

LEGAL NOTICE NO. 126

REPUBLIC OF TRINIDAD AND TOBAGO

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 of Health signifies his approval in respect of the following new drugs:

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Privigen Solution for Infusion 2.5 g	CSL Behring AG	Switzerland	Third Schedule
Privigen Solution for Infusion 5 g	do.	do.	do.
Privigen Solution for Infusion 10 g	do.	do.	do.
Erbix Solution for Infusion 5 mg/mL	Boehringer Ingelheim Pharma GmbH & Co. KG	Germany	do.
Prezista Film-Coated Tablets 400 mg	Manufactured by: Janssen Ortho LLC Puerto Rico Packaged by: Janssen-Cilag S.p.A., Via C. Janssen	Italy	do.
Prezista Film-Coated Tablets 600 mg	do.	do.	do.
Simva-Denk 20 Film-Coated Tablets 20 mg	DENK PHARMA GmbH & Co. KG	Germany	do.
Simva-Denk 40 Film-Coated Tablets 40 mg	do.	do.	do.
Amlod-Denk 5 Tablets 5 mg	do.	do.	do.
Amlod-Denk 10 Tablets 10 mg	do.	do.	do.
Glimepiride Denk 2 Tablets	do.	do.	do.
Glimepiride Denk 3 Tablets	do.	do.	do.
Clopidogrel Winthrop Film-Coated Tablets 75 mg	Sanofi Winthrop Industrie	France	do.
Zerodol Film-Coated Tablets 100 mg	Ipsca Laboratories Ltd.	India	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Mofilet-500 Film-Coated Tablets 500 mg	Emcure Pharmaceuticals Ltd.	India	Third Schedule
Panimun Bioral Soft Gelatin Capsules 25 mg	Panacea Biotec Ltd.	do.	do.
Panimun Bioral Soft Gelatin Capsules 50 mg	do.	do.	do.
Panimun Bioral Soft Gelatin Capsules 100 mg	do.	do.	do.
Mycept-250 Hard Gelatin Capsules 250 mg	do.	do.	do.
Sports Balm Ultra with Capsicum—Stick Applicator	Genethics Pharmaceuticals Ltd.	Trinidad and Tobago	Freely
Baby Chest Rub Nighttime	do.	do.	do.
Afinitor Tablets 5 mg	Manufactured by: Novartis Pharma Stein AG for Novartis Pharma AG Switzerland	Switzerland	Third Schedule
Afinitor Tablets 10 mg	do.	do.	do.
Tasigna Capsules 200 mg	do.	do.	do.
Gonapeptyl Depot Powder for Solution for Injection—Pre-Filled Syringe	Manufactured by: Ferring GmbH Germany Packed by: Ferring International Centre S.A.	do.	do.
Rumifen-600 Film-Coated Tablets BP 600 mg	Manufactured by: Aurochem Laboratories (I) Pvt. Ltd. Marketed by: Trinpharm Co. Ltd. Trinidad and Tobago	India	do.
Gofen 400 Softgel Capsules	Mega Lifesciences Ltd.	Thailand	do.
Mab Thera Concentrate for Solution for Infusion 100 mg/10 ml (New Indication, Change of Packaging and Additional Source)	Made for F. Hoffmann-La Roche Ltd., Switzerland by Roche Diagnostics GmbH	Germany	do.
Mab Thera Concentrate for Solution for Infusion 500 mg/50 ml (New Indication, Change of Packaging and Additional Source)	do.	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Xeloda Film-Coated Tablets 500 mg (New Indication, Additional Source and Change of Artwork Design)	Made for F. Hoffmann- La Roche Ltd., Switzerland by Productos Roche S.A. DE C.V.	Mexico	Third Schedule
Lasix Tablets 40 mg (Additional Source)	sanofi-aventis Farmacêutica Ltda.	Brazil	do.

Dated this 5th day of March, 2012.

F. KHAN
Minister of Health