

LEGAL NOTICE No. 63

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
Articaine Injectable Solution	DFL Industria E Comercio S/A	Brazil	Specialist Use Only
ROFAST 20 Film Coated Tablets 20 mg	Aurobindo Pharma Ltd.	India	Third Schedule
ROFAST 40 Film Coated Tablets 40 mg	do.	do.	do.
KARDAM 10 Tablets 10mg	do.	do.	do.
M-KAST 5 Chewable Tablets 5 mg	do.	do.	do.
Dynapar AQ, Diclofenac Sodium Injection 75mg/mL	Troikaa Pharmaceuticals Limited	India	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
HYLAND'S Muscle Therapy Gel with Arnica	Standard Homeopathic Company	USA	Freely
HYLAND'S Apple Cider Vinegar Blast Vegan Gummies	do.	do.	do.
HYLAND'S Elderberry Plus + Vegan Gummies	do.	do.	do.
Nature's Truth Norwegian Cod Liver Oil with EPA/DHA	Piping Rock Health Products, LLC / Nature's Truth LLC	USA	Freely
Nature's Truth Men's Multivitamin + B12, D3, Zinc Gummies	do.	do.	do.
Nature's Truth® Just 4 Kidz: Black Elderberry + Vitamin C, Zinc Gummies	Nature's Truth	USA	Freely
Nature's Truth® Sambucus Black Elderberry Immune Complex + Vitamin C, Zinc	do.	do.	do.
Nature's Truth® Echinacea, Capsules, 1300 mg	do.	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Nature's Truth® Standardized Gingko Biloba, Capsules, 120 mg	Nature's Truth	USA	Freely
Nature's Truth® Standardized Korean Ginseng, 1500 mg	do.	do.	do.
Nature's Truth® Horny Goat Weed with MACA	do.	do.	do.
Nature's Truth® ProstAid Saw Palmetto Herbal Complex	do.	do.	do.
LENIOL (Paracetamol Infusion 1% W/V) 100 mL	Otsuka Pharmaceutical India Private Limited	India	Third Schedule
Oplev Levofloxacin Hemihydrate 5 mg/mL	do.	do.	Specialist Use Only
Quifol (Propofol Injection BP 1% w/v) Solution for Intravenous Injection 1% w/v	Aculife Healthcare Pvt. Ltd.	India	Third Schedule
PALOXI (Palonosetron Hydrochloride Injection 0.25 mg/ 5 mL)	Aspiro Pharma Limited	India	Specialist Use Only
Dimethyl Fumarate Delayed Release Capsules 120 mg	Hetero Labs Limited	India	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Donepezil Hydrochloride Tablets USP 10 mg	Hetero Labs Limited	India	Third Schedule
Montelukast Sodium Tablets 10 mg	do.	do.	do.
Telmisartan and Hydrochlorothiazide Tablets 40 mg/ 12.5 mg	do.	do.	do.
Telmisartan and Hydrochlorothiazide Tablets 80 mg/ 12.5 mg	do.	do.	do.
Losartan Potassium Film Coated Tablets 50 mg	do.	do.	do.
Losartan Potassium Film Coated Tablets 100 mg	do.	do.	do.
Rivaroxaban Film Coated Tablets 10 mg	do.	do.	do.
Rivaroxaban Film Coated Tablets 15 mg	do.	do.	do.
Rivaroxaban Film Coated Tablets 20 mg	do.	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Temozolomide Capsules 140 mg	Hetero Labs Limited	India	Specialist Use Only
Hydralazine Hydrochloride Tablets USP 25 mg	SGPharma Pvt. Ltd.	India	Third Schedule
Bendroflumethiazide Tablets B.P. 5 mg	do.	do.	do.
Pyridoxine Tablets B.P. 25 mg	do.	do.	do.
Cisatracurium Besylate Injection USP 2 mg/mL	SGPharma Pvt. Ltd.	India	Specialist Use Only
Dapsone Tablets USP 100 mg	do.	do.	do.
VI DERM BEAUTY Retinoic Serum with 0.1% Tretinoin	Personal Care Performance Group	USA	Specialist Use Only
APO-VALACYCLOVIR Tablets 500 mg	Apotex Ltd.	Canada	Third Schedule
Momate AZ Nasal Spray 50 / 140 mcg	Otsuka Pharmaceutical Private Limited	India	Third Schedule
Momate Nasal Spray 50 mcg	Glenmark Pharmaceuticals Ltd.	India	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Gallbladder Complete Cleanse & Balance	Complete Natural Products	USA	Freely
VitalDure Xtreme Testosterone Formula	American Natural Products Lab	USA	Third Schedule
Tresiba Flex Touch Solution for Injection in Pre-filled Pen 100U/mL (Additional Manufacturing Site)	Novo Nordisk Production SAS	France	Third Schedule
NovoSeven® RT Powder and Solvent for Solution for Injection 1 mg/vial (Extension of Indication)	Novo Nordisk A/S	Denmark	Specialist Use Only
Paraconica™ Plus 500 mg / 150 mg Film Coated Tablets (Change of Marketing Authorization Holder and Artwork)	Sigma Laboratories Limited For: Acino Pharma AG, Switzerland	India	Freely
Trabilin-50 Capsules (Change in Shelf Life (Reduction to 36 months), Change of Primary and Secondary Packaging Artwork, Update to Summary of Product Characteristics, Update to Patient Information Leaflet)	Merckle GmbH For: Acino Pharma AG	Germany	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
MISOPROSTOL Tablets 200 mcg (Change of Artwork and Marketing Authorization Holder)	Apotex Inc.	Canada	Third Schedule
Apo-Hydrochlorothiazide Tablets 25 mg (Change of Trade Name)	do.	do.	do.
Apo-Hydrochlorothiazide Tablets 50 mg (Change of Trade Name)	do.	do.	do.

Dated this 8th day of February, 2023.

T. DEYALSINGH
Minister of Health