

LEGAL NOTICE NO. 9

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
Advancis® Flexjoints SOS, solution in vials	Labialfarma – Laboratório de Produtos Farmacêuticos e Nutracêuticos, S.A.	Portugal	Freely
Simparica Trio Chewable Tablets 24mg/0.48mg/100mg	Corden Pharma GmbH	Germany	Veterinary Use Only
Lenangio Capsules 5mg	Dr. Reddy's Laboratories Ltd.	India	Third Schedule
Lenangio Capsules 10mg	Dr. Reddy's Laboratories Ltd.	India	Third Schedule
Lenangio Capsules 15mg	Dr. Reddy's Laboratories Ltd.	India	Third Schedule
Lenangio Capsules 25mg	Dr. Reddy's Laboratories Ltd.	India	Third Schedule
Octanate Powder and Solvent for Injection 500IU	Octapharma AB Octopharma Vienna	Switzerland	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Rewisca Hard Capsules 75mg	KRKA, d.d., Novo mesto	Slovenia	Third Schedule
Doreta Film-Coated Tablets 37.5mg/325mg	KRKA, d.d., Novo mesto	Slovenia	Third Schedule
Cetamol Cold & Flu Daytime Caplets	Federated Pharmaceutical	Jamaica	Freely
Cetamol Cold & Flu Nighttime Caplets	Federated Pharmaceutical	Jamaica	Freely
Children's Cetamol Cold Nighttime Liquid	Federated Pharmaceutical	Jamaica	Freely
Children's Cetamol Cold Daytime Liquid	Federated Pharmaceutical	Jamaica	Freely
Creon® 10,000 (Pancreatin) Capsules 150mg	Abbott Laboratories de México, S.A. De C.V.	México	Third Schedule
Botox Cosmetic Powder for Solution for Injection	Allergan Pharmaceuticals Ireland	Ireland	Specialist Use Only
Zemplar Solution for Injection 5mcg/mL	Avara Liscate Pharmaceutical Services S.p.A.	Italy	Third Schedule
Triveram Film-Coated Tablets 10mg/5mg/5mg	Les Laboratoires Servier Industrie	France	Third Schedule
Triveram Film-Coated Tablets 20mg/10mg/10mg	Les Laboratoires Servier Industrie	France	Third Schedule
Synjardy Film-Coated Tablets 12.5mg/1000mg	Boehringer Ingelheim Pharma, GmbH & Co, KG	Germany	Third Schedule
Synjardy Film-Coated Tablets 12.5mg/850mg	Boehringer Ingelheim Pharma, GmbH & Co, KG	Germany	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Xolair Solution for Injection in Pre-Filled Syringe 150mg/1.0mL	Vetter Pharma-Fertigung GmbH & Co. KG Germany For Novartis Pharma AG, Basel, Switzerland Packaged by: Vetter Pharma-Fertigung GmbH & Co. KG, Ravensburg, Germany	Germany	Third Schedule
Xolair Solution for Injection in Pre-Filled Syringe 75mg/0.5mL	Vetter Pharma-Fertigung GmbH & Co. KG, Germany For Novartis Pharma AG, Basel, Switzerland Packaged by: Vetter Pharma-Fertigung GmbH & Co. KG, Ravensburg, Germany	Germany	Third Schedule
Semglee (Insulin Glargine) Solution for Subcutaneous Injection in Pre-filled Pen, 100 units/mL	Biocon SDN. BHD.	Malaysia	Third Schedule
Semglee (Insulin Glargine) Solution for Subcutaneous Injection in Vial, 100 units/mL	Biocon SDN. BHD.	Malaysia	Third Schedule
Ogivri™ (Trastuzumab) Lyophilized Powder for Injection for I.V. Infusion 440mg	Biocon Biologics India Limited	India	Third Schedule
NexGard SPECTRA Chewable Tablets for dogs 7.6 – 15kg, 37.5mg Afoxolaner / 7.5mg Milbemycin Oxime	Boehringer Ingelheim Animal Health Do Brasil Ltda.	Brazil	Veterinary Use Only
Paracetamol B. Braun Solution for Infusion, 10mg/mL	B. Braun Medical, S.A.	Spain	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Phesgo® 600 Solution for Subcutaneous Injection 600mg/600mg/10mL	F. Hoffmann-La Roche Ltd. Kaiseraugst	Switzerland	Specialist Use Only
Phesgo® 1200 Solution for Subcutaneous Injection 1200mg/600mg/15mL	F. Hoffmann-La Roche Ltd. Kaiseraugst	Switzerland	Specialist Use Only
Evrysdi Powder for Oral Solution 0.75mg/1mL	Made by F. Hoffmann-La Roche Ltd., Basel Packed by (secondary): F. Hoffmann-La Roche Ltd., Kaiseraugst	Switzerland	Specialist Use Only
Systane Gel Lubricant Eye Drops	Alcon Laboratories, INC.	USA	Freely
immun active Denk	C. Hedenkamp GmbH & Co. KG	Germany	Freely
BioGaia Protectis Chewable Tablets 100 million CFU	Farmasierra Manufacturing SL for: BioGaia AB, Sweden Packager: Sanico NV, Belgium	Spain	Freely
BioGaia Protectis Baby Drops 100 million CFU	BioGaia Production AB for: BioGaia AB, Sweden	Sweden	Freely
Taxtas 20 (Docetaxel Injection USP 20mg/mL, 1mL Vial)	Intas Pharmaceuticals Ltd.	India	Specialist Use Only
Taxtas 80 (Docetaxel Injection USP 20mg/mL, 4mL Vial)	Intas Pharmaceuticals Ltd.	India	Specialist Use Only
Taxtas 160 (Docetaxel Injection USP 20mg/mL, 8mL Vial)	Intas Pharmaceuticals Ltd.	India	Specialist Use Only
Natrol B-Complex Fast Dissolve Coconut Natural Flavor	Natrol LLC	USA	Freely
Natrol Melatonin Advanced 10mg Maximum Strength Time Release	Natrol LLC	USA	Freely

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Zinc Vegetarian Capsules 50mg	Newton-Everett Neutraceuticals	USA	Freely
Vitamin D3 Vegetarian Tablets 5000IU	Newton-Everett Neutraceuticals	USA	Freely
Turbo Urgan-C Immune Boost +	Novafoods S.A.	Chile	Freely
Atropine Eye Drops BP 1.0% w/v, Eye Drops	Tubilux Pharma SPA	Italy	Third Schedule
Skyrizi Solution for Injection 75mg/0.83mL (90mg/mL)	Manufacturer: Boehringer Ingelheim Pharma GmbH & Co. KG, Germany Packager: AbbVie S.r.L., Italy	Italy	Third Schedule
Calquence Capsules 100mg	AstraZeneca AB, Södertälje, Sweden	Sweden	Specialist Use Only
Rosuvastatin Denk Film-Coated Tablets 10mg	Pharmaceutical Works Polpharma S.A.	Poland	Third Schedule
Budesonide Aqueous Nasal Spray 50mcg/200 doses	Jewim Pharmaceutical (Shandong) Co., Ltd.	China	Third Schedule
Budesonide Pressurized Inhalation 200mcg/dose	Jewim Pharmaceutical (Shandong) Co., Ltd.	China	Third Schedule
Ipratropium Pressurized Inhalation 20mcg/dose	Jewim Pharmaceutical (Shandong) Co., Ltd.	China	Third Schedule
Rosuvastatin Tablets 10mg	Macleods Pharmaceuticals Limited	India	Third Schedule
Rosuvastatin Tablets 20mg	Macleods Pharmaceuticals Limited	India	Third Schedule
Aleve Liqui-Gels Liquid Filled Capsules 200mg	Catalent Argentina SAIC	Argentina	Freely

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Imatinib Hard Capsules 400mg	Dr. Reddy's Laboratories Ltd.	India	Specialist Use Only
Targeflo Film Coated Tablets 500mg	Actavis Limited	Malta	Third Schedule
M-PRIB 3.5 (Bortezomib for Injection 3.5mg/Vial)	Naprod Life Sciences PVT. Limited	India	Specialist Use Only (Specialized in antineoplastic therapy)
Naproplat (Carboplatin for Injection BP 450mg/45mL)	Naprod Life Sciences PVT. Limited	India	(Specialist Use Only)

Dated this 19th day of January, 2022.

T. DEYALSINGH
Minister of Health