

LEGAL NOTICE NO 290

REPUBLIC OF TRINIDAD AND TOBAGO

THE FOOD AND DRUGS ACT, CHAP. 30:01

NOTIFICATION

APPROVAL IN RESPECT OF NEW DRUGS

ISSUED by the Minister of Health on the advice of the Drug Advisory Committee in accordance with paragraph 7, Division 3 of the Second Schedule of the Food and Drugs Act.

The Minister of Health signifies his approval in respect of the following new drugs listed hereunder:

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Selecim Tablets 5 mg	Cimex Ltd.	Switzerland	Third Schedule
Pantogar Capsules	do.	do.	Freely
Fluocim Capsules	do.	do.	Third Schedule
Tydin 150 Tablets	Eros Pharma Limited	India	do.
Tydin 300 Tablets	do.	do.	do.
SedoSolvin Suspension	Ipca Laboratories Ltd.	do.	Freely
BronchoSolvin Suspension	do.	do.	Third Schedule
Ascodex Cough Syrup	Glenmark Pharmaceuticals Limited	do.	Freely
Scalpe Shampoo	do.	do.	Third Schedule
Elovera Cream	do.	do.	Freely
Oxyace Capsules	Unique Pharmaceutical Labs (A Division of J.B. Chemicals & Pharmaceutiucals Ltd.)	do.	do.
Hydrocortisone Cream USP 1%	E. Fougera and Co. (A Division of Altana Inc.)	USA	Third Schedule
Analgesic Balm	do.	do.	Freely
Swim-EAR Ear-Water Drying Aid Drops	do.	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Gonal-F 37.5 IU Powder and Solvent for Solution for Injection	Serono Pharma S.p.A.	Italy	Third Schedule
Saizen 24 IU (8 mg) for Easyject Power and Solvent for Solution for Injection	do.	do.	do.
Lamivir Tablets 150 mg	Cipla Limited	India	do.
Zidovir-300 Tablets	do.	do.	do.
Alerid Syrup	do.	do.	do.
Braithwaite All Purpose Liniment	S.M. Braithwaite	Trinidad & Tobago	Freely
Braithwaite Vapourising Balm	do.	do.	do.
Theragran Heart Right Caplets	Bristol-Myers Products (A Bristol-Myers Squibb Company)	USA	do.
Isotrex Gel 0.05%	Stiefel Mexicana S.A. de C.V.	Mexico	Third Schedule
Asacol Enema 4 g	Tillotts Pharma AG	Switzerland	do.
Asacol Suppositories 500 mg	do.	do.	do.
Enatec-5 Tablets	Mepha Ltd.	do.	do.
Enatec-10 Tablets	do.	do.	do.
Enatec-20 Tablets	do.	do.	do.
Duadacin Cold Capsules	Kenwood Laboratories (A Division of Bradley Pharmaceuticals Inc.)	USA	Freely
Sore Throat Spray-Cherry	Perrigo	do.	do.
Diamicron MR Tablets	Les Laboratoires Servicer	France	Third Schedule
Apo-Beclomethasone Nasal Spray	Apotex Inc.	Canada	do.
Apo-Oflox Tablets 200 mg	do.	do.	do.
Apo-Oflox Tablets 400 mg	do.	do.	do.
Apo-Ketotifen Syrup 1 mg/5 mL	do.	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Apo-Fluconazole- 150 Capsules 150 mg	Apotex Inc.	Canada	Third Schedule
Apo-Ipravent Sterules (500 mcg/2 mL)	do.	do.	do.
Apo-Sertraline Capsules 50 mg	do.	do.	do.
Apo-Sertraline Capsules 100 mg	do.	do.	do.
Apo-Valproic Capsules 250 mg	do.	do.	do.
Apo-Norflox Tablets 400 mg	do.	do.	do.
Infed injection 50 mg/mL	Schein Pharmaceutical Inc.	USA	do.
Acypront Effervescent Tablets	Heinrich Mack Nachf. GMBH & Co. KG	Germany	do.
Ritalin SR Tablets 20 mg	Novartis Pharmaceutical Canada Inc.	Canada	Controlled Drug
Trileptal 150 Tablets	Novartis Pharma AG	Switzerland	Third Schedule
Trileptal 300 Tablets	do.	do.	do.
Trileptal 600 Tablets	do.	do.	do.
Co-Diovan 160/ 12,5 Tablets	do.	do.	do.
Vitamin E Capsules 400 IU	Wampole Canada Inc.	Canada	Freely
Vitamin E Capsules 800 IU	do.	do.	do.
Vitamin C Chewable Tablets 500 mg -Cherry Flavour	do.	do.	do.
Vitamin C Chewable Tablets 500 mg -Grape Flavour	do.	do.	do.
Vitamin C Chewable Tablets 500 mg -Orange Flavour	do.	do.	do.
Vitamin B12 Tablets 25 mcg	do.	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Infant Multiple Vitamin Drops	Wampole Canada Inc.	Canada	Freely
Children's Fever Halt Chewable Acetaminophen Tablets 160 mg-Grape Flavour	do.	do.	do.
Bronchial Cough Syrup	do.	do.	do.
Stress Formula Capsules	do.	do.	do.
Stress Formula with Iron Capsules	do.	do.	do.
Stress Formula with Zinc Capsules	do.	do.	do.
Mulvitone Forte Tablets	Strides Arcolab Limited	India	do.
Folic Acid Tablets BP 5 mg	Flamingo Pharmaceuticals Limited	do.	do.
Tricogyn-500 Tablets	do.	do.	Third Schedule
Losec Mups Tablets 10 mg	Astra Pharmaceutical Production AB Sweden. Packed by Hoechst Marion Roussel S.A.	Guatemala	do.
Losec Mups Tablets 20 mg	do.	do.	do.
Losec Mups Tablets 40 mg	do.	do.	do.
Allegra Film-Coated Tablets 180 mg	Hoechst Marion Roussel S.A.	do.	do.
Arava Film-Coated Tablets 10 mg	Usiphar France Packed by Hoechst Marion Roussel S.A.		
Arava Film-Coated Tablets 20 mg	do.	do.	do.
Arava Film-Coated Tablets 100 mg	do.	do.	do.
Avelox Film-Coated Tablets 400 mg	Bayer AG Germany Packed by Bayer S.A.	El Salvador	Third Schedule
Lipobay Film Coated Tablets 0.2 mg	Bayer AG Germany Packed by Bayer de El Salvador S.A.	do.	do.
Canesten 1 Vaginal Tablets 0.5 G	Bayer de El Salvador S.A.	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Canesten 3 Vaginal Tablets 0.2 G	Bayer de El Salvador S.A.	El Salvador	Third Schedule
Canesten Vaginal Cream 1%	do.	do.	do.
Canesten 1 Vaginal Cream 10%	do.	do.	do.
Baycuten N Cream	do.	do.	do.
Prevnar Pneumococcal 7-Valent Conjugate Vaccine (Diphtheria CRM 197 Protein)	Laderle Laboratories Division American Cyanamid Company	USA	do.
Zeet Expectorant Liquid	Alembic Ltd.	India	Freely
Nimesic Tablets 100 mg	do.	do.	Third Schedule
Ephedrex Syrup	do.	do.	Freely
Tears Naturele Free Lubricant Eye Drops	Alcon Laboratories Inc.	USA	do.
Buckley's Lemon Time Powder	W.K. Buckley Limited	Canada	do.
Advil Pediatric Drops- Grape Flavoured	Whitehall-Robins Healthcare	USA	do.
Advil Pediatric Drops- Fruit Flavored	do.	do.	do.
Precedex Injection 100 mcg/mL	Abbott Labs.	do.	Third Schedule
Rapamune Oral Solution 1 mg/mL	Wyeth Laboratories (Division of Wyeth-Ayerst Pharmaceutical Inc.)	do.	do.
Erostimin 42 Syrup	Eros Pharma Ltd.	India	Freely
Novo-Terazosin Tablets 1 mg	Novopharm Limited	Canada	Third Schedule
Novo-Terazosin Tablets 2 mg	do.	do.	do.
Novo-Terazosin Tablets 5 mg	do.	do.	do.
Novo-Terazosin Tablets 10 mg	do.	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Novo-Gliclazide Tablets 80 mg	Novopharm Limited	Canada	Third Schedule
Warfarin Tablets BP 1 mg	Norton Healthcare Ltd.	UK	do.
Warfarin Tablets BP 3 mg	do.	do.	do.
Warfarin Tablets BP 5 mg	do.	do.	do.
Diovol Extra Strength Antacid Suspension- Fresh Mint	Cater-Horner Inc.	Canada	Freely
Gravol FilmKote Tablets 15 mg	do.	do.	do.
Gravol FilmKote Tablets 25 mg	do.	do.	do.
Oestrofeminal Capsules 0.3 mg	Heinrich Mack Nachf. GMBH & Co. KG	Germany	Third Schedule
Oestrofeminal Capsules 0.6 mg	do.	do.	do.
Oestrofeminal Capsules 1.25 mg	do.	do.	do.
Buckley's Cold & Flu Daytime Relief Extra Strength Caplets	W.K. Buckley Limited	Canada	Freely
Buckley's Cold & Flu Nighttime Relief Extra Strength Caplets	do.	do.	do.
Caltrate 600 Tablets	Whitehall-Robins Healthcare	USA	do.
Caltrate 600+D Tablets	do.	do.	do.
Caltrate 600 Plus Tablets	do.	do.	do.
Caltrate 600 Plus Chewable Tablets- Assorted Fruit Flavours	do.	do.	do.
Curevite Multivitamin Tablets	Strides Arcolab Limited	India	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Prolixin Decanoate Injection 25 mg/ml	Apothecon (A Bristol-Myers Squibb Company)	USA	Third Schedule
Carboplatin-do-Ebewe-do 10 mg/ml IV Infusion	Ebewe Arzneimittel Ges m.b.H	Austria	do.
5 Fluorouracil-do-Ebewe-do 500 mg/10 ml IV, IA or Intracavitary Infusion	do.	do.	do.
Hidrasec Paediatric Oral Powder Sachets 6 mg	SmithKline Beecham Laboratoires Pharmaceutiques	France	do.
Hidrasec Paediatric Oral Powder Sachets 18 mg	do.	do.	do.
Hidrasec Paediatric Oral Powder Sachets 30 mg	do.	do.	do.
Panadol Cold Hot Rem Soluble Powder Sachets	SmithKline Beecham Costa Rica S.A.	Costa Rica	Freely
Cofal Sport Cream Extra Strength	SmithKline Beecham	do.	do.
Cofalito Oil-Infants	SmithKline Beecham Costa Rica S.A.	do.	do.
Cofalito Cream-Children	do.	do.	do.
Solpaflex Gelpcaps	L.P. Scherer for SmithKline Beecham	Argentina	do.
Tussin Expectorant Cough Syrup (Change of Name of Manufacturer)	Perrigo	USA	do.
Nite Time Multi-Symptom Cold/Flu Relief Syrup-Original Flavour (Change of Name of Manufacturer)	do.	do.	do.
Children's Pain Reliever Cold Liquid-Cherry (Change of Name of Manufacturer)	do.	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Enteric Coated Aspirin Tablets 325 mg (Change of Name of Manufacturer)	Perrigo	USA	Freely
Children's Chewable Aspirin Tablets 81 mg- Orange Flavoured (Change of Name of Manufacturer)	do.	do.	do.
Milk of Magnesia-Mint (Change of Name of Manufacturer)	do.	do.	do.
Vumon Injection 50 mg/ 5 ml (Change of Country of Origin)	Bristol-Myers Squibb S.p.A.	Italy	Third Schedule
Megace Oral Suspension 40 mg/ml (Additional Source)	Squibb Manufacturing Inc. Puerto Rico (A Subsidiary of Bristol-Myers Squibb Co.)	Puerto Rico	do.
Flucin Skin Cream (Change of Name of Product)	Gufic Limited	India	do.
Lotensin 10 Tablets (Additional Source)	Novartis Farma S.p.A.	Italy	do.
Sandimmun Neoral Oral Solution 100 mg/ml (Additional Source)	Novartis Pharma S.A	France	do.
Methergin Sugar Coated Tablets 0.125 mg (Additional Source)	Norvartis Pharma GmbH	Germany	do.
Cafergot Tablets (Additional Source)	Norvartis Pharmaceuticals UK Ltd.	UK	do.
Miacalcic Nasal Spray 200 (Additional Source)	Novartis Pharma S.A	France	do.
Gonal-F75 Powder and Solvent for Solution for Injection (Additional Source)	Serono Pharma S.p.A.	Italy	do.
Gonal-F150 Powder and Solvent for Solution for Injection (Additional Source)	do.	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Paracetamol Tablets BP 500 mg (Additional Packaging)	Flamingo Pharmaceuticals Ltd.	India	Freely
Centrum Tablets with Lutein (Change of Formulation)	Whitehall-Robins Healthcare	USA	do.
Auralgan Eardrops (Reduction in Shelf Life to 24 Months)	Wyeth-Ayerst Canada Inc.	Canada	do.
Histal Allergy Relief Tablets (Change of Label on Outer and Inner Packaging. Changes in Artwork Design Only)	Carlisle Laboratories Limited	Barbados	do.
Histal Allergy Relief Elixir (Change of Label on Outer and Inner Packaging. Changes in Artwork Design Only)	do.	do.	do.
Vitaplex M Capsules (Change of Label on Outer and Inner Packaging. Changes in Artwork Design Only)	do.	do.	do.
Vitaplex P Capsules (Change of Label on Outer and Inner Packaging. Changes in Artwork Design Only)	do.	do.	do.
Metronidazole Intraven- ous Infusion 500 mg/ 100 ml (Change of Name of Manufacturer)	Pharmacia & Upjohn (Perth) Pty Ltd.	Australia	Third Schedule
Tritace Tablets 2.5 mg (Additional Indications)	Hoechst Marion Roussel S.A.	Guatemala	do.
Tritace Tablets 5 mg (Additional Indications)	do.	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Baralgin 'M' Tablets (Change of Name of Manufacturer)	Hoechst Marion Roussel S.A.	Guatemala	Third Schedule
Primalan Syrup (Change of Name of Manufacturer and Country of Origin)	Pierre Fabre Medicament	France	Freely
Primalan Tablets 5 mg (Change of Name of Manufacturer and Country of Origin)	do.	do.	do.
Ciproxina 250 Film Coated Tablets (Additional Indication)	Bayer de El Salvador S.A.	El Salvador	Third Schedule
Ciproxina 500 Film Coated Tablets (Additional Indication)	do.	do.	do.
Ciproxina 750 Film Coated Tablets (Additional Indication)	do.	do.	do.
Ciproxina Infusion Solution 0.1 G (Additional Indication)	do.	do.	do.
Ciproxina Infusion Solution 0.2 G (Additional Indication)	do.	do.	do.
Ciproxina Infusion Solution 0.4 G (Additional Indication)	do.	do.	do.
Zaroxolyn Tablets 5 mg (Change of Address)	Medeva Pharmaceuticals Inc.	USA	do.
GlucaGen Injection 1 IU/ml (Change of Name of Product)	Novo Nordisk A/S	Denmark	do.
Cetavlex Antiseptic Cream (Change of Packaging, Label and Name of Manufacturer)	Bioglan Laboratories Ltd.	UK	Freely
Metosyn FAPG Cream (Change of Packaging, Label and Name of Manufacturer)	do.	do.	Third Schedule

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Synalar Cream (Change of Packaging, Label and Name of Manufacturer)	Bioglan Laboratories Ltd.	UK	Third Schedule
Synalar Ointment (Change of Packaging, Label and Name of Manufacturer)	do.	do.	do.
Synalar-C Cream (Change of Packaging, Label and Name of Manufacturer)	do.	do.	do.
Synalar-C Ointment (Change of Packaging, Label and Name of Manufacturer)	do.	do.	do.
Synalar Gel (Change of Packaging, Label and Name of Manufacturer)	do.	do.	do.
Hibitane Obstetric Cream (Change of Packaging, Label and Name of Manufacturer)	do.	do.	Freely
Children's Dimetapp Infant Drops Nasal Decongestant (Change of Name of Product)	Whitehall-Robins Healthcare	USA	do.
Voltaren Emulgel 1% (Additional Source and Change of Name of Manufacturer)	Novartis Pharma GmbH	Germany	Third Schedule
Voltaren 50 Suppositories (Additional Source and Change of Name of Manufacturer)	Novartis Pharma S.A.	France	do.
Viramune Oral Suspension 50 mg/5 mL (Change in Route of Administration)	Roxane Laboratories Inc.	USA	do.
Sanatogen Multivitamins + Iron Tablets (Change in Inactive Ingredient)	Roche Consumer Health	UK	Freely
Phensic Tablets (Change of Source)	Sterling Products International S.A.	Panama	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Trental Injectable Solution 20 mg/ml (Additional Source)	Hoechst Marion Roussel S.A. de C.V.	Mexico	Third Schedule
Tussadryl Cough & Cold Baby Formula-Liquid	Twin Manufacturing Chemists	Guyana	Freely
Trimethoprim Sulfamethoxazole Baykid ® Tablets 80 mg/400 mg	Corporacion Bonima S.A. de C.V.	El Salvador	Third Schedule
Pantecta I.V. Injection Solution 40 mg	Byk Gulden Lomberg	Germany	do.
Cataflam I.M. Injectable Solution 75 mg/3 ml	Novartis Biociencias S.A.	Brasil	do.
Aromasin Tablets 25 mg	Pharmacia & Upjohn S.p.A	Italy	do.
Naturvite St. John's Wort Capsules 300 mg	Pharmetics Inc.	Canada	do.
Cascara Sagrada Capsules 425 mg	Nature's Way Products Inc.	USA	Freely
Aloe Vera Capsules	do.	do.	do.
Seven Seas Cranberry Forte Capsules 200 mg	Seven Seas Healthcare Limited	UK	do.
Liv. 52 Tablets	The Himalaya Drug Company	India	do.
Liv. 52 Drops	do.	do.	do.
Diabecon Tablets	do.	do.	Third Schedule
Abana Tablets	do.	do.	do.
Diarex Tablets	do.	do.	Freely
Tentex Forte Tablets	do.	do.	Third Schedule
Speman Tablets	do.	do.	do.
Speman Forte Tablets	do.	do.	do.
Himcolin Cream	do.	do.	do.

VETERINARY PRODUCTS

Leukocell 2 Vaccine	Pfizer Animal Health	USA	To Veterinarians or by Veterinary Prescription only
---------------------	----------------------	-----	---

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Felocell CVR Vaccine	Pfizer Animal Health	USA	To Veterinarians or by Veterinary Prescription only
Ivomec Eprinex Pour-On Liquid	Merial Limited	do.	Freely

Dated this 6th day of November, 2000.

H. RAFEEQ
Minister of Health