimend 80	Aprepitant	Eurolab (Pty) Ltd	Ronti Hellas S.A., Medical and Pharmaceutical Products, Greece	21/5.7.2/0034	
6	Repimend 125	Aprepitant	Eurolab (Pty) Ltd	Ronti Hellas S.A., Medical and Pharmaceutical Products, Greece	21/5.7.2/0035	
7	Repimend Combi Pack	Aprepitant	Eurolab (Pty) Ltd	Ronti Hellas S.A., Medical and Pharmaceutical Products, Greece	21/5.7.2/0036	
8	Endulin Cart	Insulin Glargine	Mylan Laboratories Limited	Biocon Limited, India	21/21.1/0037	
9	Endulin Vial	Insulin Glargine	Mylan Laboratories Limited	Biocon Limited, India	21/21.1/0038	
10	Doxol	Docetaxel	Venus Remedies Limited	Venus Remedies Limited, India	21/26/0039	
11	Gsunate-120	Artesunate	Cospharm Investments (Pty) Ltd	Bliss Indasi Lifescience Pvt. Ltd., India	21/20.2.6/0040	
12	Gsunate-60	Artesunate	Cospharm Investments (Pty) Ltd	Bliss Indasi Lifescience Pvt. Ltd., India	21/20.2.6/0041	
13	Valosar 50	Losartan Potassium	Varichem Pharmaceuticals (Pvt) Ltd	Varichem Pharmaceuticals (Pvt) Ltd., Zimbabwe	21/7.1.3/0042	
14	Valosar 100	Losartan Potassium	Varichem Pharmaceuticals (Pvt) Ltd	Varichem Pharmaceuticals (Pvt) Ltd., Zimbabwe	21/7.1.3/0043	
15	Rivar 10	Rivaroxaban	Innovata Pharmaccutials Ltd	Alembic Pharmaceuticals Limited, India	21/8.2/0044	
16	Rivar 15	Rivaroxaban	Innovata Pharmaccutials Ltd	Alembic Pharmaceuticals Limited, India	21/8.2/0045	
17	Rivar 20	Rivaroxaban	Innovata Pharmaccutials Ltd	Alembic Pharmaceuticals Limited, India	21/8.2/0046	

18	CP-Oxytocin 5 IU Injection	Oxytocin	Cospharm Investments (Pty) Ltd	Steril-Gene Life Sciences (P) Ltd., India	21/19/0047
19	CP-Docetaxel 20mg/ml	Docetaxel	Cospharm Investments (Pty) Ltd	Biolyse Pharma Corporation, Canada	21/26/0048
20	CP-Docetaxel 80mg/4ml	Docetaxel	Cospharm Investments (Pty) Ltd	Biolyse Pharma Corporation, Canada	21/26/0049
21	CP-Docetaxel 160mg/8ml	Docetaxel	Cospharm Investments (Pty) Ltd	Biolyse Pharma Corporation, Canada	21/26/0050
22	G-out 0.5	Colchicine	Macleods Pharmaceuticals Limited	Macleods Pharmaceuticals Limited, India	21/3.3/0051
23	Hulio 40mg Prefilled Pen	Adalimumab	Mylan Pharmaceuticals Private Limited	Terumo Yamaguchi D&D Corporation, Japan	21/30.2/0052
24	Almiral	Diclofenac sodium	Medochemie Limited	Medochemie Limited, Cyprus	21/2.8/0053
25	Zepilen	Cafazolin sodium	Medochemie Limited	Medochemie Limited, Cyprus	21/20.1.1/0054
26	Lamivudine & Tenofovir Disoproxil Fumarate Tablets 300/300 mg	Lamivudine & Tenofovir Disoproxil Fumarate	Lupin Limited	Sun Pharmaceutical Industries Limited, India	21/20.2.8/0055
27	Scadrea	Hydroxycarbamide	Sandoz SA (Pty) Ltd	Haupt Pharma Amareg GmbH, Germany	21/26/0056
28	Innovax-ND-ILT	Live recombinant turkey Herpes Virus expressing the F protein of Newcastle Disease Virus and gD and GI glycoproteins of Infectious Laryngo Tracheitis virus	Intervet SA Pty Ltd	1. Intervet International B.V., Netherlands 2. Intervet Inc, USA	V21/24.3/1472
29	Atropine 0.5 injection	Atropine sulphate	Elanco Animal Health (Pty) Ltd	Pharma-Q (Pty) Ltd, South Africa	V21/2.4/1473
30	Tioctan- Vet injection	Thioctic acid	Elanco Animal Health (Pty) Ltd	Pharma-Q (Pty) Ltd, South Africa	V21/9.2/1474
31	Kortico Injection	Dexamethasone	Elanco Animal Health (Pty) Ltd	Pharma-Q (Pty) Ltd, South Africa	V21/12.3/1475
32	Catosal 10%	Butophosphan and Cyanocobalamin	Elanco Animal Health (Pty) Ltd	Bayer HealthCare LLC, USA	V21/19.2/1476
33	Zerorab	Inactivated rabies virus propagated in cell line BHK-21	Afrivet Business Management (Pty) Ltd	Indian Immunologicals Limited, India	V21/24.4/1477
34	Otomax Ear Drops	Betamethasone, Gentamicin sulphate and Clotrimazole	Intervet SA (Pty) Ltd	Vet Pharma Friesoythe GmbH, Germany	V21/13.3.1/1478
35	Milpro Kittens	Milbemycin Oxime and Praziquantel	Virbac RSA (Pty) Ltd	1. Virbac France, France 2. Virbac RSA (Pty) Ltd., South Africa	V21/18.1.8/1479
36	Milpro Cats	Milbemycin Oxime and Praziquantel	Virbac RSA (Pty) Ltd	1. Virbac France, France 2. Virbac RSA (Pty) Ltd., South Africa	V21/18.1.8/1480
37	Milpro Dogs	Milbemycin Oxime and Praziquantel	Virbac RSA (Pty) Ltd	1. Virbac France, France 2. Virbac RSA (Pty) Ltd., South Africa	V21/18.1.8/1481
38	Milpro Puppies	Milbemycin Oxime and Praziquantel	Virbac RSA (Pty) Ltd	1. Virbac France, France 2. Virbac RSA (Pty) Ltd., South Africa	V21/18.1.8/1482

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 authorized 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 may determine the intervals when such review will take place.
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