



GOVERNMENT GAZETTE

OF THE

REPUBLIC OF NAMIBIA

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Government Notice

MINISTRY OF HEALTH AND SOCIAL SERVICES

No. 50

2018

REGISTRATION OF CERTAIN VETERINARY MEDICINES: MEDICINES AND RELATED SUBSTANCES CONTROL ACT, 2003

Under 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 the medicine is manufactured and controlled in terms of existing good manufacturing practices as determined by the Namibia Medicines Regulatory Council (hereafter referred to as “the Council”);
- (b) inspections and investigations of the medicine may be carried out regularly by inspectors appointed in terms of section 35 of the Act to assess compliance with existing good manufacturing practices;
- (c) the applicant must ensure the information contained in the medicine 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. 13 of 2003);

- (e) the registration of medicine is subject to regular review by the Council regarding 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 of the medicine 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 of the medicine at intervals determined by the Council.

J. GAESEB
REGISTRAR OF MEDICINES

Windhoek, 6 March 2018

SCHEDULE

S/N	APPLICANT NAME	PROPRIETARY NAME	APPROVED NAME OF ACTIVE(S)	REGISTRATION NUMBER
1	Eli Lilly (SA)(Pty) Limited	Surolan	Each 1ml contains Miconazol Nitrate 23mg, Prednisolone Acetate 5mg and Polymixin B Sulphate 0.5293mg/ml	V15/14.3/1288
2	Eli Lilly (SA)(Pty) Limited	Stresnil	Each 1ml contains Azaperone 40mg	V15/1.6.2/1289
3	Elanco Animal Health, Division of Eli Lilly (SA)(Pty) Limited	Tylan 200	Each ml Tylan 200 contains Tylosin 200mg	V15/17.1.4/1290
4	Eli Lilly (SA)(Pty) Limited	Pulmotil AC	Each 1,0ml solution contains Tilmicosin Phosphate equivalent to Tilmicosin 250mg	V15/17.1.4/1291
5	Eli Lilly (SA)(Pty) Limited	Pulmotil 200	Each Pulmotil 200 contains Tilmicosin 200g/kg	V15/17.1.4/1292
6	Eli Lilly (SA)(Pty) Limited	Tylosin 100 Plus Sulfa	Each 1 kg contains Tylosin 100g and Sulphamethazine 100g	V15/17.1.10/1293
7	Virbac RSA (Pty) Limited	Titanium 5 FP + L5	Each ml contains modified live vaccine containing BVD type 1 and 11,IBR<PI3, BRSV<I, canicola,L, grippotyphosa and L Icterohaemorrhagiae	V15/24.4/1294
8	Virbac RSA (Pty) Limited	Rabigen mono	Each ml contains inactivated rabies suspension (VP12 strain) and minimum titre 1 IU	V15/24.8/1295
9	Virbac RSA (Pty) Limited	Trigger Strike	Each ml contains Triflumuron 2,5% m/v	V15/18.3.8/1296
10	Virbac RSA (Pty) Limited	Terralon 200LA	Each ml contains Oxytetracycline 200mg	V15/17.1.2/1297
11	Virbac RSA (Pty) Limited	Tylo 200	Each ml contains Tylosin 200mg	V15/17.1.4/1298
12	Oberon Pharma (Pty) Ltd	Swamycin	Each ml contains Oxytetracycline 200 mg Hydrochloride 12.5% m/v	V15/ 17. 1.2 /1299
13	Swavet RSA (Pty) Ltd	Swavet Equine Paste	Each ml contains Ivermectin 1.87% m/v	V15/18.1.2/1300
14	Cipla Agrimed (Pty) Ltd	Deltadip Tick Grease	Each ml contains Deltamethrin 0.10% m/m and Piperonyl butoxide 0.05% m/m	V16/18.3.3/1301
15	Cipla Agrimed (Pty) Ltd	Moxiject 1% Injectable	Each ml contains Moxidectin 1% m/v	V16/18.1.2/1302
16	Virbac RSA (Pty) Ltd	Tri-Aplucine	Each 100g powder contains Josamycine 18 million IU and Trimethoprim 10g	V16/7.1.10/1303
17	Virbac RSA (Pty) Ltd	Colistine 1200	Each g contains Colistin sulphate 1 200 000 I.U	V16/17.1.9/1304

18	Medpet (Pty) Ltd	Medpet mediworm Plus for Dogs	Each tablet contains Praziquantel 75mg, Pyrantel Pamoate 200mg, Febantel 300mg	V16/18.1.8/1306
19	Medpet (Pty) Ltd	Mediworm for large Dogs	Each tablet contains praziquantel 300mg, pyrantel pamoate 800mg	V16/18.1.8/1307
20	Medpet (Pty) Ltd	Medpet Doxydog 50mg	Each tablet contains Doxycycline 50mg	V16/17.1.2/1308
21	Medpet (Pty) Ltd	Medpet Doxydog 100mg	Each tablet contains Doxycycline 100mg	V16/17.1.2/1309
22	Medpet (Pty) Ltd	Medpet Doxydog 300mg	Each tablet contains Doxycyclin 300mg	V16/17.1.2/1310
23	Medpet (Pty) Ltd	Medpet mediworm powder	Each 5 gram contains Pyrantel Pamoate 50mg and Praziquantel 10mg	V16/18.1.8/1311
24	Medpet (Pty) Ltd	Marltons Dewormer	Each 5ml contains 938mg piperazine citrate equivalent to 18,7% m/v piperazine citrate	V16/18.1.6/1312
25	Medpet (Pty) Ltd	Doxybiotic	Each kg of powder contain Doxycycline Hydrochloride 25g	V16/17.1.2/1313
26	Medpet (Pty) Ltd	Medpet Doxysyrup	Each ml contain doxycycline hyclate 10mg	V16/17.1.2/1314
27	Marltons Pets & Products (Pty) Ltd	Marltons Tick & Flea Shampoo for Dogs & Cats	Each ml contains 720mg cypermethrin, 3280mg piperonyl butoxide and lanolin 50g	V16/18.3.9/1315
28	Marltons Pets & Products (Pty) Ltd	Marltons Flyrid	Contains 0,28% m/v cypermethrin, 1,25 % m/v piperonyl butoxide	V16/18.3.9/1516
29	Marltons Pets & Products (Pty) Ltd	Marltons Tick & Flea powder for Dogs & Cats	Contains 0,2% m/v cypermethrin, piperonyl butoxide, 1,0% m/v	V16/18.3.9/1317
30	Marltons Pets & Products (Pty) Ltd	Marltons Tick & Flea Dip for Dogs & Cats	Contains 0,25% m/v cypermethrin, 1,25 % m/v piperonyl butoxide	V16/18.3.9/1318
31	Zoetis South Africa (Pty) Ltd	Zeniquin 25	Each tablet contains Marbofloxacin 25mg	V16/17.1.6/1319
32	Zoetis South Africa (Pty) Ltd	Zeniquin 50	Each tablet contains Marbofloxacin 50mg	V16/17.1.6/1320
33	Zoetis South Africa (Pty) Ltd	Zeniquin 100	Each tablet contains Marbofloxacin 100mg	V16/17.1.6/1321
34	Zoetis South Africa (Pty) Ltd	Synulox 50mg	Each tablet contains Amoxicillin 40mg and clavulanic acid 10mg	V16/17.1.1.1/1322
35	Zoetis South Africa (Pty) Ltd	Synulox 250mg	Each tablet contains Amoxicillin 200mg and clavulanic acid 50mg	V16/17.1.1.1/1323

36	Zoetis South Africa (Pty) Ltd	Synulox RTU	Each 1,0 ml suspension contains Amoxicillin trihydrate equivalent to amoxicillin 140,0mg and potassium clavulanate equivalent to clavulanic acid 35,0mg	V16/17.1.1.1/1324
37	Zoetis South Africa (Pty) Ltd	Excenel	Each ml contains ceftiofur 50mg	V16/17.1.1.2/1325
38	Zoetis South Africa (Pty) Ltd	Excenel RTU	Each ml contains ceftiofur hydrochloride 50mg	V16/17.1.1.2/1326
39	Zoetis South Africa (Pty) Ltd	Draxxin 100mg/ml	Each ml contain Tulathromycin 100mg	V16/17.1.4/1327
40	Zoetis South Africa (Pty) Ltd	Diluent for Convenia	Each vial of diluents contains water for injections	V16/29/1328
41	Zoetis South Africa (Pty) Ltd	Clamoxyl 200mg	Each tablet contains Amoxicillin trihydrate equivalent to Amoxicillin 200mg	V16/17.1.1.1/1329
42	Zoetis South Africa (Pty) Ltd	Clamoxyl RTU	Each ml suspension contains Amoxicillin trihydrate equivalent to amoxicillin 150mg	V16/17.1.1.1/1330
43	Zoetis South Africa (Pty) Ltd	LIQUAMYCIN LA	Each ml contains Oxytetracycline 200mg	V16/17.1.2/1331
44	Zoetis South Africa (Pty) Ltd	Terra-cortril eye/ear suspension	Each ml contains oxytetracycline 10mg, Hydrocortisone acetate 5mg and Polymyxin B sulphate 10 000 unit	V16/14.3/1332
45	Zoetis South Africa (Pty) Ltd	Rimadyl Aqueous injection	Each ml contains Carprofen 50mg	V16/3.1.2.3/1333
46	Zoetis South Africa (Pty) Ltd	Excede	Each ml contains ceftiofur 200mg	V16/17.1.1.2/1334
47	Zoetis South Africa (Pty) Ltd	Advocin Injectable Solution	Each ml contains danofloxacin mesylate equivalent to Danofloxacin 25mg	V16/17.1.6/1335
48	Zoetis South Africa (Pty) Ltd	Domitor	Each ml contains medetomidine hydrochloride 1mg	V16/14.2/1336
49	Zoetis South Africa (Pty) Ltd	Rimadyl Chewable 75	Each chewable tablet contains Carprofen 75mg	V16/3.1.2.3/1337
50	Zoetis South Africa (Pty) Ltd	Rimadyl Chewable 100	Each chewable tablet contains Carprofen 100mg	V16/3.1.2.3/1338
51	Zoetis South Africa (Pty) Ltd	Cerenia	Each ml contains maropitant 10mg	V16/8.3/1339
52	Zoetis South Africa (Pty) Ltd	Linco-spectin sterile solution (S4)	Each ml contains Lincomycin hydrochloride equivalent to lincomycin base 50mg and spectinomycin sulphate equivalent to spectinomycin base 100mg	V16/17.1.10/1340
53	Zoetis South Africa (Pty) Ltd	Predef 2X	Each ml contains 2mg Isoflupredone acetate	V16/12.3/1341
54	Merial South Africa (Pty) Ltd	Gallimune SE + ST	Each 0.3ml dose contains inactivated Salmonella Enteritidis PT4 at least 42 IP.U and inactivated Salmonella Typhimurium DT 104 of at least 149 SAT.U	V16/24.3/1342

55	Virbac RSA (Pty) Ltd	Ypozane 1.875 mg	Each tablet contains Osaterone acetate 1.875mg	V16/11.2.3/1343
56	Virbac RSA (Pty) Ltd	Ypozane 3.75 mg	Each tablet contains Osaterone acetate 3.75mg	V16/11.2.3/1344
57	Virbac RSA (Pty) Ltd	Ypozane 7.5 mg	Each tablet contains Osaterone acetate 7.5mg	V16/11.2.3/1345
58	Virbac RSA (Pty) Ltd	Ypozane 15 mg	Each tablet contains Osaterone acetate 15mg	V16/11.2.3/1346
59	Zoetis South Africa (Pty) Ltd	Lectade	Sachet A (19,4 g) contains Glycine 31,8% m/m Electrolytes and citric acid 68,2% m/m. Sachet B (44.6 g) contains Dextrose 100% m/m	V16/19.3/1347
60	Zoetis South Africa (Pty) Ltd	Paracide	Contains Alphamethrin 7% m/v	V16/18.3.3/1348
61	Zoetis South Africa (Pty) Ltd	Pouracide	Contains Alphamethrin 0,5%, cyper-methrin 1%, tetrachlorvinphos 2% and piperonyl butoxide 7,5%.	V16/18.3.9/1349
62	Zoetis South Africa (Pty) Ltd	Terramycin Eye Powder	Each g contains Oxytetracycline HCl 20 mg and benzocaine 10mg	V16/14.1/1350
63	Zoetis South Africa (Pty) Ltd	Terramycin 100 Injectable Solution	Each ml contains oxytetracycline hydrochloride 100mg	V16/17.1.2/1351
64	Zoetis South Africa (Pty) Ltd	Terramycin LA Injectable Solution	Each ml contains oxytetracycline hydrochloride 200mg	V16/17.1.2/1352
65	Zoetis South Africa (Pty) Ltd	Terramycin IU Super Oblet	Each oblet contains Oxytetracycline hydrochloride 2 000mg	V16/17.1.2/1353
66	Zoetis South Africa (Pty) Ltd	Terramycin Animal Formula Powder	Each gram contains Oxytetracycline Hydrochloride 55mg	V16/17.1.2/1354
67	Zoetis South Africa (Pty) Ltd	Terravit Soluble Powder with vitamins	Each gram contains Oxytetracycline HCl 55mg, Riboflavin 2,8mg, Pantothenic acid 4,6mg, Niacinamide 13mg, Vitamin A 2200 iu, Vitamin B12 2,2 µg, Vitamin D3 397 IU, Vitamin E 0,66IU and Vitamin K 0,79mg	V16/17.1.10/1355
68	Zoetis South Africa (Pty) Ltd	Valbantel	Contains Albendazole 1,9 % m/v and Closantyl sodium 3 % m/v	V16/18.1.8/1356
69	Zoetis South Africa (Pty) Ltd	Valbazen for cattle	Contains Albendazole 7,5 % m/v	V16/18.1.1/1357
70	Zoetis South Africa (Pty) Ltd	Valbazen for sheep	Contains Albendazole 1,9% m/v	V16/18.1.1/1358
71	Zoetis South Africa (Pty) Ltd	Vibrin	Vaccine which is inactivated Campylobacter fetus bacteria	V16/24.4/1359

72	Zoetis South Africa (Pty) Ltd	Alphamune	Consists of brewer's yeast, deproteinated containing min 24% β -Glycans and 5-15% Mannans	V16/29/1360
73	Zoetis South Africa (Pty) Ltd	Aurofac 100	Each kg powder contains Aureomycin chlortetracycline 100g	V16/17.1.2/1361
74	Zoetis South Africa (Pty) Ltd	Aureo-S-700 G	Each kg powder contains Aureomycin chlortetracycline 77g and sulphamethazine 77g	V16/17.1.10/1362
75	Virbac SA (Pty) Ltd	Methoxasol - T	Contains Trimethoprim 2% m/v and Sulphamethoxazole 10% m/v	V16/17.1.7/1363
76	Virbac SA (Pty) Ltd	Promote	Contains Tylosin 10%	V16/25.1/1364
77	Swavet (Pty) Ltd	SWA-DOXY-MYCIN	Each 1000mg powder contains Doxycycline Hydrochloride 541.02mg equivalent to Doxycycline 500.0mg	V16/17.1.2/1365
78	Boehringer Ingelheim Animal Health South Africa (Pty) Ltd	Nexgard chewable tablets for dogs	Each tablet contains 2.27% w/w Afoxolaner	V16/18.3.6/1367
79	Boehringer Ingelheim Animal Health South Africa (Pty) Ltd	Broadline top spot for cats	Contains Fipronil 83mg/ml, Praziquantel 83mg, (s)-methoprene 4mg/ml and Eprinomectin 100mg/ml	V16/18.3.6/1368
80	Ingelheim Pharmaceuticals (Pty) Ltd	Pexion 400mg tablets	Each tablet contains Imepitoin 400mg	V16/1.5/1369
81	Ingelheim Pharmaceuticals (Pty) Ltd	Pexion 100mg tablets	Each tablet contains Imepitoin 100mg	V16/1.5/1370
82	Intervet (SA) (Pty) Ltd	Nobilis Gumboro 228E	Consists of 2.0 log ₁₀ EID ₅₀ of live Gumboro Disease virus strain 228E in stabilizer	V16/24.3/1371
83	Eli Lilly (S.A.) (Pty) Ltd	Micotil 300	Each ml contains Tilmicosin, as Tilmicosin aqueous, 300mg/ml	V16/17.1.4/1372
84	Ingelheim Pharmaceuticals (Pty) Ltd	Bar-Vac 10	Each 2.0ml contains at least 80% protection Clostridium chauvoei, 1.5IU antitoxin/ml Clostridium septicum, 0.5IU of alpha antitoxin/ml Clostridium novyi, 1.0 IU of antitoxin/ml and Clostridium sordellii, 10.0IU of beta antitoxin/ml Clostridium perfringens	V16/24.4.2/1373
85	Zoetis South Africa (Pty) Ltd	Veterinary Depo-Medrol 20mg/ml	Each ml contains 20mg of methylprednisolone acetate	V16/3.1.1/1374
86	Zoetis South Africa (Pty) Ltd	Veterinary Depo-Medrol 40mg/ml	Each ml contains 40mg of methylprednisolone acetate	V16/3.1.1/1375
87	Zoetis South Africa (Pty) Ltd	Domosedan	Each ml contains Detomidine hydrochloride 10mg and methyl parahydroxybenzoate 1mg as preservatives	V16/1.4.2/1376

88	Zoetis South Africa (Pty) Ltd	Convenia	Each vial of lyophilized powder contains cefovecin Sodium, the equivalent to cefovecin 852mg	V16/17.1.1.2/1377
89	Zoetis South Africa (Pty) Ltd	Antisedan	Each ml contains Atipamezole hydrochloride 5mg	V16/1.4.3/1378
90	Adeva Health and Pharmaceutical (Pty) Ltd	Adeva eQuine Joint Endurance	Each scoop contains Glucoseamine Hcl 8500mg, chondroitin sulphate 5000mg, MSM (methylsulfonylmethane) 8500mg, papain Enzyme 50mg and bromelain 50mg	V16/19.5/1379
91	Adeva Health and Pharmaceutical (Pty) Ltd	Adeva Mobimax	Each capsule contains Glucosamine sulphate 250mg; Chondroitin sulphate 150mg and MSM (Methylsulfonylmethane) 135mg	V16/19.5/1380
92	Zoetis South Africa (Pty) Ltd	Cydectin Eweguard	Contains 0,5 % Moxidectin, antigens of Pulpy Kidney, Black Quarter, Malignant Oedema, Gangrene, Tetanus and Caseous Lymphadenitis	V16/18.1.9/1381
93	Zoetis South Africa (Pty) Ltd	Vanguard Plus 5/CV-L	Freeze-dried preparation of attenuated strains of CD virus ≥ 10 3.5TCID ₅₀ , CAV-2 ≥ 10 3.4TCID ₅₀ , CPI viru ≥ 10 5.5TCID ₅₀ s, CPV ≥ 10 7.25TCID ₅₀ and inactivated whole cultures of L. canicola 600 NU and L. icterohaemorrhagiae 600 NU, plus a liquid preparation of inactivated CCV ≥ 1.49 RP	V16/24.1/1382
94	Cipla Vet (Pty) Ltd	Agra Bolic	Each ml contains Phosphorous 6mg, Selenium 0.01mg, Vitamin B1 1mg, Casein acid 50mg, Vitamin B12 0.05mg and Vitamin B6 0.66mg	V17/19.4/1383
95	Cipla Vet (Pty) Ltd	Pegaquest	Contains Moxidectin 2.0g/100ml and Praziquantel 12.5g/100ml	V17/18.1.8/1384
96	Cipla Agrimed (Pty) Ltd	DIB 0.5 g Implant	Each intravaginal device contains progesterone 0.5g	V17/11.2.3/1385
97	Cipla Agrimed (Pty) Ltd	Cipla Oestradiol Benzoate	Each 100 ml bottle contains Oestradiol benzoate 0.1g (0.1% m/v)	V17/11.2.2/1386
98	Merial South Africa (Pty) Ltd	Gallivac IBD	Each dose of vaccine contains attenuated infectious bursal disease (Gumboro) virus S706 strain at least 10sq.4.0 CCID ₅₀	V17/24.3/1387
99	Cipla Agrimed (Pty) Ltd	Complex + A & E for Sheep and Goats	Each ml contains Vitamin A 7500 IU, Vitamin E 24 IU, Zinc 11mg, Selenium 0.8mg and Manganese 2.7mg	V17/19.2/1388
100	Cipla Agrimed (Pty) Ltd	Agra Vitamin & Minerals Sheep/Goats	Each ml contains Vitamin A 7500 IU, Vitamin E 24 IU, Zinc 11 mg, Selenium 0.8 mg and Manganese 2.7mg	V17/19.2/1389

101	Cipla Agrimed (Pty) Ltd	Complex + A & E for Cattle	Each ml contains Vitamin A 25 000 IU, Vitamin E 50 IU, Copper 4mg, Zinc 11mg, Selenium 1.25mg and Manganese 2.7 mg	V17/19.2/1390
102	Cipla Agrimed (Pty) Ltd	Agra Vitamin & Minerals Cattle	Each ml contains Vitamin A 25 000 IU, Vitamin E 50 IU, Copper 4mg, Zinc 11mg, Selenium 1.25 mg and Manganese 2.7 mg	V17/19.2/1391
103	Cipla Agrimed (Pty) Ltd	Arapour	Contains Flumethrin 1% m/v	V17/18.3.3/1392
104	Cipla Agrimed (Pty) Ltd	Agramycin 10%	Contains Oxytetracycline 100 mg/ml	V17/17.1.2/1393
105	Ceva Animal Health (Pty) Ltd	Ceva Super	Contains Ivermectin 1.0% m/v and Clorsulon 10.0% m/v	V17/18.1.8/1394
106	Zoetis South Africa (Pty) Ltd	Special Formula 17900 Forte	Each 10ml plastet contains Pencillin G procaine 110 000 IU, Polymyxin B sulphate 53 500 IU, Sodium novobiocin 157.5mg, Dihydrostreptomycin sulphate 106mg, Hydrocortisone acetate 20 107mg and Hydrocortisone sodium succinate 13.25mg	V17/16.1/1395