

LEGAL NOTICE No. 210

REPUBLIC OF TRINIDAD AND TOBAGO

THE FOOD AND DRUGS ACT, CHAP. 30:01

NOTIFICATION

APPROVAL IN RESPECT OF NEW DRUGS

ISSUED by the Minister on the recommendation of the Drug Advisory Committee in accordance with paragraph 7, Division 3 of the Second Schedule of the Food and Drugs Regulations.

The Minister signifies his approval in respect of the following new drugs:

| TRADE NAME AND FORM | MANUFACTURER | COUNTRY OF ORIGIN | CONDITION OF SALE |
|---|--|-------------------|-------------------|
| Telmisartan Tablets 80 mg | Boehringer Ingelheim Promeco, S.A. de C.V. | Mexico | Third Schedule |
| Trajentamet Tablets 2.5 mg/850 mg | Boehringer Ingelheim Promeco, S.A. de C.V. | Mexico | Third Schedule |
| Trajentamet Tablets 2.5 mg/1000 mg | Boehringer Ingelheim Promeco, S.A. de C.V. | Mexico | Third Schedule |
| Glyxambi Film-Coated Tablet 25 mg/5 mg | Boehringer Ingelheim Pharma, GmbH & Co. KG | Germany | Third Schedule |
| Vitalux Plus Time Release Multivitamin/Multimineral Coated Tablets with Lutein (Change of License Holder from Novartis Entity to Alcon Entity and Change of Logo and Artwork) | Jamieson Laboratories Ltd./Nutricorp International | Canada | Freely |

| TRADE NAME AND FORM | MANUFACTURER | COUNTRY OF ORIGIN | CONDITION OF SALE |
|---|---|-------------------|-------------------|
| GenTeal Lubricant Eye Drops (Change of License Holder from Novartis Entity to Alcon Entity and Change of Logo and Artwork) | Excelvision | France | Freely |
| Azopt Ophthalmic Suspension 1% (Additional Manufacturing Site and Change of Label) | S.A Alcon-Couvreur N.V. For: Novartis Pharma AG, Switzerland | Belgium | Third Schedule |
| Vigamox Ophthalmic Solution 0.5% (Additional Manufacturing Site and Labelling Presentation as Bilingual with an Addition of Spanish) | S.A Alcon-Couvreur N.V. For: Novartis Pharma AG, Switzerland | Belgium | Third Schedule |
| Nevanac Ophthalmic Suspension 0.1% (Change in Manufacturer and Artwork from English to Bilingual with an Addition of Spanish) | S.A Alcon-Couvreur N.V. For: Novartis Pharma AG, Switzerland | Belgium | Third Schedule |
| Seven Seas Once-A-Day Pure Cod Liver Oil Plus Vitamin E Capsules (Additional Manufacturing Site and Change of Artwork) | Catalent Italy S.P.A. For: Seven Seas Limited | Italy | Freely |
| Foligain Biotin Fast Dissolve Tablet 10,000 mcg | Nutritional Manufacturing Services for FOLIGAIN® | USA | Freely |
| Paraconica™ Plus 500 mg/150 mg Tablets | Sigma Laboratories Limited For: Acino Pharma AG, Switzerland | India | Freely |

| TRADE NAME AND FORM | MANUFACTURER | COUNTRY OF ORIGIN | CONDITION OF SALE |
|---|---|-------------------|---------------------|
| Wellstra Advanced Women's Health Support Vegetarian Capsules | Nutritional Manufacturing Services for NEWTON-EVERETT® | USA | Freely |
| Essential Plus Multivitamin Vegetarian Tablets | Nutritional Manufacturing Services for NEWTON-EVERETT® | USA | Freely |
| Probiogen Women's Vitality Spore Probiotic Vegetarian Capsules | Nutritional Manufacturing Services For: NEWTON-EVERETT® | USA | Freely |
| OcuVisi Advanced Vegetarian Capsules | Nutritional Manufacturing Services For: NEWTON-EVERETT® | USA | Freely |
| Simepar Capsule (Change of Packaging, Change of Label, Change of Artwork, Change of Manufacturing and Packaging Sites, Change of Specifications of Finished Product, Change of Method of Analysis and Change of Condition of Sale) | Acino Pharma AG | Switzerland | Freely |
| Curetero 50 (Rocuronium bromide Injection 50 mg/5 mL) | Aspiro Pharma Limited | India | Specialist Use Only |
| PIROTON 40 (Esomeprazole Sodium for Injection 40 mg/Vial) | Aspiro Pharma Limited | India | Third Schedule |
| PANTIN Pentoprazole Sodium 40 mg/Vial Injection | Aspiro Pharma Limited | India | Third Schedule |

| TRADE NAME AND FORM | MANUFACTURER | COUNTRY OF ORIGIN | CONDITION OF SALE |
|--|---------------------|--------------------------|--------------------------|
| Esomeprazole Magnesium Delayed Release Capsules 40 mg | Hetero Labs Limited | India | Third Schedule |
| ZITRAS M 50/1000 (Sitagliptin and Metformin) Film-Coated Tablets | Hetero Labs Limited | India | Third Schedule |
| Salbutamol Pressurised Inhalation BP 100 mcg | Hetero Labs Limited | India | Third Schedule |
| STATINOR 20 (Rosuvastatin Calcium) Tablets 20 mg | Hetero Labs Limited | India | Third Schedule |
| Temozolomide Capsules 100 mg | Hetero Labs Limited | India | Specialist Use Only |
| Atazanavir Capsules 300 mg | Hetero Labs Limited | India | Specialist Use Only |
| BICAHET 150 mg (Bicalutamide Tablets, 150 mg) | Hetero Labs Limited | India | Specialist Use Only |
| Levocetirizine Dihydrochloride Tablets 5 mg | Hetero Labs Limited | India | Third Schedule |
| Granisetron Hydrochloride Injection USP 1 mg/mL | SG Pharma Pvt. Ltd. | India | Third Schedule |
| Dimenhydrinate Tablets USP 50 mg | SG Pharma Pvt. Ltd. | India | Third Schedule |
| Dimenhydrinate Injection USP 50 mg | SG Pharma Pvt. Ltd. | India | Third Schedule |
| Doxapram Hydrochloride Injection USP 20 mg/mL | SG Pharma Pvt. Ltd. | India | Specialist Use Only |

| TRADE NAME AND FORM | MANUFACTURER | COUNTRY OF ORIGIN | CONDITION OF SALE |
|---|----------------------------------|-------------------|---------------------|
| Chlorpromazine Hydrochloride Injection USP 25 mg/mL | SG Pharma Pvt. Ltd. | India | Specialist Use Only |
| Montelukast Sodium Paediatric Chewable Tablets 5 mg | Hetero Labs Limited | India | Third Schedule |
| Granisetron Hydrochloride Tablets 1 mg | SG Pharma Pvt. Ltd. | India | Third Schedule |
| Agomelatine Tablets 25 mg | SG Pharma Pvt. Ltd. | India | Third Schedule |
| HAIRtamin Gummy Stars | Intermountain Nutrition | USA | Freely |
| Telminorm-40 (Telmisartan 40 mg Tablets USP) | Ipca Laboratories Ltd. | India | Third Schedule |
| Telminorm-80 (Telmisartan 80 mg Tablets USP) | Ipca Laboratories Ltd. | India | Third Schedule |
| Latanoprost Ophthalmic Solution 0.005% | FDC Limited | India | Specialist Use Only |
| FERASIRO 125 DT, Dispersible Tablets, 125 mg | MSN Laboratories Private Limited | India | Third Schedule |
| FERASIRO 250 DT, Dispersible Tablets, 250 mg | MSN Laboratories Private Limited | India | Third Schedule |
| FERASIRO 500 DT, Dispersible Tablets, 500 mg | MSN Laboratories Private Limited | India | Third Schedule |
| Atorem 10 (Atorvastatin Coated Tablets 10 mg) | MSN Laboratories Private Limited | India | Third Schedule |
| Atorem 20 (Atorvastatin Coated Tablets 20 mg) | MSN Laboratories Private Limited | India | Third Schedule |

| TRADE NAME AND FORM | MANUFACTURER | COUNTRY OF ORIGIN | CONDITION OF SALE |
|---|----------------------------------|--------------------------|--------------------------|
| Atorem 40 (Atorvastatin Coated Tablets 40 mg) | MSN Laboratories Private Limited | India | Third Schedule |
| Prasupan Film-Coated Tablet 5 mg | Panacea Biotec Pharma Limited | India | Third Schedule |
| Prasupan Film-Coated Tablet 10 mg | Panacea Biotec Pharma Limited | India | Third Schedule |
| Rizapan 5 Orally Disintegrating Tablet 5 mg | Panacea Biotec Pharma Limited | India | Third Schedule |
| Rizapan 10 Orally Disintegrating Tablet 10 mg | Panacea Biotec Pharma Limited | India | Third Schedule |
| VagaCyte 450 Tablets (Valganciclovir 450 mg) | Panacea Biotec Pharma Limited | India | Third Schedule |
| Carmuther 100 (Carmustine for Injection USP 100 mg/Vial) | TherDose Pharma Private Ltd. | India | Specialist Use Only |
| Doceted 20 (Docetaxel for Injection 20 mg) | TherDose Pharma Private Ltd. | India | Specialist Use Only |
| Gemcither 200 (Gemcitabine for Injection USP 200 mg/Vial) | TherDose Pharma Private Ltd. | India | Specialist Use Only |
| Gemcither 1000 (Gemcitabine for Injection USP 1000 mg/Vial) | TherDose Pharma Private Ltd. | India | Specialist Use Only |
| Oxalither 50 (Oxaliplatin Injection USP 50 mg/10 mL) | TherDose Pharma Private Ltd. | India | Specialist Use Only |
| Paclither 300 (Paclitaxel Injection USP 300 mg/50 mL) | TherDose Pharma Private Ltd. | India | Specialist Use Only |

| TRADE NAME AND FORM | MANUFACTURER | COUNTRY OF ORIGIN | CONDITION OF SALE |
|---|--|-------------------|------------------------|
| Ciclopirox Olamine Cream USP 1% w/w | Manufactured by: Alaina Healthcare Pvt. Ltd. For: Remus Pharmaceuticals Pvt. Ltd. | India | Third Schedule |
| Clotrimazole Cream BP 1% | Remus Pharmaceuticals Pvt. Ltd. | India | Third Schedule |
| Tranexamic Acid Injection BP 500 mg/5 mL | Remus Pharmaceuticals Pvt. Ltd. | India | Specialist Use Only |
| Darunavir Tablets 600 mg | Manufactured by: Sai Mirra Innopharm Pvt. Ltd. For: Remus Pharmaceuticals Pvt. Ltd. | India | Specialist Use Only |
| Quadracal Liquid | Quadragen VetHealth Private Limited | India | Veterinary Use Only |
| Aminovit Plus Liquid | Quadragen VetHealth Private Limited | India | Veterinary Use Only |
| Immunogen Liquid | Quadragen VetHealth Private Limited | India | Veterinary Use Only |
| Dololyte Powder | Quadragen VetHealth Private Limited | India | Veterinary Use Only |
| Salbutamol Sulphate and Beclomethasone Dipropionate Pressurized Inhalation 100 mcg/50 mcg/dose | Jewim Pharmaceutical (Shandong) Co. Ltd. | India | Third Schedule |
| Bromhexine Hydrochloride Syrup 8 mg/5 mL | Accretion Pharmaceuticals | India | Third Schedule |
| Tenvir-EM Tablets 200 mg/300 mg | Cipla Ltd. | India | Specialist Use Only |

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|---|--|--------------------------|--------------------------|
| Lopimune Tablets 200 mg/ 50 mg | Cipla Ltd. | India | Specialist Use Only |
| Viraday Tablets Tenofovir Disoproxil Fumarate, Emtricitabine, Efavirenz USP 300 mg/200 mg/ 600 mg | Cipla Ltd. | India | Specialist Use Only |
| Pirfenex Pirfenidone Tablets 200 mg | Cipla Ltd. | India | Specialist Use Only |
| Enalapril Tablets 10 mg | Emil Pharmaceutical Industries Pvt. Ltd. | India | Third Schedule |
| Ibuprofen Soft Gel Capsules 600 mg | Ocean Healthcare Pvt Ltd. | India | Third Schedule |
| Losartan and Hydrochlorothiazide Tablets 100 mg/25 mg | Baroque Pharmaceuticals Pvt. Ltd. | India | Third Schedule |
| Shark Liver Oil Soft Capsules | Bell Lifestyle Products Inc. | Canada | Freely |
| Nolpaza 40 mg Powder for Solution for Injection | KRKA | Slovenia | Third Schedule |
| Lenalidomide Tablets 5 mg | Reliance Life Sciences PVT Limited | India | Specialist Use Only |
| Lenalidomide Tablets 10 mg | Reliance Life Sciences PVT Limited | India | Specialist Use Only |
| Lenalidomide Tablets 25 mg | Reliance Life Sciences PVT Limited | India | Specialist Use Only |
| Bortezomib Lyophilized Powder for Solution for Injection 3.5 mg | Fresenius Kabi Oncology Ltd. | India | Specialist Use Only |

| TRADE NAME AND FORM | MANUFACTURER | COUNTRY OF ORIGIN | CONDITION OF SALE |
|---|---|-------------------|-----------------------------|
| Jamieson Multi 100 % Complete Vitamin | Jamieson Laboratories Ltd. | Canada | Freely |
| Jamieson Multi 100 % Complete Vitamin Women | Jamieson Laboratories Ltd. | Canada | Freely |
| Jamieson Multi 100 % Complete Vitamin Men | Jamieson Laboratories Ltd. | Canada | Freely |
| Jamieson Multi 100 % Complete Vitamin Adult 50+ | Jamieson Laboratories Ltd. | Canada | Freely |
| VI DERM BEAUTY Skin Lightening Complex 4 % Hydroquinone | Personal Care Performance Group | USA | Third Schedule |
| VitalDure C-1000 Immune Support Boost Capsules | American Natural Products Lab | USA | Freely |
| Nuwiq Powder and Solvent for Solution for Injection 500 IU/Vial | Octapharma AB | Sweden | Specialist Use Only |
| Nuwiq Powder and Solvent for Solution for Injection 1000 IU/Vial | Octapharma AB | Sweden | Specialist Use Only |
| NeuRemedy Capsules 150 mg | Realm Labs, LLC | USA | Freely |
| JYNNEOS®/IMVAMUNE®/IMVANEX® Smallpox and Monkeypox Vaccine, Live, Non-Replicating Suspension for Subcutaneous Injection Single-dose Vial 0.5 mL | Bavarian Nordic A/S Hejreskovvej 10A, 3490 Kvistgaard | Denmark | Emergency Use Authorization |

Dated this 7th day of November, 2022.

T. DEYALSINGH
Minister of Health