

# MEDICINES CONTROL COUNCIL



## NOTIFICATION OF REGISTRATION OF MEDICINES BY THE REGISTRAR IN TERMS OF SECTION 17 OF THE MEDICINES AND RELATED SUBSTANCES ACT 101 OF 1965

Application Number	Holder of registration of Certificate	Proprietary Name	Active Compound
97/3.1/5	MERIAL SA (PTY) LTD	KETOFEN 05 MG TABLETS	EACH TABLET CONTAINS: KETOPROFEN 5,0 TABLET
97/3.1/6	MERIAL SA (PTY) LTD	KETOFEN 10 MG TABLETS	EACH TABLET CONTAINS: KETOPROFEN 10,0 TABLET
97/3.1/7	MERIAL SA (PTY) LTD	KETOFEN 20 MG TABLETS	EACH TABLET CONTAINS: KETOPROFEN 20,0 TABLET
F/28/606	SCHERING (PTY) LTD	UROGRAFIN 30% SOLUTION	EACH AMPOULE CONTAINS MEGLUMINE AMIDOTRIZOATE 0,26 g, SODIUM AMIDOTRIZOATE 0,40 g
H/28/2843	SCHERING (PTY) LTD	UROGRAFIN 60% 20 ML SOLUTION	EACH AMPOULE CONTAINS MEGLUMINE AMIDOTRIZOATE 10,4 g, SODIUM AMIDOTRIZOATE 1,6 g
H/28/2844	SCHERING (PTY) LTD	UROGRAFIN 76% SOLUTION	EACH AMPOULE CONTAINS MEGLUMINE AMIDOTRIZOATE 13,20 G, SODIUM AMIDOTRIZOATE 2,00 g
28/3.1/0669	GAREC (PTY) LTD	ROXOFLAM 500 MG TABLETS	EACH TABLET CONTAINS NAPROXEN 500,0 mg
33/5.8/0509	WARNER-LAMBERT SA (PTY) LTD	BENYLIN FOUR FLU TABLETS	EACH TABLET CONTAINS PARACETAMOL 500, mg, DIPHENHYDRAMINE HYDROCHLORIDE 12,5 mg, PSEUDOEPHEDRINE HYDROCHLORIDE 22,5 mg
33/16.4/0277	GROUP LABORATORIES SA (PTY) LTD	CORSODYL DENTAL GEL	EACH 100,0 GEL CONTAINS CHLORHEXIDINE GLUCONATE 1,0 g
34/30.4/0105	ALTANA MADAUS (PTY)	EPEXAL BERNA INJECTION	EACH 0,5 ML SOLUTION CONTAINS HEPATITIS A VIRUS (strain rg-sb) 500,0 units
34/1.4/0165	MICRO HEALTHCARE (PTY) LTD	MICRO NALOXONE INJECTION 0,4 MG/ML	EACH 1,0 ml AMPOULE CONTAINS NALOXONE HYDROCHLORIDE 0,4 mg

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34/1.4/0165	MICRO HEALTHCARE (PTY) LTD	MICRO NALOXONE INJECTION 0,4 MG/ML	EACH 1,0ml AMPOULE CONTAINS NALOXONE HYDROCHLORIDE 0,4 mg
34/20.1.2/0224	NOVO NORDISK (PTY) LTD	NOVOMENTIN 625	EACH TABLET CONTAINS AMOXYCILLIN TRIHYDRATE EQUIVALENT TO AAMOXYCILLIN 500,0 mg POTASSIUM CLAVULANATE EQUIVALENT TO CLUVULANIC ACID 125,0 mg
34/20.1.2/0225	NOVO NORDISK (PTY) LTD	NOVOMENTIN FORTE	EACH 5,0 ml SUSPENSION CONTAINS AMOXYCILLIN TRIHYDRATE EQUIVALENT TO AMOXYCILLIN 250,0 mg POTASSIUM CLAVULANATE EQUIVALENT TO CLAVULANIC ACID 62,5 mg
34/24/0370	LEBASI PHARMACEUTICALS CC	EUROSOL-M	EACH 100,0 ml SOLUTION CONTAINS DEXTROSE MONOHYDRATE 5,0 g SODIUM CHLORIDE 234,0 mg POTASSIUM ACETATE 128,0 mg MAGNESIUM ACETATE 32,2 mg
34/24/0373	LEBASI PHARMACEUTICALS (PTY) LTD	EUROSOL-R	EACH 100,0 ml SOLUTION CONTAINS DEXTROSE MONOHYDRATE 5,0 g MAGNESIUM ACETATE 32,20 mg POTASSIUM ACETATE 49,0 mg SODIUM ACETATE (ANHYDROUS) 346,0 mg SODIUM CHLORIDE 573,0 mg
35/5.8/0150	PHARMACARE LIMITED	ENDCOL EFFERVESCENT	EACH TABLET CONTAINS PARACETAMOL 500,0 mg CHLORPHENIRAMINE MALEATE 4,0 mg PSEUDOEPHEDRINE HYDROCHLORIDE 50,0 mg VITAMIN C 330,0 mg
35/5.8/0151	PHARMACARE LIMITED	FLUTEX FIZZY	EACH TABLET CONTAINS PARACETAMOL 500,0 mg CHLORPHENIRAMINE MALEATE 4,0 mg PSEUDOEPHEDRINE HYDROCHLORIDE 50,0 mg VITAMIN C 330,0 mg
35/5.8/0152	PHARMACARE	FLUTEX EFFERVESCENT	EACH TABLET CONTAINS PARACETAMOL 500,0 mg CHLORPHENIRAMINE MALEATE 4,0 mg PSEUDOEPHEDRINE HYDROCHLORIDE 50,0 mg VITAMIN C 330,0 mg
35/20.1.2/0402	NOVO NORDISK (PTY) LTD	NOVO-AMOXYCILLIN 250 MG	EACH CAPSULE CONTAINS AMOXYCILLIN TRIHYDRATE EQUIVALENT TO AMOXYCILLIN 250,0 mg
35/20.1.2/0403	NOVO NORDISK (PTY) LTD	NOVO-AMOXYCILLIN 500 MG	EACH CAPSULE CONTAINS AMOXYCILLIN TRIHYDRATE EQUIVALENT TO AMOXYCILLIN 500,0 mg
35/18/0406	ALTANA MADAUS (PTY) LTD	URICON TABLETS	EACH TABLETS CONTAINS: TROSPIDIUM CHLORIDE
36/30.1/0129	AVENTIS PHARMA (PTY) LTD	DUKORAL	EACH DOSE CONTAINS VIBRIO CHOLERAE 01 INABA CLASSIC STRAIN

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			VIBRIO CHOLERAЕ 01 INABA EL TOR STRAIN VIBRIO CHOLERA 01 OGAWA CLASSIC STRAIN, HEAT INACTIVATED VIBRIO CHOLERAЕ 01 OGAWA CLASSIC STRAIN, FORMALIN INACTIVATED TOTAL 1,0 mg RECOMBINANT CHOLERA TOXIN B SUBUNIT
36/20.1.1/0165	BE-TABS PHARMACEUTICALS (PTY) LTD	AZIMAX CAPSULES	EACH CAPSULE CONTAINS AZITHROMYCIN
36/20.1.2/0365	NORBROOK LABORATORIES S.A (PTY) LTD	NORBROOK AMOXYCILLIN FOR INJECTION	EACH VIAL CONTAINS AMOXYCILLIN SODIUM EQUIVALENT TO AMOXYCILLIN 500,0 mg
36/3.1/0433	BOOTS HEALTHCARE (S.A) (PTY) LTD	NUROFEN GEL	EACH 1,0 g GEL CONTAINS IBUPROFEN 50,0 mg
37/5.2/0010	ADCOCK INGRAM LIMITED	ADCO-BISOCOR 5 MG	EACH TABLET CONTAINS BISOPROLOL HEMIFUMERATE 5,0 mg
37/5.2/0011	ADCOCK INGRAM LIMITED	ADCO-BISOCOR 10MG	EACH TABLET CONTAINS BISOPROLOL HEMIFUMERATE 10,0 mg
37/20.1.1/0055	ROLAB (PTY) LTD	ROLAB-CEFUROXIME 250	EACH TABLET CONTAINS CEFUROXIME AXETIL EQUIVALENT TO CEFUROXIME 250,0 mg
37/20.1.1/0056	ROLAB (PTY) LTD	ROLAB-CEFUROXIME 500	EACH TABLET CONTAINS CEFUROXIME AXETIL EQUIVALENT TO CEFUROXIME 500,0 mg
37/10.1/0061	WARNER-LAMBERT S.A (PTY) LTD	BENYLIN WET COUGH	EACH 10,0 ml LIQUID CONTAINS GUAIFENESIN 200,0 mg
37/20.1.1/0079	CIPLA-MEDPRO (PTY) LTD	MEDPRO-CIPROFLOXACIN 250	EACH TABLET CONTAINS CIPROFLOXACIN HYDROCHLORIDE EQUIVALENT TO CIPROFLOXACIN 250,0 mg
37/20.1.1/0080	CIPLA-MEDPRO (PTY) LTD	MEDPRO-CIPROFLOXACIN 500	EACH TABLET CONTAINS CIPROFLOXACIN HYDROCHLORIDE EQUIVALENT TO CIPROFLOXACIN 500,0 mg
37/20.1.1/0081	CIPLA-MEDPRO (PTY) LTD	MEDPRO-CIPROFLOXACIN 750	EACH TABLET CONTAINS CIPROFLOXACIN HYDROCHLORIDE EQUIVALENT TO CIPROFLOXACIN 750,0 mg
37/11.4.3/0155	CIPLA LIFE SCIENCES (PTY) LTD	LANSOLOC 30	EACH CAPSULE CONTAINS LANSOPRAZOLE 30,0 mg
37/14.2/0206	BRISTOL-MYERS SQUIBB (PTY) LTD	AQUACEL	EACH DRESSING CONTAINS SODIUM CARBOXYMETHYLCELLULOSE 100,0 g
37/11.4.3/0238	CIPLA LIFE SCIENCES (PTY) LTD	LANSOLOC 15	EACH CAPSULE CONTAINS LANSOPRAZOLE 15,0 mg
37/21.2/0272	MERCK (PTY) LTD	GLUCOPHAGE 1000 MG	EACH TABLET CONTAINS METFORMIN HYDROCHLORIDE 1000,0 mg
37/20.1.1/0284	CIPLA-MEDPRO (PTY) LTD	CIPLACEF 500	EACH VIAL CONTAINS CEFTRIAXONE SODIUM EQUIVALENT TO CEFTRIAXONE 500,0 mg
37/20.1.1/0285	CIPLA-MEDPRO (PTY) LTD	CIPLACEF 1000	EACH VIAL CONTAINS CEFTRIAXONE SODIUM EQUIVALENT TO CEFTRIAXONE 1000,0 mg
37/20.1.1/0287	CIPLA LIFE SCIENCES (PTY) LTD	CIPLA-CEFTRIAXONE 500	EACH VIAL CONTAINS CEFTRIAXONE SODIUM EQUIVALENT TO CEFTRIAXONE 500,0 mg

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37/20.1.1/0288	CIPLA LIFE SCIENCES (PTY) LTD	CIPLA-CEFTRIAXONE 1000	EACH VIAL CONTAINS CEFTRIAXONE SODIUM EQUIVALENT TO CEFTRIAXONE 1000,0 mg
37/20.2.8/0296	ROCHE PRODUCTS (PTY) LTD	VALCYTE 450	EACH TABLET CONTAINS VALGANCICLOVIR 450,0 mg
37/1.2/0298	ELI LILLY (S.A) (PTY) LTD	CYMBALTA 20	EACH CAPSULE CONTAINS DULOXETINE HYDROCHLORIDE EQUIVALENT TO DULOXETINE 20,0 mg
37/1.2/0299	ELI LILLY (S.A) (PTY) LTD	CYMBALTA 30	EACH CAPSULE CONTAINS DULOXETINE HYDROCHLORIDE EQUIVALENT TO DULOXETINE 30,0 mg
37/1.2/0300	ELI LILLY (S.A) (PTY) LTD	CYMBALTA 40	EACH CAPSULE CONTAINS DULOXETINE HYDROCHLORIDE EQUIVALENT TO DULOXETINE 40,0 mg
37/1.2/0301	ELI LILLY (S.A) (PTY) LTD	CYMBALTA 60	EACH CAPSULE CONTAINS DULOXETINE HYDROCHLORIDE EQUIVALENT TO DULOXETINE 60,0 mg
37/26/0305	SCHERING (PTY) LTD	MABCAMPATH	EACH 1,0 ml SOLUTION CONTAINS ALEMTUZUMAB 10,0 mg
37/5.7.1/0342	AVENTIS PHARMA (PTY) LTD	TELFASST JUNIOR	EACH TABLET CONTAINS FEXOFENADINE HYDROCHLORIDE 30,0 mg
37/21.5.1/0343	INGELHEIM PHARMACEUTICALS (PTY) LTD	INFLAMMIDE 200 NOVOLIZER	EACH METERED DOSE CONTAINS BUDESONIDE 200,0 ug
36/3.1/0405	AUSTELL LABORATORIES (PTY) LTD	AUSTELL-DICLOFENAC SODIUM 25 MG/ML INJECTION	EACH AMPOULE CONTAINS: DICLOFENAC SODIUM 75,0 mg
37/20.1.1/0414	GENERIX INTERNATIONAL SA (PTY) LTD	TRAXCEPHIN 0,5 G INJECTION	EACH VIAL CONTAINS CEFTRIAXONE SODIUM EQUIVALENT TO CEFTRIAXONE 0,5 g
37/20.1.1/0415	GENERIX INTERNATIONAL SA (PTY) LTD	TRAXCEPHIN 2,0 G INJECTION	EACH VIAL CONTAINS CEFTRIAXONE SODIUM EQUIVALENT TO CEFTRIAXONE 2,0 g
37/20.1.1/0416	GENERIX INTERNATIONAL SA (PTY) LTD	GENERIX-CEFTRIAXONE SODIUM 0,5 G INJECTION	EACH VIAL CONTAINS CEFTRIAXONE SODIUM EQUIVALENT TO CEFTRIAXONE 0,5 g
37/20.1.1/0418	GENERIX INTERNATIONAL SA (PTY) LTD	TRAXCEPHIN 0,5 G INJECTION	EACH VIAL CONTAINS CEFTRIAXONE SODIUM EQUIVALENT TO CEFTRIAXONE 0,5 g
37/5.7.1/0497	HEXAL PHARMA (SA) (PTY) LTD	CETIRIZINE-HEXAL 10MG TABLETS	EACH TABLET CONTAINS CETIRIZINE DIHYDROCHLORIDE 10,0 mg
37/5.7.1/0498	HEXAL PHARMA (SA) (PTY) LTD	CETIRIZINE-HEXAL 10,0 MG/ML ORAL DROPS	EACH 1,0 ml SOLUTION CONTAINS CETIRIZINE DIHYDROCHLORIDE 10,0 mg
37/20.1.1/0499	HEXAL PHARMA (SA) (PTY) LTD	CEFTRIAXONE-HEXAL 1 G	EACH VIAL CONTAINS CEFTRIAXONE SODIUM EQUIVALENT TO CEFTRIAXONE 1,0 g
37/20.1.1/0500	HEXAL PHARMA (SA) (PTY) LTD	CEFTRIAXONE-HEXAL 2 G	EACH VIAL CONTAINS CEFTRIAXONE SODIUM EQUIVALENT TO CEFTRIAXONE 2,0 g
37/20.1.1/0573	ARROW PHARMA SOUTH AFRICA (PTY) LTD	CIPROL 250	EACH TABLET CONTAINS CIPROFLOXACIN HYDROCHLORIDE EQUIVALENT TO CIPROFLOXACIN 250,0 mg

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37/20.1.1/0574	ARROW PHARMA SOUTH AFRICA (PTY) LTD	CIPROL 500	EACH TABLET CONTAINS CIPROFLOXACIN HYDROCHLORIDE EQUIVALENT TO CIPROFLOXACIN 500,0 mg
37/5.7.1/0579	AUSTELL LABORATORIES (PTY) LTD	AUSTELL-CETIRIZINE 5MG	EACH TABLET CONTAINS CETIRIZINE DIHYDROCHLORIDE 5,0 mg
37/20.1.1/0575	ARROW PHARMA SOUTH AFRICA (PTY) LTD	CIPROL 750	EACH TABLET CONTAINS CIPROFLOXACIN HYDROCHLORIDE EQUIVALENT TO CIPROFLOXACIN 750,0 MG
37/5.7.1/0580	AUSTELL LABORATORIES (PTY) LTD	AUSTELL-CETIRIZINE 10 MG	EACH TABLET CONTAINS CETIRIZINE DIHYDROCHLORIDE 10,0 mg
37/20.1.2/0606	YAMANOUCI PHARMA (PTY) LTD	FORCID SOLUTAB 875/125	EACH TABLET CONTAINS AMOXYCILLIN TRIHYDRATE EQUIVALENT TO AMOXYCILLIN 875,0 mg POTASSIUM CLAVULANATE EQUIVALENT TO CLAVULANIC ACID 125,0 mg
37/20.1.1/0655	SPECPHARMA (PTY) LTD	SPEC-TOPISTIN	EACH 1,0 ml SOLUTION CONTAINS CIPROFLOXACIN LACTATE EQUIVALENT TO CIPROFLOXACIN 200,0 mg
38/7.1/0146	PHARMA DYNAMICS (PTY) LTD	PHARMA DYNAMICS AMLODIPINE 5 MG	EACH TABLET CONTAINS AMLODIPINE MALEATE EQUIVALENT TO AMLODIPINE 5,0 mg
38/7.1/0147	PHARMA DYNAMICS (PTY) LTD	AMLOC 10 MG	EACH TABLET CONTAINS AMLODIPINE MALEATE EQUIVALENT TO AMLODIPINE 10,0 mg
38/7.1/0183	PHARMA DYNAMICS (PTY) LTD	AMLOC 5 MG	EACH TABLET CONTAINS AMLODIPINE MALEATE EQUIVALENT TO AMLODIPINE 5,0 mg
38/7.1/0184	PHARMA DYNAMICS (PTY) LTD	PHARMA DYNAMICS AMLODIPINE 10 MG	EACH TABLET CONTAINS AMLODIPINE MALEATE EQUIVALENT TO AMLODIPINE 10,0 mg
38/20.1.1/0191	SPECPHARM (PTY) LTD	SPEC-CIPROFLOXACIN 200	EACH 100,0 ml SOLUTION CONTAINS CIPROFLOXACIN LACTATE EQUIVALENT TO CIPROFLOXACIN 200,0 mg
A38/20.2.8/0339	CIPLA-MEDPRO (PTY) LTD	NEVIMUNE ORAL SUSPENSION	EACH 5,0 ml SUSPENSION CONTAINS NEVIRAPINE HEMIHYDRATE EQUIVALENT TO NEVIRAPINE 50,0 mg EACH TABLET CONTAINS AMLODIPINE MALEATE EQUIVALENT TO AMLODIPINE 5,0 mg
37/5.7.1/0579	AUSTELL LABORATORIES (PTY) LTD	AUSTELL-CETIRIZINE 5 MG TABLET	EACH TABLET CONTAINS CETIRIZINE DIHYDROCHLORIDE 5.0 MG

**REGISTRAR OF MEDICINES  
MS M.P. MATSOSO**