

DEPARTMENT OF HEALTH

NO. R. 2079

13 May 2022

Annexure A

NOTIFICATION OF REGISTRATION OF MEDICINES IN TERMS OF SECTION 17 OF THE MEDICINES AND RELATED SUBSTANCES ACT, 1965 (ACT 101 OF 1965) AS AMENDED

Registration number	Registration date	Product name	Dosage form	Applicant	API ingredients	Conditions of Registration
56/30.2/0002	2022/01/25	COMINARTY	INJECTION	PFIZER LABORATORIES (PTY) LTD	EACH 0,3 ml DOSE CONTAINS COVID-19 MRNA VACCINE 30,0 ug	Annexure A
53/20.2.8/0232	2022/01/25	PIFELTRO	TABLET	MSD (PTY) LTD	EACH TABLET CONTAINS DORAVIRINE 100,0 mg	Annexure C
56/30.2/0795	2022/01/31	COVID-19 VACCINE MC PHARMA	INJECTION	MC PHARMA (PTY) LTD	EACH 0,5 ml DOSE CONTAINS SARS-COV-2 VACCINE (VERO CELL) INACTIVATED 6,5 U	Annexure B
55/18.5/0207	2022/02/01	UNITRO 50	CAPSULES	AUOGEN SOUTH AFRICA (PTY) LTD	EACH CAPSULE CONTAINS NITROFURANTOIN 50,0 mg	Annexure C
55/18.5/0208	2022/02/01	UNITRO 100	CAPSULES	AUOGEN SOUTH AFRICA (PTY) LTD	EACH CAPSULE CONTAINS NITROFURANTOIN 100,0 mg	Annexure C
55/18.5/0209.207	2022/02/01	ZOCZEN 50	CAPSULES	AUOGEN SOUTH AFRICA (PTY) LTD	EACH CAPSULE CONTAINS NITROFURANTOIN 50,0 mg	Annexure C
55/18.5/0210.208	2022/02/01	ZOCZEN 100	CAPSULES	AUOGEN SOUTH AFRICA (PTY) LTD	EACH CAPSULE CONTAINS NITROFURANTOIN 100,0 mg	Annexure C
55/18.5/0211.207	2022/02/01	MACRIXTIR 50	CAPSULES	AUOGEN SOUTH AFRICA (PTY) LTD	EACH CAPSULE CONTAINS NITROFURANTOIN 50,0 mg	Annexure C
55/18.5/0212.208	2022/02/01	MACRIXTIR 100	CAPSULES	AUOGEN SOUTH AFRICA (PTY) LTD	EACH CAPSULE CONTAINS NITROFURANTOIN 100,0 mg	Annexure C
55/11.5/0446	2022/01/25	LEBALAX 5 mg	SUPPOSITORY	LEBASI PHARMACEUTICALS (PTY) LTD	EACH SUPPOSITORY CONTAINS BISACODYL 5,0 mg	Annexure C
55/11.5/0447	2022/01/25	LEBALAX 10 mg	SUPPOSITORY	LEBASI PHARMACEUTICALS (PTY) LTD	ACH SUPPOSITORY CONTAINS BISACODYL 10,0 mg	Annexure C
55/1.2/0307	2022/01/25	DULOXETINE DR 30 TEVA	CAPSULES	TEVA PHARMACEUTICALS (PTY) LTD	EACH CAPSULE CONTAINS DULOXETINE HYDROCHLORIDE EQUIVALENT TO DULOXETINE 30,0 mg	Annexure C
55/1.2/0308	2022/01/25	DULOXETINE DR 60 TEVA	CAPSULES	TEVA PHARMACEUTICALS (PTY) LTD	EACH CAPSULE CONTAINS DULOXETINE HYDROCHLORIDE EQUIVALENT TO DULOXETINE 60,0 mg	Annexure C
21/17.1.4/05	2022/02/15	DRAXXIN PLUS 100 mg/ml & 120 mg/ml	SOLUTION	ZOETIS SOUTH AFRICA (PTY) LTD	EACH 1,0 ml SOLUTION CONTAINS KETOPROFEN 120,0 mg & TULATHROMYCIN 100,0 mg	Annexure C
20/17.1.4/08	2022/02/15	TULAVEN	INJECTION	CEVA ANIMAL HEALTH (PTY) LTD	EACH 1,0 ml SOLUTION CONTAINS TULATHROMYCIN 100,0 mg	Annexure C
54/32.16/0811	2022/02/22	TALOMUNE 0,5 mg	CAPSULES	STRIDES PHARMA SA (PTY) LTD	EACH CAPSULE CONTAINS TACROLIMUS 0,5 mg	Annexure C
54/32.16/0812	2022/02/22	TALOMUNE 1 mg	CAPSULES	STRIDES PHARMA SA (PTY) LTD	EACH CAPSULE CONTAINS TACROLIMUS 1,0 mg	Annexure C
54/32.16/0813	2022/02/22	TALOMUNE 5 mg	CAPSULES	STRIDES PHARMA SA (PTY) LTD	EACH CAPSULE CONTAINS TACROLIMUS 5,0 mg	Annexure C
54/32.16/0814.811	2022/02/22	GRAFOLIN 0,5 mg	CAPSULES	STRIDES PHARMA SA (PTY) LTD	EACH CAPSULE CONTAINS TACROLIMUS 0,5 mg	Annexure C
54/32.16/0815.812	2022/02/22	GRAFOLIN 1 mg	CAPSULES	STRIDES PHARMA SA (PTY) LTD	EACH CAPSULE CONTAINS TACROLIMUS 1,0 mg	Annexure C
54/32.16/0816.813	2022/02/22	GRAFOLIN 5 mg	CAPSULES	STRIDES PHARMA SA (PTY) LTD	EACH CAPSULE CONTAINS TACROLIMUS 5,0 mg	Annexure C
54/21.12/0880	2022/02/22	BICALUTAMIDE 150 ACCORD	TABLET	ACCORD HEALTHCARE (PTY) LTD	EACH TABLET CONTAINS BICALUTAMIDE 150,0 mg	Annexure C

55/18.6/0091	2022/02/22	FLUOIMIZIN VAGINAL TABLET	ADCOCK INGRAM LIMITED	ADCOCK INGRAM LIMITED	ADCOCK INGRAM LIMITED	EACH TABLET CONTAINS DEQUALINIUM CHLORIDE 10,0 mg	Annexure C
55/18.8/0034	2022/02/28	VISAFEM	ADCOCK INGRAM LIMITED	ADCOCK INGRAM LIMITED	ADCOCK INGRAM LIMITED	EACH TABLET CONTAINS DIENOGEST 2,0 mg	Annexure C
55/18.8/0035.034	2022/02/28	DIENOGEST ADCO	ADCOCK INGRAM LIMITED	ADCOCK INGRAM LIMITED	ADCOCK INGRAM LIMITED	EACH TABLET CONTAINS DIENOGEST 2,0 mg	Annexure C
53/32.16/0183	2022/03/01	ALECENSA	ROCHE PRODUCTS (PTY) LTD	ROCHE PRODUCTS (PTY) LTD	ROCHE PRODUCTS (PTY) LTD	EACH CAPSULE CONTAINS ALECTINIB HYDROCHLORIDE EQUIVALENT TO ALECTINIB 150,0 mg	Annexure C
54/20.2.3/0160	2022/03/08	SOLODEX CO	MACLEODS PHARMACEUTICALS SA (PTY) LTD	MACLEODS PHARMACEUTICALS SA (PTY) LTD	MACLEODS PHARMACEUTICALS SA (PTY) LTD	EACH TABLET CONTAINS ISONIAZID 300,0 mg RIFAPENTINE 300,0 mg	Annexure C
54/20.2.3/0161.160	2022/03/08	INOZI-CO	MACLEODS PHARMACEUTICALS SA (PTY) LTD	MACLEODS PHARMACEUTICALS SA (PTY) LTD	MACLEODS PHARMACEUTICALS SA (PTY) LTD	EACH TABLET CONTAINS ISONIAZID 300,0 mg RIFAPENTINE 300,0 mg	Annexure C
55/20.2.8/0786	2022/03/08	DAPIRING	LEBASI PHARMACEUTICALS (PTY) LTD	LEBASI PHARMACEUTICALS (PTY) LTD	LEBASI PHARMACEUTICALS (PTY) LTD	EACH VAGINAL RING CONTAINS DAPIRINE 25,0 mg	Annexure C
55/21.12/0321	2022/03/15	NUBEQA	BAYER (PTY) LTD	BAYER (PTY) LTD	BAYER (PTY) LTD	EACH TABLET CONTAINS DAROLUTAMIDE 300,0 mg	Annexure C
54/21.12/0825	2022/03/15	ABIKEM	ASCEND LABORATORIES (PTY) LTD	ASCEND LABORATORIES (PTY) LTD	ASCEND LABORATORIES (PTY) LTD	EACH TABLET CONTAINS ABIRATERONE 250,0 mg	Annexure C
56/21.12/0606	2022/03/15	FREXIVO	ASTRAZENECA PHARMACEUTICALS (PTY) LTD	ASTRAZENECA PHARMACEUTICALS (PTY) LTD	ASTRAZENECA PHARMACEUTICALS (PTY) LTD	EACH 5,0 ml SOLUTION CONTAINS FULVESTRANT 250,0 mg	Annexure C
55/1.2/0580	2022/03/15	VORTIOXETINE 5 mg LUNDBECK	H. LUNDBECK (PTY) LTD	H. LUNDBECK (PTY) LTD	H. LUNDBECK (PTY) LTD	EACH TABLET CONTAINS VORTIOXETINE HYDROBROMIDE EQUIVALENT TO VORTIOXETINE 5,0 mg	Annexure C
55/1.2/0581	2022/03/15	VORTIOXETINE 10 mg LUNDBECK	H. LUNDBECK (PTY) LTD	H. LUNDBECK (PTY) LTD	H. LUNDBECK (PTY) LTD	EACH TABLET CONTAINS VORTIOXETINE HYDROBROMIDE EQUIVALENT TO VORTIOXETINE 10,0 mg	Annexure C
55/1.2/0582	2022/03/15	VORTIOXETINE 15 mg LUNDBECK	H. LUNDBECK (PTY) LTD	H. LUNDBECK (PTY) LTD	H. LUNDBECK (PTY) LTD	EACH TABLET CONTAINS VORTIOXETINE HYDROBROMIDE EQUIVALENT TO VORTIOXETINE 15,0 mg	Annexure C
55/1.2/0583	2022/03/15	VORTIOXETINE 20 mg LUNDBECK	H. LUNDBECK (PTY) LTD	H. LUNDBECK (PTY) LTD	H. LUNDBECK (PTY) LTD	EACH TABLET CONTAINS VORTIOXETINE HYDROBROMIDE EQUIVALENT TO VORTIOXETINE 20,0 mg	Annexure C
20/17.1.3/17	2022/03/29	PARAFOR 70 mg/g	HUVEPHARMA SOUTH AFRICA (PTY) LTD	HUVEPHARMA SOUTH AFRICA (PTY) LTD	HUVEPHARMA SOUTH AFRICA (PTY) LTD	EACH 1,0 g POWDER CONTAINS PAROMOMYCIN SULFATE EQUIVALENT TO PAROMOMYCIN 70,0 mg	Annexure C
53/7.1/0521	2022/03/29	DAPINELAT 30	BIOTECH LABORATORIES (PTY) LTD	BIOTECH LABORATORIES (PTY) LTD	BIOTECH LABORATORIES (PTY) LTD	EACH TABLET CONTAINS NIFEDIPINE 30,0 mg	Annexure C
53/7.1/0522	2022/03/29	DAPINELAT 60	BIOTECH LABORATORIES (PTY) LTD	BIOTECH LABORATORIES (PTY) LTD	BIOTECH LABORATORIES (PTY) LTD	EACH TABLET CONTAINS NIFEDIPINE 60,0 mg	Annexure C
56/8.1/0497	2022/03/29	TRANMENXIO IV	BIOTECH LABORATORIES (PTY) LTD	BIOTECH LABORATORIES (PTY) LTD	BIOTECH LABORATORIES (PTY) LTD	EACH AMPOULE CONTAINS TRANEXAMIC ACID 500,0 mg	Annexure C
56/21.2/0607	2022/03/29	DUFORZIG 5	ASTRAZENECA PHARMACEUTICALS (PTY) LTD	ASTRAZENECA PHARMACEUTICALS (PTY) LTD	ASTRAZENECA PHARMACEUTICALS (PTY) LTD	EACH TABLET CONTAINS DAPAGLIFLOZIN PROPRANEDIOL EQUIVALENT TO DAPAGLIFLOZIN 5,0 mg	Annexure C
56/21.2/0608	2022/03/29	DUFORZIG 10	ASTRAZENECA PHARMACEUTICALS (PTY) LTD	ASTRAZENECA PHARMACEUTICALS (PTY) LTD	ASTRAZENECA PHARMACEUTICALS (PTY) LTD	EACH TABLET CONTAINS DAPAGLIFLOZIN PROPRANEDIOL EQUIVALENT TO DAPAGLIFLOZIN 10,0 mg	Annexure C

56/21.2/0609.607	2022/03/29	KEDGEO 5	TABLET	ASTRAZENECA PHARMACEUTICALS (PTY) LTD	EACH TABLET CONTAINS DAPAGLIFLOZIN PROPRANEDIOL EQUIVALENT TO DAPAGLIFLOZIN 5,0 mg	Annexure C
56/21.2/0610.608	2022/03/29	KEDGEO 10	TABLET	ASTRAZENECA PHARMACEUTICALS (PTY) LTD	EACH TABLET CONTAINS DAPAGLIFLOZIN PROPRANEDIOL EQUIVALENT TO DAPAGLIFLOZIN 10,0 mg	Annexure C
56/21.2/0611.607	2022/03/29	TAPLEO 5	TABLET	ASTRAZENECA PHARMACEUTICALS (PTY) LTD	EACH TABLET CONTAINS DAPAGLIFLOZIN PROPRANEDIOL EQUIVALENT TO DAPAGLIFLOZIN 5,0 mg	Annexure C
56/21.2/0612.608	2022/03/29	TAPLEO 10	TABLET	ASTRAZENECA PHARMACEUTICALS (PTY) LTD	EACH TABLET CONTAINS DAPAGLIFLOZIN PROPRANEDIOL EQUIVALENT TO DAPAGLIFLOZIN 10,0 mg	Annexure C
55/26/0390	2022/03/29	CALQUENCE	CAPSULES	ASTRAZENECA PHARMACEUTICALS (PTY) LTD	EACH CAPSULE CONTAINS ACALABRUTINIB 100,0 mg	Annexure C
55/8.2/0311	2022/03/29	RIVAR 10	TABLET	INNOVATA PHARMACEUTICALS (PTY) LTD	EACH TABLET CONTAINS RIVAROXABAN 10,0 mg	Annexure C
55/8.2/0312	2022/03/29	RIVAR 15	TABLET	INNOVATA PHARMACEUTICALS (PTY) LTD	EACH TABLET CONTAINS RIVAROXABAN 15,0 mg	Annexure C
55/8.2/0313	2022/03/29	RIVAR 20	TABLET	INNOVATA PHARMACEUTICALS (PTY) LTD	EACH TABLET CONTAINS RIVAROXABAN 20,0 mg	Annexure C
55/8.2/0314.311	2022/03/29	RAVELTO 10	TABLET	INNOVATA PHARMACEUTICALS (PTY) LTD	EACH TABLET CONTAINS RIVAROXABAN 10,0 mg	Annexure C
55/8.2/0315.311	2022/03/29	RAVELTO 15	TABLET	INNOVATA PHARMACEUTICALS (PTY) LTD	EACH TABLET CONTAINS RIVAROXABAN 15,0 mg	Annexure C
55/8.2/0316.313	2022/03/29	RAVELTO 20	TABLET	INNOVATA PHARMACEUTICALS (PTY) LTD	EACH TABLET CONTAINS RIVAROXABAN 20,0 mg	Annexure C
55/8.2/0317.311	2022/03/29	VARIAXA 10	TABLET	INNOVATA PHARMACEUTICALS (PTY) LTD	EACH TABLET CONTAINS RIVAROXABAN 10,0 mg	Annexure C
55/8.2/0318.312	2022/03/29	VARIAXA 15	TABLET	INNOVATA PHARMACEUTICALS (PTY) LTD	EACH TABLET CONTAINS RIVAROXABAN 15,0 mg	Annexure C
55/8.2/0319.313	2022/03/29	VARIAXA 20	TABLET	INNOVATA PHARMACEUTICALS (PTY) LTD	EACH TABLET CONTAINS RIVAROXABAN 20,0 mg	Annexure C
20/17.1.4/16	2022/03/29	TILMOVET 300 mg/ml	INJECTION	HUVEPHARMA SOUTH AFRICA (PTY) LTD	EACH 1,0 ml SOLUTION CONTAINS TILMICOSIN 300,0 mg	Annexure C
54/1.2/0681	2022/03/29	VEIKIRIN 10	TABLET	STRIDES PHARMA SA (PTY) LTD	EACH TABLET CONTAINS AMITRIPTYLINE HCl 10,0 mg	Annexure C
54/1.2/0682	2022/03/29	VEIKIRIN 25	TABLET	STRIDES PHARMA SA (PTY) LTD	EACH TABLET CONTAINS AMITRIPTYLINE HCl 25,0 mg	Annexure C
54/1.2/0683	2022/03/29	VEIKIRIN 50	TABLET	STRIDES PHARMA SA (PTY) LTD	EACH TABLET CONTAINS AMITRIPTYLINE HCl 50,0 mg	Annexure C
54/1.2/0684.681	2022/03/29	AMDERIP 10	TABLET	STRIDES PHARMA SA (PTY) LTD	EACH TABLET CONTAINS AMITRIPTYLINE HCl 10,0 mg	Annexure C
54/1.2/0685.682	2022/03/29	AMDERIP 25	TABLET	STRIDES PHARMA SA (PTY) LTD	EACH TABLET CONTAINS AMITRIPTYLINE HCl 25,0 mg	Annexure C
54/1.2/0686.683	2022/03/29	AMDERIP 50	TABLET	STRIDES PHARMA SA (PTY) LTD	EACH TABLET CONTAINS AMITRIPTYLINE HCl 50,0 mg	Annexure C
55/17.1/0102	2022/03/29	IMMAROC	INJECTION	RUBY PHARMACEUTICALS (PTY) LTD	EACH VIAL CONTAINS ROCURONIUM BROMIDE 50,0 mg	Annexure C
55/8.1/0127	2022/03/29	IMMATRA	INJECTION	RUBY PHARMACEUTICALS (PTY) LTD	EACH 1,0 ml SOLUTION CONTAINS TRANEXAMIC ACID 100,0 mg	Annexure C
55/8.1/0128.127	2022/03/29	RUBINEX	INJECTION	RUBY PHARMACEUTICALS (PTY) LTD	EACH 1,0 ml SOLUTION CONTAINS TRANEXAMIC ACID 100,0 mg	Annexure C