

GOVERNMENT NOTICES • GOEWERMENSKENNISGEWINGS

DEPARTMENT OF HEALTH

NO. R. 1032

15 October 2021

Registration Number	Date issued	Product name	Dosage form	Applicant	API	Conditions of Registrations
46/2.5/0046	2021/04/06	CONVULEX IV	INJECTION	TAKEDA (PTY) LTD	EACH 1,0 ml CONTAINS SODIUM VALPROATE 100,0 mg	Annexure A
52/3.1/0420	2021/04/13	RUMATOR 30 mg	TABLET	HETERO DRUGS SA (PTY) LTD	EACH TABLET CONTAINS ETORICOXIB 30,0 mg	Annexure A
52/3.1/0421	2021/04/13	RUMATOR 60 mg	TABLET	HETERO DRUGS SA (PTY) LTD	EACH TABLET CONTAINS ETORICOXIB 60,0 mg	Annexure A
52/3.1/0422	2021/04/13	RUMATOR 90 mg	TABLET	HETERO DRUGS SA (PTY) LTD	EACH TABLET CONTAINS ETORICOXIB 90,0 mg	Annexure A
52/3.1/0423	2021/04/13	RUMATOR 120 mg	TABLET	HETERO DRUGS SA (PTY) LTD	EACH TABLET CONTAINS ETORICOXIB 120,0 mg	Annexure A
52/3.1/0424.420	2021/04/13	REPOFEM 30	TABLET	HETERO DRUGS SA (PTY) LTD	EACH TABLET CONTAINS ETORICOXIB 30,0 mg	Annexure A
52/3.1/0425.421	2021/04/13	REPOFEM 60	TABLET	HETERO DRUGS SA (PTY) LTD	EACH TABLET CONTAINS ETORICOXIB 60,0 mg	Annexure A
52/3.1/0426.422	2021/04/13	REPOFEM 90	TABLET	HETERO DRUGS SA (PTY) LTD	EACH TABLET CONTAINS ETORICOXIB 90,0 mg	Annexure A
52/3.1/0427.423	2021/04/13	REPOFEM 120	TABLET	HETERO DRUGS SA (PTY) LTD	EACH TABLET CONTAINS ETORICOXIB 120,0 mg	Annexure A
52/3.1/0528.420	2021/04/13	OSTEORIX 30 mg	TABLET	HETERO DRUGS SA (PTY) LTD	EACH TABLET CONTAINS ETORICOXIB 30,0 mg	Annexure A
52/3.1/0429.421	2021/04/13	OSTEORIX 60 mg	TABLET	HETERO DRUGS SA (PTY) LTD	EACH TABLET CONTAINS ETORICOXIB 60,0 mg	Annexure A
52/3.1/0430.422	2021/04/13	OSTEORIX 90 mg	TABLET	HETERO DRUGS SA (PTY) LTD	EACH TABLET CONTAINS ETORICOXIB 90,0 mg	Annexure A
52/3.1/0431.423	2021/04/13	OSTEORIX 120 mg	TABLET	HETERO DRUGS SA (PTY) LTD	EACH TABLET CONTAINS ETORICOXIB 120,0 mg	Annexure A
17/12.2/13	2021/04/06	VIDALTA 10 mg	TABLET	INTERVET SA (PTY) LTD	EACH TABLET CONTAINS CARBIMAZOLE 10,0 mg	Annexure A
17/12.2/14	2021/04/06	VIDALTA 15 mg	TABLET	INTERVET SA (PTY) LTD	EACH TABLET CONTAINS CARBIMAZOLE 15,0 mg	Annexure A
54/34/0653	2021/04/06	KIENDRA 0,25	TABLET	SANDOZ SOUTH AFRICA (PTY) LTD	EACH TABLET CONTAINS SIPONIMOD 0,25 mg	Annexure A
54/34/0654	2021/04/06	KIENDRA 2	TABLET	SANDOZ SOUTH AFRICA (PTY) LTD	EACH TABLET CONTAINS SIPONIMOD 2,0 mg	Annexure A
19/17.4/27	2021/04/20	ERADIA	ORAL SOLUTION	VIRBAC RSA (PTY) LTD	EACH 1,0 ml SOLUTION CONTAINS METRONIDAZOLE 125,0 mg	Annexure A
17/17.1.10/02	2021/04/20	CUROCEF DUO	INJECTION	VIRBAC RSA (PTY) LTD	EACH 1,0 ml SUSPENSION CONTAINS CEFTIOFUR 50,0 mg KETOPROFEN 150,0 mg	Annexure A
54/26/0275	2021/04/28	TILOMIA 200	CAPSULES	HETERO DRUGS SA (PTY) LTD	EACH CAPSULE CONTAINS NILOTINIB 200,0 mg	Annexure A
54/26/0276.274	2021/04/28	TASICAP 150	CAPSULES	HETERO DRUGS SA (PTY) LTD	EACH CAPSULE CONTAINS NILOTINIB 150,0 mg	Annexure A
54/26/0277.275	2021/04/28	TASICAP 200	CAPSULES	HETERO DRUGS SA (PTY) LTD	EACH CAPSULE CONTAINS NILOTINIB 200,0 mg	Annexure A
54/26/0278.274	2021/04/28	TASILEUK 150	CAPSULES	HETERO DRUGS SA (PTY) LTD	EACH CAPSULE CONTAINS NILOTINIB 150,0 mg	Annexure A
54/26/0279.275	2021/04/28	TASILEUK 200	CAPSULES	HETERO DRUGS SA (PTY) LTD	EACH CAPSULE CONTAINS NILOTINIB 200,0 mg	Annexure A
54/26/0344	2021/04/28	VALOMA 1	INJECTION	CURANTO PHARMA (PTY) LTD	EACH VIAL CONTAINS BORTEZOMIB 1,0 mg	Annexure A
54/26/0345	2021/04/28	VALOMA 2,5	INJECTION	CURANTO PHARMA (PTY) LTD	EACH VIAL CONTAINS BORTEZOMIB 2,5 mg	Annexure A
54/26/0346	2021/04/28	VALOMA 3,5	INJECTION	CURANTO PHARMA (PTY) LTD	EACH VIAL CONTAINS BORTEZOMIB 3,5 mg	Annexure A
55/13.12/0287	2021/05/04	STACUIS	OINTMENT	Pfizer Laboratories (PTY) LTD	EACH 1,0 g OINTMENT CONTAINS CHRISABOROLE 20,0 mg	Annexure A
53/20.1.1/0043	2021/05/04	ALKOZID	TABLET	ALKEM LABORATORIES (PTY) LTD	EACH TABLET CONTAINS LINEZOLID 600,0 mg	Annexure A
53/20.1.1/0044.043	2021/05/04	LINOKEM	TABLET	ALKEM LABORATORIES (PTY) LTD	EACH TABLET CONTAINS LINEZOLID 600,0 mg	Annexure A
53/20.1.1/0045.043	2021/05/04	LINEZOLID ALKEM	TABLET	ALKEM LABORATORIES (PTY) LTD	EACH TABLET CONTAINS LINEZOLID 600,0 mg	Annexure A
19/1.4.1/15	2021/05/11	SEDOLAM 50	INJECTION	WILDLIFE PHARMACEUTICALS (PTY) LTD	EACH 1,0 ml SOLUTION CONTAINS MIDAZOLAM 50,0 mg	Annexure A
					EACH CAPSULE CONTAINS GLYCOPYRRONIUM BROMIDE EQUIVALENT TO GLYCOPYRRONIUM 50,0 ug INDACATEROL ACETATE EQUIVALENT TO INDACATEROL 150,0 ug	Annexure A
54/10.2.1/0873	2021/05/11	ENERZAIR BREEZHALER 150/50/80	INHALER	NOVARTIS SOUTH AFRICA (PTY) LTD	MOMETASONE FUROATE 80,0 ug	Annexure A
54/10.2.1/0874	2021/05/11	ENERZAIR BREEZHALER 150/50/160	INHALER	NOVARTIS SOUTH AFRICA (PTY) LTD	EACH CAPSULE CONTAINS GLYCOPYRRONIUM BROMIDE EQUIVALENT TO GLYCOPYRRONIUM 50,0 ug INDACATEROL ACETATE EQUIVALENT TO INDACATEROL 150,0 ug	Annexure A

54/10.2.1/0875.873	2021/05/11	ZIMBUS BREEZHALER 150/50/80	INHALER	NOVARTIS SOUTH AFRICA (PTY) LTD	EACH CAPSULE CONTAINS GLYCOPHYRRONIUM BROMIDE EQUIVALENT TO GLYCOPHYRRONIUM 50,0 ug INDACATEROL ACETATE EQUIVALENT TO INDACATEROL 150,0 ug MOMETASONE FURATE 80,0 ug	Annexure A
54/10.2.1/0876.874	2021/05/11	ZIMBUS BREEZHALER 150/50/160	INHALER	NOVARTIS SOUTH AFRICA (PTY) LTD	EACH CAPSULE CONTAINS GLYCOPHYRRONIUM BROMIDE EQUIVALENT TO GLYCOPHYRRONIUM 50,0 ug INDACATEROL ACETATE EQUIVALENT TO INDACATEROL 150,0 ug MOMETASONE FURATE 160,0 ug	Annexure A
53/34/0187	2021/05/18	IMATINIB 100 mg ADCO	TABLET	ADCOCK INGRAM CRITICAL CARE (PTY) LTD	EACH TABLETS CONTAINS IMATINIB MESILATE EQUIVALENT TO IMATINIB 100,0 mg	Annexure A
53/34/0188	2021/05/18	IMATINIB 400 mg ADCO	TABLET	ADCOCK INGRAM CRITICAL CARE (PTY) LTD	EACH TABLETS CONTAINS IMATINIB MESILATE EQUIVALENT TO IMATINIB 400,0 mg	Annexure A
54/2.8/0538	2021/05/18	SKUDEXA	TABLET	LEBASI PHARMACEUTICALS CC	EACH TABLET CONTAINS DEKETOPIROFEN 25,0 mg TRAMADOL HYDROCHLORIDE 75,0 mg	Annexure A
54/2.8/0539.538	2021/05/18	LENIZAK	TABLET	LEBASI PHARMACEUTICALS CC	EACH TABLET CONTAINS DEKETOPIROFEN 25,0 mg TRAMADOL HYDROCHLORIDE 75,0 mg	Annexure A
54/20.1.1/0754	2021/05/18	LISOLVID	TABLET	MYLAN (PTY) LTD	EACH TABLET CONTAINS LINEZOLID 600,0 mg	Annexure A
54/20.1.1/0755.754	2021/05/18	LINEZOLID MYLAN 600 mg	TABLET	MYLAN (PTY) LTD	EACH TABLET CONTAINS LINEZOLID 600,0 mg	Annexure A
54/20.1.1/0756.754	2021/05/18	LIDOMYL	TABLET	MYLAN (PTY) LTD	EACH TABLET CONTAINS LINEZOLID 600,0 mg	Annexure A
54/20.2.8/0641	2021/05/25	DALVUTIN	TABLET	CIPLA MEDPRO (PTY) LTD	EACH TABLET CONTAINS DOLUTEGRAVIR SODIUM 50,0 mg LAMIVUDINE 300,0 mg	Annexure A
54/20.2.8/0642.641	2021/05/25	LOMIDA	TABLET	CIPLA MEDPRO (PTY) LTD	EACH TABLET CONTAINS DOLUTEGRAVIR SODIUM 50,0 mg LAMIVUDINE 300,0 mg	Annexure A
55/34/0713	2021/05/25	XOLAIR 75 mg/0,5 ml	INJECTION	NOVARTIS SOUTH AFRICA (PTY) LTD	EACH 0,5 ml SOLUTION CONTAINS OMALIZUMAB 75,0 mg	Annexure A
55/34/0714	2021/05/25	XOLAIR 150 mg/1,0 ml	INJECTION	NOVARTIS SOUTH AFRICA (PTY) LTD	EACH 1,0 ml SOLUTION CONTAINS OMALIZUMAB 150,0 mg	Annexure A
53/26/0743	2021/06/08	NAVILIN 20	CAPSULES	EUROLAB (PTY) LTD	EACH CAPSULE CONTAINS VINOELBINE TARTRATE EQUIVALENT TO VINOELBINE 20,0 mg	Annexure A
53/26/0744	2021/06/08	NAVILIN 30	CAPSULES	EUROLAB (PTY) LTD	EACH CAPSULE CONTAINS VINOELBINE TARTRATE EQUIVALENT TO VINOELBINE 30,0 mg	Annexure A
54/8.2/0417	2021/06/15	RIVAROXABAN TEVA 10	TABLET	TEVA PHARMACEUTICALS (PTY) LTD	EACH TABLET CONTAINS RIVAROXABAN 10,0 mg	Annexure A
54/8.2/0418	2021/06/15	RIVAROXABAN TEVA 15	TABLET	TEVA PHARMACEUTICALS (PTY) LTD	EACH TABLET CONTAINS RIVAROXABAN 15,0 mg	Annexure A
54/8.2/0419	2021/06/15	RIVAROXABAN TEVA 20	TABLET	TEVA PHARMACEUTICALS (PTY) LTD	EACH TABLET CONTAINS RIVAROXABAN 20,0 mg	Annexure A
53/1.2/0048	2021/06/15	DEPVEN 50 XL	TABLET	CIPLA MEDPRO (PTY) LTD	EACH TABLET CONTAINS DESVENLAFAXINE SUCCINATE EQUIVALENT TO DESVENLAFAXINE 50,0 mg	Annexure A
53/1.2/0049	2021/06/15	DEPVEN 100 XL	TABLET	CIPLA MEDPRO (PTY) LTD	EACH TABLET CONTAINS DESVENLAFAXINE SUCCINATE EQUIVALENT TO DESVENLAFAXINE 100,0 mg	Annexure A
54/2.7/0534	2021/06/15	KETESSE 50 mg/2 ml	INJECTION	LEBASI PHARMACEUTICALS CC	EACH 2,0 ml SOLUTION CONTAINS DEKETOPIROFEN 50,0 mg	Annexure A
54/2.7/0535.534	2021/06/15	KERAL 50 mg/2 ml	INJECTION	LEBASI PHARMACEUTICALS CC	EACH 2,0 ml SOLUTION CONTAINS DEKETOPIROFEN 50,0 mg	Annexure A
54/21.12/0491	2021/06/15	ZEDRAST	CAPSULES	ZYDUS HEALTHCARE S.A. (PTY) LTD	EACH CAPSULE CONTAINS DUTASTERIDE 0,5 mg	Annexure A
50/3.1/0756	2021/06/22	COXETORI 30	TABLET	TEVA PHARMACEUTICALS (PTY) LTD	EACH TABLET CONTAINS ETORICOXIB 30,0 mg	Annexure A
50/3.1/0757	2021/06/22	COXETORI 60	TABLET	TEVA PHARMACEUTICALS (PTY) LTD	EACH TABLET CONTAINS ETORICOXIB 60,0 mg	Annexure A
50/3.1/0758	2021/06/22	COXETORI 90	TABLET	TEVA PHARMACEUTICALS (PTY) LTD	EACH TABLET CONTAINS ETORICOXIB 90,0 mg	Annexure A
50/3.1/0759	2021/06/22	COXETORI 120	TABLET	TEVA PHARMACEUTICALS (PTY) LTD	EACH TABLET CONTAINS ETORICOXIB 120,0 mg	Annexure A
55/5.4/0028	2021/06/22	SOLIREST 5	TABLET	IPARMA (PTY) LTD	EACH TABLET CONTAINS SOLIFENACIN SUCCINATE 5,0 mg	Annexure A
55/5.4/0029	2021/06/22	SOLIREST 10	TABLET	IPARMA (PTY) LTD	EACH TABLET CONTAINS SOLIFENACIN SUCCINATE 10,0 mg	Annexure A
54/5.7.1/0789	2021/06/22	ZEALARGY	TABLET	PHARMA-Q (PTY) LTD	EACH TABLET CONTAINS RUPATADINE 10,0 mg	Annexure A

53/21.2/0649	2021/06/22	SYNGLUTRA 5/500	TABLET	CIPLA MEDPRO (PTY) LTD	EACH TABLET CONTAINS DAPAGLIFLOZIN PROPRANEDIOL EQUIVALENT TO DAPAGLIFLOZIN 5,0 mg METFORMIN HYDROCHLORIDE 500,0 mg	Annexure A
53/21.2/0650	2021/06/22	SYNGLUTRA 5/1 000	TABLET	CIPLA MEDPRO (PTY) LTD	EACH TABLET CONTAINS DAPAGLIFLOZIN PROPRANEDIOL EQUIVALENT TO DAPAGLIFLOZIN 5,0 mg METFORMIN HYDROCHLORIDE 1 000,0 mg	Annexure A
53/21.2/0651	2021/06/22	SYNGLUTRA 10/500	TABLET	CIPLA MEDPRO (PTY) LTD	EACH TABLET CONTAINS DAPAGLIFLOZIN PROPRANEDIOL EQUIVALENT TO DAPAGLIFLOZIN 10,0 mg METFORMIN HYDROCHLORIDE 500,0 mg	Annexure A
53/21.2/0652	2021/06/22	SYNGLUTRA 10/1 000	TABLET	CIPLA MEDPRO (PTY) LTD	EACH TABLET CONTAINS DAPAGLIFLOZIN PROPRANEDIOL EQUIVALENT TO DAPAGLIFLOZIN 10,0 mg METFORMIN HYDROCHLORIDE 1 000,0 mg	Annexure A
53/21.2/0653.649	2021/06/22	DAPAGLIFLOZIN METFORMIN CIPLA 5/500	TABLET	CIPLA MEDPRO (PTY) LTD	EACH TABLET CONTAINS DAPAGLIFLOZIN PROPRANEDIOL EQUIVALENT TO DAPAGLIFLOZIN 5,0 mg METFORMIN HYDROCHLORIDE 500,0 mg	Annexure A
53/21.2/0654/650	2021/06/22	DAPAGLIFLOZIN METFORMIN CIPLA 5/1 000	TABLET	CIPLA MEDPRO (PTY) LTD	EACH TABLET CONTAINS DAPAGLIFLOZIN PROPRANEDIOL EQUIVALENT TO DAPAGLIFLOZIN 10,0 mg METFORMIN HYDROCHLORIDE 1 000,0 mg	Annexure A
53/21.2/0655.651	2021/06/22	DAPAGLIFLOZIN METFORMIN CIPLA 10/500	TABLET	CIPLA MEDPRO (PTY) LTD	EACH TABLET CONTAINS DAPAGLIFLOZIN PROPRANEDIOL EQUIVALENT TO DAPAGLIFLOZIN 10,0 mg METFORMIN HYDROCHLORIDE 500,0 mg	Annexure A
53/21.2/0656.652	2021/06/22	DAPAGLIFLOZIN METFORMIN CIPLA 10/1 000	TABLET	CIPLA MEDPRO (PTY) LTD	EACH TABLET CONTAINS DAPAGLIFLOZIN PROPRANEDIOL EQUIVALENT TO DAPAGLIFLOZIN 10,0 mg METFORMIN HYDROCHLORIDE 1 000,0 mg	Annexure A
55/21.12/0204	2021/06/29	ROZILAT	TABLET	AUROGEN SOUTH AFRICA (PTY) LTD	EACH TABLET CONTAINS LETROZOLE 2,5 mg	Annexure A
55/21.12/0205.204	2021/06/29	FAZALET	TABLET	AUROGEN SOUTH AFRICA (PTY) LTD	EACH TABLET CONTAINS LETROZOLE 2,5 mg	Annexure A
55/21.12/0206.204	2021/06/29	LEROTIZAR	TABLET	AUROGEN SOUTH AFRICA (PTY) LTD	EACH TABLET CONTAINS LETROZOLE 2,5 mg	Annexure A
55/20.1.2/0222	2021/07/06	XINOCLOC 250	CAPSULES	AUSTELL PHARMACEUTICALS (PTY) LTD	EACH CAPSULE CONTAINS FLUCLOXACILLIN SODIUM EQUIVALENT TO FLUCLOXACILLIN 250,0 mg	Annexure A
55/20.1.2/0223.222	2021/07/06	FLOXACILLIN 250 mg AUSTELL	CAPSULES	AUSTELL PHARMACEUTICALS (PTY) LTD	EACH CAPSULE CONTAINS FLUCLOXACILLIN SODIUM EQUIVALENT TO FLUCLOXACILLIN 250,0 mg	Annexure A
53/1.2/0467	2021/07/13	ILLOVEX XR 300 mg	TABLET	PHARMA DYNAMICS (PTY) LTD	EACH TABLET CONTAINS VENLAFAXINE 300,0 mg	Annexure A
54/21.12/0027	2021/07/20	ZYBERA 250 mg	TABLET	TEVA PHARMACEUTICALS (PTY) LTD	EACH TABLET CONTAINS ABIRATERONE 250,0 mg	Annexure A
53/1.2/0699	2021/07/27	VORELLIX 5	TABLET	CIPLA MEDPRO (PTY) LTD	EACH TABLET CONTAINS VORTIOXETINE HYDROBROMIDE EQUIVALENT TO VORTIOXETINE 5,0 mg	Annexure A
53/1.2/0700	2021/07/27	VORELLIX 10	TABLET	CIPLA MEDPRO (PTY) LTD	EACH TABLET CONTAINS VORTIOXETINE HYDROBROMIDE EQUIVALENT TO VORTIOXETINE 10,0 mg	Annexure A
53/1.2/0701	2021/07/27	VORELLIX 15	TABLET	CIPLA MEDPRO (PTY) LTD	EACH TABLET CONTAINS VORTIOXETINE HYDROBROMIDE EQUIVALENT TO VORTIOXETINE 15,0 mg	Annexure A
53/1.2/0702	2021/07/27	VORELLIX 20	TABLET	CIPLA MEDPRO (PTY) LTD	EACH TABLET CONTAINS VORTIOXETINE HYDROBROMIDE EQUIVALENT TO VORTIOXETINE 20,0 mg	Annexure A
53/1.2/0703.699	2021/07/27	VORTIOXETINE CIPLA 5	TABLET	CIPLA MEDPRO (PTY) LTD	EACH TABLET CONTAINS VORTIOXETINE HYDROBROMIDE EQUIVALENT TO VORTIOXETINE 5,0 mg	Annexure A
53/1.2/0704.700	2021/07/27	VORTIOXETINE CIPLA 10	TABLET	CIPLA MEDPRO (PTY) LTD	EACH TABLET CONTAINS VORTIOXETINE HYDROBROMIDE EQUIVALENT TO VORTIOXETINE 10,0 mg	Annexure A
53/1.2/0705.701	2021/07/27	VORTIOXETINE CIPLA 15	TABLET	CIPLA MEDPRO (PTY) LTD	EACH TABLET CONTAINS VORTIOXETINE HYDROBROMIDE EQUIVALENT TO VORTIOXETINE 15,0 mg	Annexure A

53/1.2/0706.702	2021/07/27	VORTIOXETINE CIPLA 20	TABLET	CIPLA MEDPRO (PTY) LTD	EACH TABLET CONTAINS VORTIOXETINE HYDROBROMIDE EQUIVALENT TO VORTIOXETINE 20,0 mg	Annexure A
54/2.7/0536	2021/07/27	KETESSE 25 mg	TABLET	LEBASI PHARMACEUTICALS CC	EACH TABLET CONTAINS DEKETOPROFEN 25,0 mg	Annexure A
54/2.7/0537.536	2021/07/27	KERAL 25 mg VEKLURY POWDER FOR SOLUTION FOR INFUSION	TABLET	LEBASI PHARMACEUTICALS CC	EACH TABLET CONTAINS DEKETOPROFEN 25,0 mg	Annexure A
55/20.2.8/0458	2021/07/27	100 mg	INFUSION	GILEAD SCIENCES SOUTH AFRICA (PTY) LTD	EACH VIAL CONTAINS REMDESIVIR 100,0 mg	Annexure A
54/20.2.8/0705	2021/08/03	ENVUTEG	TABLET	MYLAN (PTY) LTD	EACH TABLET CONTAINS DOLUTEGRAVIR 50,0 mg LAMIVUDINE 300,0 mg TENOFOVIR DISOPROXIL FUMARATE 25,0 mg	Annexure A
54/20.2.8/0706.705	2021/08/03	TEGLATAF	TABLET	MYLAN (PTY) LTD	EACH TABLET CONTAINS DOLUTEGRAVIR 50,0 mg LAMIVUDINE 300,0 mg TENOFOVIR DISOPROXIL FUMARATE 25,0 mg	Annexure A
54/20.2.8/0707.705	2021/08/03	TOLEVTRI	TABLET	MYLAN (PTY) LTD	EACH TABLET CONTAINS DOLUTEGRAVIR 50,0 mg LAMIVUDINE 300,0 mg TENOFOVIR DISOPROXIL FUMARATE 25,0 mg	Annexure A
54/20.2.8/0708.705	2021/08/03	MYDOLTAF	TABLET	MYLAN (PTY) LTD	EACH TABLET CONTAINS DOLUTEGRAVIR 50,0 mg LAMIVUDINE 300,0 mg TENOFOVIR DISOPROXIL FUMARATE 25,0 mg	Annexure A
53/20.2.8/0233	2021/08/31	DELSTRIGO	TABLET	MSD (PTY) LTD	EACH TABLET CONTAINS DORAVIRINE 100,0 mg LAMIVUDINE 300,0 mg TENOFOVIR DISOPROXIL FUMARATE 300,0 mg	Annexure A
53/21.1/0720	2021/08/24	SAGALATIN 5	TABLET	CIPLA MEDPRO (PTY) LTD	EACH TABLET CONTAINS DAPAGLIFLOZIN PROPANEDIOL EQUIVALENT TO DAPAGLIFLOZIN 5,0 mg	Annexure A
53/21.1/0721	2021/08/24	SAGALATIN 10	TABLET	CIPLA MEDPRO (PTY) LTD	EACH TABLET CONTAINS DAPAGLIFLOZIN PROPANEDIOL EQUIVALENT TO DAPAGLIFLOZIN 10,0 mg	Annexure A
53/21.2/0722.720	2021/08/24	DAPAGLIFLOZIN CIPLA 5	TABLET	CIPLA MEDPRO (PTY) LTD	EACH TABLET CONTAINS DAPAGLIFLOZIN PROPANEDIOL EQUIVALENT TO DAPAGLIFLOZIN 5,0 mg	Annexure A
53/21.2/0723.721	2021/08/24	DAPAGLIFLOZIN CIPLA 10	TABLET	CIPLA MEDPRO (PTY) LTD	EACH TABLET CONTAINS DAPAGLIFLOZIN PROPANEDIOL EQUIVALENT TO DAPAGLIFLOZIN 10,0 mg	Annexure A
55/3.1/0392	2021/08/31	ERELZI 25 mg	INJECTION	SANDOZ SOUTH AFRICA (PTY) LTD	EACH PRE-FILLED SYRINGE CONTAINS ETANERCEPT 25,0 mg	Annexure A
55/3.1/0393	2021/08/31	ERELZI 50 mg	INJECTION	SANDOZ SOUTH AFRICA (PTY) LTD	EACH PRE-FILLED SYRINGE CONTAINS ETANERCEPT 50,0 mg	Annexure A
19/17.1.3/10	2021/08/31	PARACOR CRYPTO 140 mg/ml ORAL SOLUTION	ORAL SOLUTION	HUVEPHARMA SOUTH AFRICA (PTY) LTD	EACH 1,0 ml SOLUTION CONTAINS PAROMOMYCIN SULFATE EQUIVALENT TO PAROMOMYCIN 140,0 mg	Annexure A
55/20.2.8/0349	2021/09/07	DOLTELAM	TABLET	AUSTELL PHARMACEUTICALS (PTY) LTD	EACH TABLET CONTAINS DOLUTEGRAVIR SODIUM EQUIVALENT TO DOLUTEGRAVIR 50,0 mg LAMIVUDINE 300,0 mg TENOFOVIR DISOPROXIL FUMARATE 300,0 mg	Annexure A
54/21.12/0619	2021/09/07	MEDABON CO	TABLET	RANBAXY PHARMACEUTICALS (PTY) LTD	EACH COMBIPACK CONTAINS MIFEPRISTONE 200,0 mg (ORAL TAB) MISOPROSTOL 0,2 mg (VAGINAL TAB)	Annexure A
55/20.2.8/0089	2021/09/14	VENLAMID	TABLET	CIPLA MEDPRO (PTY) LTD	EACH TABLET CONTAINS TENOFOVIR ALAFENAMIDE 25,0 mg	Annexure A
55/20.2.8/0090.089	2021/09/14	TEFUMID	TABLET	CIPLA MEDPRO (PTY) LTD	EACH TABLET CONTAINS TENOFOVIR ALAFENAMIDE 25,0 mg	Annexure A
54/15.3/0836	2021/09/14	VOXIDEX	EYEDROPS	PHARMACARE LIMITED	EACH 1,0 ml SOLUTION CONTAINS DEXAMETHASONE SODIUM PHOSPHATE EQUIVALENT TO DEXAMETHASONE 1,0 mg LEVOFLOXACIN 5,0 mg	Annexure A
53/11.5/0111	2021/09/14	MOVONSTI	POWDER	CIPLA MEDPRO (PTY) LTD	EACH SACHET CONTAINS POLYETHYLENE GLYCOL 3,350 13,125 mg POTASSIUM CHLORIDE 46,6 mg SODIUM BICARBONATE 178,5 mg SODIUM CHLORIDE 350,7 mg	Annexure A
53/11.5/0112.111	2021/09/14	CONVILAX	POWDER	CIPLA MEDPRO (PTY) LTD	EACH SACHET CONTAINS POLYETHYLENE GLYCOL 3,350 13,125 mg POTASSIUM CHLORIDE 46,6 mg SODIUM BICARBONATE 178,5 mg SODIUM CHLORIDE 350,7 mg	Annexure A
54/28/0559	2021/09/14	CLARISCAN	INJECTION	GE HEALTHCARE (PTY) LTD	EACH 1,0 ml SOLUTION CONTAINS GADOTERIC ACID 279,3 mg	Annexure A

14/17.1.6/12	2021/09/21	AFROXIN 5 %	INJECTION	AFRIVET BUSINESS MANAGEMENT (PTY) LTD	EACH 1,0 ml SOLUTION CONTAINS ENROFLOXACIN 50,0 mg	Annexure A
14/17.1.6/13	2021/09/21	AFROXIN 10 %	INJECTION	AFRIVET BUSINESS MANAGEMENT (PTY) LTD	EACH 1,0 ml SOLUTION CONTAINS ENROFLOXACIN 100,0 mg	Annexure A
53/20.1.1/0060	2021/09/21	ZAVICEFTA 2 g/0,5 g	INFUSION	PFIZER LABORATORIES (PTY) LTD	EACH VIAL CONTAINS AVIBACTAM SODIUM EQUIVALENT TO AVIBACTAM 0,5 g CEFTAZIDIME 2,0 g	Annexure A
53/7.5/0268	2021/09/21	CRUVOR 5	TABLET	TEVA PHARMACEUTICALS (PTY) LTD	EACH TABLET CONTAINS ROSUVASTATIN CALCIUM EQUIVALENT TO ROSUVASTATIN 5,0 mg	Annexure A
53/7.5/0269	2021/09/21	CRUVOR 10	TABLET	TEVA PHARMACEUTICALS (PTY) LTD	EACH TABLET CONTAINS ROSUVASTATIN CALCIUM EQUIVALENT TO ROSUVASTATIN 10,0 mg	Annexure A
53/7.5/0270	2021/09/21	CRUVOR 20	TABLET	TEVA PHARMACEUTICALS (PTY) LTD	EACH TABLET CONTAINS ROSUVASTATIN CALCIUM EQUIVALENT TO ROSUVASTATIN 20,0 mg	Annexure A
53/7.5/0271	2021/09/21	CRUVOR 40	TABLET	TEVA PHARMACEUTICALS (PTY) LTD	EACH TABLET CONTAINS ROSUVASTATIN CALCIUM EQUIVALENT TO ROSUVASTATIN 40,0 mg	Annexure A
55/32.16/0368	2021/09/28	BONSPRI	INJECTION	NOVARTIS SOUTH AFRICA (PTY) LTD	EACH PRE-FILLED SYRINGE CONTAINS OFATUMUMAB 20,0 mg	Annexure A
54/5.4.1/0701	2021/09/28	RASAPAR	TABLET	ADCOCK INGRAM LIMITED	EACH TABLET CONTAINS RASAGLINE TARTRATE 1,0 mg	Annexure A
20/21/05	2021/09/28	CYCLAVANCE	SOLUTION	VIRBAC RSA (PTY) LTD	EACH 1,0 ml SOLUTION CONTAINS CICLOSPORIN 100,0 mg	Annexure A

ANNEXURE A

CONDITIONS OF REGISTRATIONS

1. The applicant shall ensure that the medicine is manufactured and controlled in terms of current Good Manufacturing Practices as determined by SAHPRA.
2. The manufacture of this medicine is subject to regular investigation and inspections by the inspectors appointed in terms of Section 26 of the Act, to assess compliance with current Good Manufacturing Practices.
3. The information in the professional information shall be updated on a regular basis to conform to the professional information recently approved by SAHPRA.
4. The applicant must comply with all the legal requirements of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965) as amended.
5. The registration of this medicine shall be subject to review at intervals as determined by SAHPRA regarding its quality, safety and efficacy, and the registration of this medicine may be varied subject to issues SAHPRA may deem fit.
6. The first two production batches must be fully validated in terms of the detailed process validation protocol submitted at the time of application for registration, and the validation report must be submitted within a month after completion of the validation.
7. The product may be advertised to the professions only.