

LEGAL NOTICE NO. 142

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 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>
Vitamin D Tablets 400 IU	Jamieson Laboratories	Canada	Third Schedule
Optive Lubricant Eye Drops-Sterile	Allergan, Inc.	USA	Freely
Extra Strength Tylenol PM Rapid Release Gels RR Gelcaps	Distributed by: McNeil Consumer Healthcare DIVISION OF MCNEIL-PPC, INC. USA (Product of USA)	do.	do.
Mircera Solution for Injection 50 micrograms/1 ml	F. Hoffmann-La Roche Ltd.	Switzerland	Third Schedule
Mircera Solution for Injection 100 micrograms/1 ml	do.	do.	do.
Mircera Solution for Injection 200 micrograms/1 ml	do.	do.	do.
Mircera Solution for Injection 300 micrograms/1 ml	do.	do.	do.
Mircera Solution for Injection 1000 micrograms/1 ml	do.	do.	do.
Medised Oral Solution for Children-3+ months (Sugar Free)-Strawberry Flavour	Distributed by: SSL International plc UK (Product of UK)	UK	Freely
Differin Gel 0.3%	Manufactured by: DPT Laboratories, Ltd. Marketed by: Galdema Laboratories, L.P. USA	USA	Third Schedule

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Metrogel Gel 1%	Manufactured by: Galderma Production Canada Inc. Marketed by: Galderma Laboratories, L.P. USA	Canada	Third Schedule
Flexitol Cuticle and Nail Cream	Laderma Pty Ltd.	Australia	Freely
Flexitol Hand Balm with Vitamin E & 10% Urea	do.	do.	do.
Terbi Antifungal Spray	Cipla Ltd.	India	Third Schedule
Mobix G Topical Analgesic Spray	do.	do.	do.
Diclo Spray	do.	do.	do.
Ibugesic Spray	do.	do.	do.
Cofsils Lozenges-Orange	do.	do.	Freely
Rapid Relief Cool Spray	L'amar Natural Products Pvt. Ltd.	do.	do.
Rapid Relief Hot Spray	do.	do.	do.
Exelon Patch 5 Transdermal Patches 4.6 mg/24h	Manufactured by: LTS Lohmann Therapie-Systeme for Novartis Pharma AG Switzerland	Germany	Third Schedule
Exelon Patch 10 Transdermal Patches 9.5 mg/24h	do.	do.	do.
Systane Ultra Lubricant Eye Drops-Sterile	Alcon Laboratories, Inc.	USA	Freely
Rocaltrol Capsules 0.25 μ g (Change of Colouring Agent)	Made for: F. Hoffmann-La Roche Ltd. Switzerland by R.P. Scherer GmbH & Co. KG	Germany	Third Schedule
Cymbalta Hard Gastro- Resistant Capsules 30 mg (New Indication)	Lly S.A.	Spain	do.
Cymbalta Hard Gastro- Resistant Capsules 60 mg (New Indication)	do.	do.	do.
FluaRIX Suspension for Injection Prefilled Syringe (Change of Strain)	GlaxoSmithKline Biologicals, Branch of SB Pharma GmbH & Co. KG	Germany	do. do.
Extra Strength Panadol Tablets (Change of Logo on Tablets)	GlaxoSmithKline Panamá, S.A.	Panama	Freely

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Cataflam Injectable Solution 75 mg/3 ml (Additional Source)	Novartis Pharma S.A.E.	Egypt	Third Schedule
Atacand Tablets 8 mg (Additional Source)	Manufactured by: AstraZeneca AB Sweden under the licence from: Takeda Pharmaceutical Company Limited Japan Packed and distributed by: AstraZeneca, S.A. de C.V.	Mexico	do.
Atacand Tablets 16 mg (Additional Source)	do.	do.	do.
Atacand Plus Tablets 16 mg/12.5 mg (Additional Source)	do.	do.	do.
Batrafen 1% Cream 10 mg/g (Change of Name of Manufacturer)	Manufactured by: Lancasco, S.A. for sanofi-aventis de Guatemala, S.A. Guatemala	Guatemala	do.
Batrafen 1% Vaginal Cream 10 mg/g with Disposable Applicators (Change of Name of Manufacturer)	do.	do.	do.
Batrafen 1% Solution 10 mg/mL (Change of Name of Manufacturer)	do.	do.	do.
Lasix Tablets 40 mg (Change of Name of Manufacturer)	do.	do.	do.
Trental Sugar-Coated Tablets 400 mg (Change of Name of Manufacturer)	do.	do.	do.
Topisolon Ointment 0.25% (2.5 mg/g) (Change of Name of Manufacturer)	do.	do.	do.
Tavanic Film-Coated Tablets 500 mg (Additional Source and Change of Name of Manufacturer)	Manufactured by: Aventis Intercontinental France Packed by: Lancasco, S.A. for sanofi-aventis de Guatemala, S.A. Guatemala	Guatemala	do.
Tylox Flu Tablets (Change of Formulation)	JANSSEN CILAG, S.A. de C.V.	Mexico	Freely
Omnipred Ophthalmic Suspension 1%—Sterile (Change of Name of Product)	Alcon Laboratories, Inc.	USA	Third Schedule

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Ufen Cream	Manufactured by: U Square Lifescience Pvt. Ltd. for Trinpharm Co. Ltd. Trinidad & Tobago	India	Third Schedule
Ufen-V Vaginal Cream with Applicator Trocon Cream	do.	do.	do.
Rosec Hard Gelatin Capsules 20 mg	Manufactured by: Accure Labs Pvt. Ltd. for Trinpharm Co. Ltd. Trinidad & Tobago	do.	do.
Insugen-R (Regular) Injection 100 IU/ml	Biocon Limited	do.	do.
Insugen-30/70 (Biphasic) Injection 100 IU/ml	do.	do.	do.
Insugen-N (NPH) Injection 100 IU/ml	do.	do.	do.
Intefen-IFN Recombinant Human Interferon a-2a for Injection 1MIU	Manufactured by: Shenyang Sunshine Pharmaceutical Co. Ltd. for Biolotus Biotech, Lda Portugal	China	do.
Intefen-IFN Recombinant Human Interferon a-2a for Injection MIU3	do.	do.	do.
Intefen-IFN Recombinant Human Interferon a-2a for Injection 5MIU	do.	do.	do.
Piouno-45 Tablets 45 mg	Wockhardt Limited	India	do.
Didanosine chewable/dis- persible Tablets 200 mg	Aurobindo Pharma Limited	do.	do.
Urimax-0.4 mg Modified Release Capsules 400 mcg	Cipla Ltd.	do.	do.
Cancan Cream 2% w/w	Manufactured by: Aurochem Laboratories (1) Pvt. Ltd. Marketed by: Trinpharm Co. Ltd. Trinidad & Tobago	do.	do.
Terbitin Cream 1% w/w	do.	do.	do.
Premarin Tablets 0,3 mg (Additional Source)	Manufactured by: Wyeth Medical Ireland Packaged by: Wyeth Indústria Farmacêutica Ltda. Brazil	Ireland	do.
Premarin Tablets 0,625 mg (Additional Source)	do.	do.	do.

Dated this 10th day of June, 2009.

J. NARACE
Minister of Health