

LEGAL NOTICE No. 174

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
Aminoven Infant 10% Solution for Infusion	Fresenius Kabi Austria GmbH	Austria	Third Schedule
Creon 25,000 (Pancreatin) Capsules 300mg	Abbott Laboratories de México, S.A. De C.V., México	Mexico	do.
Tramadol Denk 100 mg Retard, Prolonged – Release Tablet, 100mg tramadol (as hydrochloride)	Distributor: Denk Pharma GmbH & Co. KG Prinzregentenstr. 79 81675 München, Germany Manufacturer: Bulk Manufacturing Site: Farmaceutici Formenti S.P.A. Via di Vittorio, 2 21040 Origgio (VA), Italy Primary and Secondary Packaging, Batch Release Site: Grünenthal GmbH Zieglerstraße 6 52078 Aachen, Germany	Germany	do.
Dichlor-12.5 (Chlorthalidone Tablets USP 12.5mg)	Ipca Laboratories Ltd. 48, Kandivli Ind. Estate, Mumbai 400467	India	do.
Birato 250 (Abiraterone Acetate Tablets USP 250mg)	M/s MSN Laboratories Private Limited	do.	do.
Epiduo Forte Gel in a Pump, (Adapalene 0.3%, Benzoyl Peroxide 2.5%)	Galderma Laboratories	Canada	do.
Brimochek 0.2% Eye Drops, Solution 2mg/mL	Indoco Remedies Limited	India	do.
Ibuprofen Oral Suspension 100mg/5mL	Sanpras Healthcare Pvt. Ltd.	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Rosuvastatin Tablets 20mg	Baroque Pharmaceuticals Pvt. Ltd.	India	Third Schedule
Ciatuff Tablets 20mg	Aurobindo Pharma Ltd.	do.	do.
M-KAST 10 Tablets 10mg	do.	do.	do.
Pegaset (Pregabalin) Capsules 150mg	do.	do.	do.
Pegaset (Pregabalin) Capsules 75mg	do.	do.	do.
Pilocarpine Eye Drops 2% w/v	Tubilux Pharma S.P.A.	Italy	do.
Pilocarpine Eye Drops 4% w/v	do.	do.	do.
RoPolivy® Powder for Concentrate for Solution for Infusion 140mg	BSP Pharmaceuticals S.p.A., Italy	Switzerland	do.
Obagi Tretinoin Cream 0.1%	Bausch Health Companies Inc.	Canada	do.
Obagi Tretinoin Cream 0.05%	do.	do.	do.
Obagi Tretinoin Gel 0.05%	do.	do.	do.
Obagi Tretinoin Cream 0.025%	do.	do.	do.
Zolasta (Zoledronic Acid Injection 4mg/5mL)	Intas Pharmaceuticals Limited	India	do.
Fluconazole Infusion 200mg/100mL	Manufactured by: Amanta Healthcare Limited Marketed by: Juvenicia Lifesciences	do.	do.
Bimatoprost Eye Drops, Solution 0.1mg/mL	Indoco Remedies Limited	do.	do.
VETERINARY PRODUCTS			
Resergen Powder	Quadragen Vet Health Pvt. Ltd.	India	Veterinary Use Only
Rminvit Liquid	do.	do.	do.
END OF VETERINARY MEDICINE			
M-PRIM 3.5 (Bortezomid for Injection, 3.5mg/vial)	Naprod Life Sciences Pvt. Ltd.	do.	Specialist Use Only (specialized in antineoplastic therapy)
Naproplat (Carboplatin for Injection BP 450mg/45mL)	do.	do.	Specialist Use Only
Nausezin (Tablets)	Revi Pharma Srl-Italy	Italy	Freely
Simoplr Junior (Liquid) 10mL	do.	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Pharmaton Geriatric 50+ Capsules	Catalent Brasil, Ltda	Brazil	Freely
COVID-19 Vaccine (Vero Cell), Inactivated Zhong Ai Ke Wei (Vial)	Beijing Institute of Biological Product Co., Ltd.	P.R. China	Pandemic Use/ Emergency Use Authorization/ Individual 18 years and above
Tozinameran COVID-19 mRNA Vaccine (nucleoside modified) Cominarity® Concentration for Injection 2ml/Multidose Vial	BioNTech Manufacturing GmbH An der Goldgrube 12, 55131 Mainz, Germany	Germany	Pandemic Use/ Emergency Use Authorization/ Individual 16 years and above
AZD1222 COVID-19 Vaccine ChAdOx1-S [recombinant]-Vaxzevria Suspension for Injection Multidose Vial	Catalent Anagni S.R.L Italy For: AstraZenca Nijmegen B.V. Netherlands	Netherlands	Pandemic Use/ Emergency Use Authorization/ Individual 18 years and above

Dated this 21st day of May, 2021.

T. DEYALSINGH
Minister of Health