

LEGAL NOTICE NO. 7

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 clause 7, Division 3 of the Second Schedule to the Food and Drugs Regulations.

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

| <i>Trade Name and Form</i> | <i>Manufacturer</i> | <i>Country of Origin</i> | <i>Condition of Sale</i> |
|--|--|--------------------------|--------------------------|
| Oxitan Injection 50 mg | Dabur Pharma Ltd. | India | Third Schedule |
| Oxitan Injection 100 mg | do. | do. | do. |
| Lamivudine 150 mg, Stavudine 40 mg and Nevirapine 200 mg Tablets | Manufactured by Meditab Specialities Pvt. Ltd. for Health 2000 Inc. Canada | do. | do. |
| Lamivudine 150 mg, Zidovudine 300 mg and Nevirapine 200 mg Film-Coated Tablets | do. | do. | do. |
| Simvastatin 20 mg Film-Coated Tablets | do. | do. | do. |
| Gen-Faxine XR Extended Release Capsules 37.5 mg | Genethics Pharmaceuticals Ltd. | Trinidad and Tobago | do. |
| Gen-Faxine XR (DS) Extended Release Capsules 75 mg | do. | do. | do. |
| Gen-Amipril Tablets 5 mg | do. | do. | do. |
| Gen-Peridone Tablets 2 mg | do. | do. | do. |
| CleanseSMART Vegetable Capsules | Distributed by ReNew Life Formulas USA (Product of USA) | USA | Freely |
| Sucrafil Suspension | Fourrts (India) Laboratories Pvt. Limited | India | do. |

| <i>Trade Name and Form</i> | <i>Manufacturer</i> | <i>Country of Origin</i> | <i>Condition of Sale</i> |
|---|---|--------------------------|--------------------------|
| LAS-Lorazepam Tablets 1 mg | Manufactured by Cipla Ltd. for Lasmed a division of Lasco Distributors Ltd. Jamaica | India | Controlled Drug |
| LAS-Lorazepam Tablets 2 mg | do. | do. | do. |
| LAS-Fluticasone Aqueous Nasal Spray | do. | do. | Third Schedule |
| Amlodipine 5 mg Tablets | Manufactured by Meditab Specialities Pvt. Ltd. for Health 2000 Inc. Canada | do. | do. |
| Amlodipine 10 mg Tablets | do. | do. | do. |
| Coligon Tablets | Fourrts (India) Laboratories Pvt. Limited | do. | do. |
| Vfend Film-Coated Tablets 50 mg | Heinrich Mack Nachf. GmbH & Co. KG | Germany | do. |
| Vfend Film-Coated Tablets 200 mg | do. | do. | do. |
| Vfend Powder for Solution for Infusion 200 mg | Manufactured by Pfizer Ireland Pharmaceuticals Limited Ireland Packaged by Pfizer | France | do. |
| Synox Tablets 0.1 mg | Uni-Sankyo Limited | India | do. |
| Choragon 5000 Powder and Solvent for Solution for Injection | Ferring GmbH | Germany | do. |
| Menopur Powder and Solvent for Solution for Injection | do. | do. | do. |
| Children's Dimetapp Nighttime Flu Syrup —Bubble Gum Flavor (Alcohol-Free) | Wyeth Consumer Healthcare | USA | Freely |
| Centrum Junior Complete Children's Chewable Multivitamin Formula Tablets—Fruit Flavors | Distributed by Whitehall- Robins Inc. Canada (Product of Canada) | Canada | do. |

| <i>Trade Name and Form</i> | <i>Manufacturer</i> | <i>Country of Origin</i> | <i>Condition of Sale</i> |
|---|---|--------------------------|--------------------------|
| Redoxon Vitamin C Chewable Tablets 500 mg—Tangerine | Productos Roche S.A.Q. e. l. | Argentina | Freely |
| Lexotan Tablets 6 mg | Produtos Roche Químicos e Farmacêuticos S.A. | Brazil | Controlled Drug |
| Tildiclo Injection | Tablets (India) Limited | India | Third Schedule |
| Trichogyl I.V. Injection | do. | do. | do. |
| Glucosamine, MSM & Chondroitin Sulfate Coated Caplets 1000 mg | Swiss Herbal Remedies Ltd. | Canada | Freely |
| MSM Caplets 500 mg | do. | do. | do. |
| Vitamin E Capsules 800 IU | do. | do. | do. |
| LAS-Clotrimazole Cream | Manufactured by Cipla Ltd. for Lasmed a division of Lasco Distributors Ltd. Jamaica | India | Third Schedule |
| LAS-Salbutamol Syrup | do. | do. | Freely |
| LAS-Ondanestron Film-Coated Tablets 8 mg | do. | do. | Third Schedule |
| LAS-Timolol Eye Drops 0.25% | do. | do. | do. |
| LAS-Timolol Eye Drops 0.5% | do. | do. | do. |
| LAS-Diclofenac Injection 25 mg/ml | do. | do. | do. |
| LAS-Cotrimoxazole DS Tablets | do. | do. | do. |
| LAS-Cotrimoxazole Suspension | do. | do. | do. |
| LAS-Fluconazole Capsules 50 mg | do. | do. | do. |
| LAS-Fluconazole Capsules 200 mg | do. | do. | do. |
| LAS-Aciclovir 800 Dispersible Tablets | do. | do. | do. |
| LAS Norfloxacin Eye Ointment | do. | do. | do. |
| Rub. A535 Dual Action Cream | Carter-Horner Corp. | Canada | Freely |
| Gravol Softgel Capsules 50 mg | do. | do. | Third Schedule |

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|--|---|--------------------------|--------------------------|
| Gravol Long-Acting Caplets 75 mg | Carter-Horner Corp. | Canada | Third Schedule |
| Diovol Plus AF Suspension —Fresh Mint | do. | do. | Freely |
| Diovol Plus AF Chewable Tablets—Fresh Mint | do. | do. | do. |
| Estalis Sequi 50/140 Transdermal Patches | Manufactured by Noven Pharmaceuticals Inc. for Novartis Pharma AG Switzerland | USA | Third Schedule |
| Estalis Sequi 50/250 Transdermal Patches | do. | do. | do. |
| Tears Naturale P.M. Lubricant Eye Ointment | Distributed by Alcon Laboratories, Inc. USA (Product of Belgium) | Belgium | Freely |
| Bayer Genuine Aspirin 81 mg Chewable Tablets —Mint Flavor | Bayer Corporation | USA | Freely |
| Bayer Women's Aspirin Plus Calcium Caplets | Bayer Corporation Consumer Care Division | do. | do. |
| Bayer Extra Strength Back & Body Pain Coated Caplets | do. | do. | do. |
| Bactine Original First Aid Antiseptic/Pain Reliever Liquid | do. | do. | do. |
| Risperdal Quicklet Tablets 1 mg | Made by Janssen Ortho LLC Puerto Rico Packed and Distributed by Janssen Cilag, S.A. de C.V. | Mexico | Third Schedule |
| Risperdal Quicklet Tablets 2 mg | do. | do. | do. |
| Seroquel Tablets 300 mg | AstraZeneca UK Limited | United Kingdom | do. |
| Lindynette 20 Coated Tablets | Gedeon Richter Ltd. | Hungary | do. |
| Bausch & Lomb Moisture Eyes Liquid Gel Lubricant Eye Drops | Bausch & Lomb | USA | Freely |
| Bausch & Lomb Soothing Eye Wash Eye Irrigating Solution | do. | do. | do. |

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|---|---|--------------------------|--------------------------|
| Otrivin Nasal Drops Solution 0.05% —Children | Norvatis Consumer Health SA | Switzerland | Freely |
| Otrivin Metered Dose Nasal Spray 0.05%—Children | do. | do. | do. |
| Otrivin Nasal Drops Solution 0.1%—Adults | do. | do. | do. |
| Otrivin Metered Dose Nasal Spray 0.1%—Adults | do. | do. | do. |
| Otrivin Nasal Spray Nebuliser 0.1%—Adults | do. | do. | do. |
| Otrivin Nasal Gel 0.1%—Adults | do. | do. | do. |
| Venoruton Effervescent Tablets 1000 mg | Manufactured by Swiss Co Services AG for Novartis Consumer Health SA Switzerland | do. | Third Schedule |
| Diovol Filmkote Caplets | Carter-Horner Corp. | Canada | Freely |
| Diovol Regular Strength Chewable Tablets —Fresh Mint | Carter-Horner Inc. | do. | do. |
| Diovol Regular Strength Suspension—Fresh Mint | Carter-Horner Corp. | do. | do. |
| Diovol Plus Chewable Tablets—Fresh Mint | do. | do. | do. |
| Diovol Plus Suspension —Fresh Mint | do. | do. | do. |
| Diovol Plus Suspension —Tropical Fruit | do. | do. | do. |
| Diovol Plus Chewable Tablets—Tropical Fruit | do. | do. | do. |
| Ovol Regular Strength Chewable Tablets 80 mg —Mint Flavour | do. | do. | do. |
| Ovol Ultra Strength Chewable Tablets 180 mg —Cherry Flavour | do. | do. | do. |
| Geodon Powder for Solution for Injection 20 mg/ml | Manufactured by Ben Venue Laboratories USA Packaged by Pfizer Ireland Pharmaceuticals | Ireland | Third Schedule |

| <i>Trade Name and Form</i> | <i>Manufacturer</i> | <i>Country of Origin</i> | <i>Condition of Sale</i> |
|---|---|--------------------------|--------------------------|
| Paraplatin (carboplatin aqueous solution) Injection 50 mg (10 mg/mL) (Change of Name of Manufacturer, Change of Pharmaceutical Form and Change of Artwork Design) | Manufactured by Bristol-Myers Squibb Caribbean Company Subsidiary of Bristol-Myers Squibb Company USA | Puerto Rico, USA | Third Schedule |
| Paraplatin (carboplatin aqueous solution) Injection 150 mg (10 mg/mL) (Change of Name of Manufacturer, Change of Pharmaceutical Form and Change of Artwork Design) | do. | do. | do. |
| Paraplatin (carboplatin aqueous solution) Injection 450 mg (10 mg/mL) (Change of Name of Manufacturer, Change of Pharmaceutical Form and Change of Artwork Design) | do. | do. | do. |
| Propofol Injection 1% (10 mg/ml) (Change of Name of Manufacturer, Change of Source and Change of Packaging) | Manufactured by Bharat Serums and Vaccines Ltd. for Baxter Healthcare Corporation USA | India | do. |
| Lescol XL Tablets 80 mg (Change of Source) | Manufactured by Novartis Farmac utica S.A. for Novartis Pharma AG Switzerland | Spain | do. |
| MetroGel Topical Gel 0.75% (Change of Source) | Galderma Production Canada, Inc. | Canada | do. |
| Gyno-Travogen Cream (Additional Source and Change of Artwork Design) | Schering S.p.A. | Italy | do. |
| Risperdal Solution 1 mg/ml (Change of Source) | Janssen Cilag, S.A. de C.V. | Mexico | do. |
| Noroxin Tablets 400 mg (Change of Source) | Merck Sharp & Dohme Mexico S.A. De C.V. | do. | do. |

| <i>Trade Name and Form</i> | <i>Manufacturer</i> | <i>Country of Origin</i> | <i>Condition of Sale</i> |
|---|--|--------------------------|--------------------------|
| Etobay Cream 10% (Change of Artwork Design) | Bayer, S.A. | El Salvador | Third Schedule |
| Etobay Gel 5% (Change of Artwork Design) | do. | do. | do. |
| Etobay Injection Solution 50% (Change of Artwork Design) | Made by Wülfing Pharma GmbH Germany for Bayer AG Germany Packaged by Bayer, S.A. | do. | do. |
| Premarin Tablets 0.3 mg (Change of Artwork Design) | Wyeth Medica Ireland | Ireland | do. |
| Premarin Tablets 0.625 mg (Change of Artwork Design) | do. | do. | do. |
| Premarin Tablets 1.25 mg (Change of Artwork Design) | do. | do. | do. |
| Premele Tablets 0.625/2.5 mg (Change of Source and Change of Artwork Design) | do. | do. | do. |
| Premele Plus Tablets 0.625/5 mg (Change of Source and Change of Artwork Design) | do. | do. | do. |
| Prempak Cyclic Tablets 0.625/5 mg (Change of Source and Change of Artwork Design) | do. | do. | do. |
| Xenical Capsules 120 mg (Change of Source) | Roche S.p.A. | Italy | do. |
| Sudafed Tablets (Change of Source) | Glaxo Wellcome Mexico, S.A. de C.V. | Mexico | Freely |
| Sudafed Syrup (Change of Source) | do. | do. | do. |
| Puri-nethol Tablets 50 mg (Additional Source, Change of Name of Manufacturer and Change of Artwork Design) | Heumann Pharma GmbH | Germany | Third Schedule |

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|--|---|--------------------------|---|
| Imuran Tablets 50 mg (Additional Source, Change of Name of Manufacturer and Change of Artwork Design) | Heumann Pharma GmbH | Germany | Third Schedule |
| Natural HRT Capsules | Swiss Herbal Remedies Ltd. | Canada | do. |
| Rub. A535 Ancient Secret Natural Source Ointment | Carter-Horner Corp. | do. | Freely |
| Tolfedine Tablets 60 mg | Vétoquinol Canada Inc. | do. | do. |
| Tolfedine Sterile Injectable Solution 4% | Vétoquinol N.-A. Inc. | do. | To Veterinarians or by Veterinary Prescription Only |
| Mineralytes Plus Soluble Powder | P.V.U., division of Vétoquinol N.-A. Inc. | do. | Freely |
| Paratak Tablets | Bomac Laboratories Ltd. | New Zealand | do. |
| Micohex Shampoo | Cipla Ltd. | India | To Veterinarians or by Veterinary Prescription Only |
| Zimecterin Gold Oral Paste | Marketed by Merial Limited USA (Product of Puerto Rico, USA) | Puerto Rico, USA | Freely |
| Multivitamin Injection Solution | Manufactured by Norbrook Laboratories Limited Distributed by Norbrook Laboratories (GB) Ltd. UK | Northern Ireland | To Veterinarians or by Veterinary Prescription Only |
| Combivit Injectable Solution | do. | do. | do. |
| Colvasone Solution for Injection | do. | do. | do. |
| Norodine 24 Injectable Solution | do. | do. | do. |
| Norodine Bolus | do. | do. | do. |
| Norodine Equine Paste | do. | do. | do. |
| Alkay-ER Extended Release Film-Coated Tablets | BDH Industries Ltd. | India | Third Schedule |
| Fluconazole Hard Gelatin Capsules 150 mg | do. | do. | do. |

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|----------------------------------|---|--------------------------|---|
| LAS-Nevirapine Tablets 200 mg | Manufactured by Cipla Ltd. for Lasmed a division of Lasco Distributors Ltd. Jamaica | India | Third Schedule |
| Protektor Liquid | Cipla Ltd. | do. | To Veterinarians or by Veterinary Prescription Only |
| Heartz Tablets | do. | do. | Freely |
| Ivocip Injection 1% w/v | do. | do. | To Veterinarians or by Veterinary Prescription Only |

Dated this 23rd day of November, 2004.

J. RAHAEL
Minister of Health