

LEGAL NOTICE No. 423

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
HeartCare® Capsules	Himalaya Wellness Company Makali, Bengaluru 562162	India	Freely
LiverCare® Capsules	do.	do.	do.
Organic Amla Caplets	do.	do.	do.
Organic Ashwagandha Caplets	do.	do.	do.
StressCare® Capsules	do.	do.	do.
Amtas-5 (Amlodipine Besylate Tablets USP 5 mg)	Intas Pharmaceuticals Ltd., Plot no. 457 & 458, Village Matoda, Bavla Road and Plot No. 191/218 P, Village Chacharwadi, Talsanand, Vill- Matoda & Chancharwadi-382 210, Dist. - Ahmedabad Gujarat State, India	India	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Amtas-10 (Amlodipine Besylate Tablets USP 10 mg)	Intas Pharmaceuticals Ltd., Plot no. 457 & 458, Village Matoda, Bavla Road and Plot No. 191/218 P, Village Chacharwadi, Talsanand, Vill- Matoda & Chancharwadi-382 210, Dist. - Ahmedabad Gujarat State, India	India	Third Schedule
Tuznue (trastuzumab) Powder for Concentrate for Solution for Infusion 150 mg	Laboratorio Reig Jofre, S.A. Gran Capitán, 10, Sant Joan Despi, 08970 Barcelona	Spain	do.
Tuznue (trastuzumab) Powder for Concentrate for Solution for Infusion 420 mg	do.	do.	do.
Allegra Pediatric Suspension 30 mg/5 mL (Change of Name and Address of Manufacturing Site; Change of Artwork)	Opella Healthcare Brazil Ltda- Rua. Conde Domingos Papaiz, 175 Suzano São Paulo, Brasil	Brazil	do.
Bellasol Chewable Lozenges	Thione International Inc. ARNET Pharmaceutical, 2525 Davie Road, Suite 330 Davie, Florida 3317	United States of America	Freely
Dimethyl Fumarate Delayed Release Capsules 120 mg (DIMAF 120)	MSN Laboratories Private Limited Formulation Division, Unit-II SY.No, 1277 & 1319-1324, Nandigama Village Nandigama Mandal, Ranga Reddy District, Pincode 509228	India	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
	Telangana State India		
Dimethyl Fumarate Delayed Release Capsules 240 mg (DIMAF 240)	MSN Laboratories Private Limited Formulation Division, Unit-II SY.No, 1277 & 1319-1324, Nandigama Village Nandigama Mandal, Ranga Reddy District, Pincode 509228 Telangana State India	India	Third Schedule
Levetiracetam Tablets 750 mg (LEVANEXT 750)	do.	do.	do.
Levetiracetam Tablets 1000 mg (LEVANEXT 1000)	do.	do.	do.
Pirfenidone Tablets 267 mg (FENIFIB 267)	do.	do.	do.
Pirfenidone Tablets 801 mg (FENIFIB 801)	do.	do.	do.
Ivabradine Tablets 5 mg	do.	do.	do.
Ivabradine Tablets 7.5 mg	do.	do.	do.
Greens Best Magnesium Glycinate Capsules 500 mg	GB International LLC 10651 SW 88th Street, Suite # 118 Miami FL 33176	United States of America	Freely
Tiova HFA Inhaler 9 mcg CFC-Free	Cipla Ltd Plot # 9-10, Indore Special Economic Zone, Phase -II, Pithampur, Dist. Dhar, Pin code 454777, Madhya Pradesh	India	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Hylupro Eye Drops (Sodium Hyaluronate 0.18%) Ophthalmic Solution 10 mL	Indoco Remedies Limited Indoco House, 166, CST Road, Santacruz (E), Mumbai 400098	India	Freely
Irivisc DS Eye Drops (Carboxymethylcellulose 1.0%) Ophthalmic Solution 10 mL	do.	do.	do.
Irivisc Eye Drops (Carboxymethylcellulose 0.5%) Ophthalmic Solution 10 ml	do.	do.	do.
Purevision Eye Drops (Hypromellose) Ophthalmic Solution 10 mL	do.	do.	do.
TearDuo Eye Drops (Polyethylene Glycol 400 & Propylene Glycol) Ophthalmic Solution 10 mL	do.	do.	do.
Cofsil Lozenges (Orange) (Change of Marketing Authorisation Holder and Change of Artwork)	Cipla Health Ltd Tower B, 7th Floor, Peninsula Business Park, Ganapatrao Kadam Marg, Lower Parel, Mumbai Mumbai City MH 400013, Maharashtra	India	do.
Buscovan Syrup 8 mg/5 mL (Change of Name of Product and Change of Label Declarations)	Accretion Pharmaceuticals Limited. 29, Xcelon Industrial Park-1, Behind Intas Pharmaceuticals, Vasna- Chacharwadi, Tal. Sanand, Dist. Ahmedabad, Gujarat- 382213	India	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Hyland's 4 Kids Cough & Mucus Daytime Liquid - Grape Flavor	Hyland's Consumer Health Inc. 13301 South Main Street, Los Angeles, CA	United States of America	Freely
Honitus Hot Sip Granules	Dabur India Ltd. 22, SITE-IV, SAHIBABAD, (U.P.) - 201010, India	India	do.
EtanerRel (Etanercept Solution for Injection 25 mg/0.5 mL)	Reliance Life Sciences Pvt. Ltd Dhirubhai Ambani Life Sciences Center, Plant 2&7, Plot No. R282, TTC Area of MIDC, Thane Belapur Road, Rabale, Navi Mumbai Thane 400701 Maharashtra State	India	Third Schedule
AdaliRel (Adalimumab Injection 20 mg/0.4 mL) (r-DNA origin)	do.	do.	do.
Bupitroy 0.5% (Bupivacaine Hydrochloride Injection USP)	Troikaa Pharmaceuticals Ltd C-1, Sara Industrial Estate, Selaqui, Dehradun -248197, Uttarakhand	do.	do.
Superoxyt 10 (Oxytocin Injection BP 10 IU/mL)	Steril-Gene Life Sciences (P) Ltd No. 45, Mangalam Main Road, Mangalam Village, Villianur Commune, Puducherry- 605110	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Tenofovir Disoproxil Fumarate, Emtricitabine and Efavirenz Tablets 300 mg/200 mg/600 mg	Mylan Laboratories Limited F-4 & F-12, MIDC, Malegaon, Tal. Sinnar, Nashik 422113 Maharashtra State	India	Third Schedule
Durart 600 (Darunavir Tablets 600 mg)	Mylan Laboratories Limited Plot No. H-12 & H-13, MIDC, WALUJ, Chhatrapati Sambhajingar 431136 Maharashtra State	do.	do.
Budesonide Aqueous Nasal Spray BP 32 mcg/spray	Jewim Pharmaceutical (Shangdong) Co., Ltd No. 5 Leigushi Street, Taian High-Tech Industrial Development Zone, Shandong Province, PRC	China	do.
Bryxta 100 (Bevacizumab 100 mg/4 mL Concentrate for Solution for Intravenous Infusion)	Zydus Lifesciences Limited Plot Survey No. 23, 25/P, 37, 40/P, 42 to 47, Sarkhej-Bavla N.H.No. 8A, Opp. Ramdev Masala, Village: Changodar, Tal: Sanand, Dist: Ahmedabad-382 213	India	do.
Bryxta 400 (Bevacizumab 400 mg/16 mL Concentrate for Solution for Intravenous Infusion)	do.	do.	do.
EtanerRel 50 (Etanercept Solution for Injection 50 mg/mL in PFS)	Reliance Life Sciences Pvt. Ltd Dhirubhai Ambani Life Sciences Center, Plant 2 & 7 Plot No. R-282, TTC Area of MIDC,	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
	Thane Belapur Road, Rabale, Navi Mumbai Thane 400701, Maharashtra State		
Terbinafine Hydrochloride Cream 1% w/v	Alaina Healthcare Pvt Ltd Kharsa No. 127-132, 707/133 & 685/608/32, Village Jharmajri, Baddi, Distt. Solan (H.P) Manufactured for: Remus Pharmaceuticals Ltd 1101-B, 1102 & 1103, 11th Floor, South Tower, One 42, Ambli Bopal Road, Opp. Jayantilal Park, Bodakdev, Ahmedabad-380054, Gujarat, India	India	Third Schedule
Intimate Rose Myo & D-Chiro Inositol Powder 40:1	Aviva Natural Supplements LLC 26 Van Dyke Avenue, New Brunswick, NJ 08901	United States of America	Freely
Tranexamic Acid Injection BP 500 mg/5 mL	Protech Telelinks Mauza Ogli, Suketi Road Kala AMB District Simour H.P 173030	India	Third Schedule
ETORIX 120 Film Coated Tablet 120 mg	Eskayef Pharmaceuticals Limited 400 Squibb Road, Tongi Industrial Area, Tongi, Gazipur 1711 Bangladesh	Bangladesh	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Teriflunomide Tablets 14 mg	MSN Laboratories Private Limited Formulation Division, Unit-II SY.No, 1277 & 1319-1324, Nandigama Village, Nandigama Mandal, Ranga Reddy District, Pincode 509228 Telangala State, India	India	Third Schedule
Detrusitol SR Prolonged Release Capsules 2 mg (Additional API Manufacturer; Change of Name of API Manufacturer; Change of Name of Distributor)	Catalent Pharma Solutions LLC, 1100 Enterprise Drive, Winchester, Kentucky (KY) 40391, USA Packager: Pfizer Italy S.r.l., Italy Localita Marino Del Tronto - 63100 Ascoli Piceno (AP) Italy	Italy	do.
Detrusitol SR Prolonged Release Capsules 4 mg (Additional API Manufacturer; Change of Name of API Manufacturer; Change of Name of Distributor)	do.	do.	do.
Depo-Provera Aqueous Suspension for Intramuscular Use Pre filled Syringe 150 mg (Update of Address of Manufacturing Site; Update of Secondary Packaging)	Pfizer Manufacturing Belgium NV, Rijksweg 12, 2870, Puurs-Sint-Amands	Belgium	do.
Depo-Provera Aqueous Suspension for Intramuscular Use Vial 150 mg (Update of Address of Manufacturing Site; Update of Primary and Secondary Artwork)	do.	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Xigduo™ XR 5/1000 mg Extended Release Film Coated Tablets (New Indication; Update of Monograph and Package Insert; Change of Name of Distributor)	Astra Zeneca Pharmaceuticals LP, 4601 Highway 62 East. Mount Vernon. IN 47620 United States of America	United States of America	Third Schedule
Xigduo™ XR 10/1000 mg Extended Release Film Coated Tablets (New Indication; Update of Monograph and Package Insert; Change of Name of Distributor)	do.	do.	do.
Peritol Tablets 4 mg (Change of Container Closure System; Reduction of Shelf life; Change of Name of Distributor)	EGIS Gyógyszergyár Zártkörűen Működő Részvénytársaság (EGIS Pharmaceuticals PLC), 9900 Körmend, Mátyás király utca 65 Hungary	Hungary	do.
Sybrava Solution for Injection in Pre-filled Syringe 284 mg/1.5 mL (Change of Name of Manufacturing and Packaging Site; Change of Artwork)	Novartis Pharmaceutical Manufacturing GmbH Biochemiestraße 10, 6336 Langkampfen Austria	Austria	do.
Co-Diovan Film-Coated Tablets 160 mg/25 mg (Change of Secondary Artwork)	Novartis Farma S.p.A. Via Provinciale Schito 131 - 80058 Torre Annunziata (NA)	Italy	do.
Clexane Solution for Injection in Pre-filled Syringe 20 mg/0.2 mL (Update of Marketing Authorisation Holder; Update of Leaflet; Change of Primary and Secondary Packaging; Change of Logo)	Sanofi Winthrop Industrie 180 Rue Jean Jaures, Maisons-Alfort, 94700	France	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Clexane Solution for Injection in Pre-filled Syringe 40 mg/0.4 mL (Update of Marketing Authorisation Holder; Update of Leaflet; Change of Primary and Secondary Packaging; Change of Logo)	Sanofi Winthrop Industrie 180 Rue Jean Jaures, Maisons-Alfort, 94700	France	Third Schedule
Clexane Solution for Injection in Pre-filled Syringe 60 mg/0.6 mL (Update of Marketing Authorisation Holder; Update of Leaflet; Change of Primary and Secondary Packaging; Change of Logo)	do.	do.	do.
Clexane Solution for Injection in Pre-filled Syringe 80 mg/0.8 mL (Update of Marketing Authorisation Holder; Update of Leaflet; Change of Primary and Secondary Packaging; Change of Logo)	do.	do.	do.
Galvus Tablets 50 mg (Change of Name of Manufacturing and Packaging Site; Change in Artwork; Change in Shelf Life; Change of Name of Distributor)	Novartis Pharmaceutical Manufacturing LLC Verovškova Ulica 57, Ljubljana, 1000	Slovenia	do.
Enbrel 50 mg Solution for Injection in Pre-filled Pen (Update of Address of Manufacturing and Packaging Site)	Pfizer Manufacturing Belgium N.V. Rijksweg 12, 2870 Puurs-Sint-Amands	Belgium	do.
Enbrel Solution for Injection in Pre-Filled Syringe 50 mg (Update of Address of Manufacturing and Packaging Site)	do.	do.	do.
Arcalion Coated Tablets 200 mg (Change of Artwork)	Les Laboratoires Servier Industrie 905 Route De Saran, 45520 Gidy	France	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Imfinzi Injection for Intravenous Use 120 mg/2.4 mL (Additional Indication; Additional Manufacturing Site of Primary and Secondary Packaging Site, Monograph, Insert and Artwork; Change of Name of Distributor)	AstraZeneca AB Gartnavagen Sodertalje, 152 57 Sweden	Sweden	Third Schedule
Imfinzi Injection for Intravenous Use 500 mg/10 mL (Additional Indication; Additional Manufacturing Site of Primary and Secondary Packaging Site, Monograph, Insert and Artwork; Change of Name of Distributor)	do.	do.	do.
Apo-Lithium Carbonate Capsules 150 mg	Apotex Inc. 150 Signet Drive, Toronto, ON, Canada, M9L 1T9 Packaged by: Apotex Inc. 4100 Weston Road, Toronto, ON, Canada, M9L 2Y6	Canada	do.
Apo-Metoprolol Tablets 50 mg	do.	do.	do.
Apo-Moxifloxacin Ophthalmic Solution 0.5% w/v	do.	do.	do.
Apo-Medroxy Tablets 10 mg	do.	do.	do.
Apo-Sitagliptin Malate Tablets 50 mg	do.	do.	do.
Zamine 21 (Drospirenone and Ethinyl Estradiol Tablets USP)	do.	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
MYA (Drospirenone and Ethinyl Estradiol Tablets USP) 3 mg/0.02 mg	Apotex Inc. 150 Signet Drive, Toronto, ON, Canada, M9L 1T9 Packaged by: Apotex Inc. 4100 Weston Road, Toronto, ON, Canada, M9L 2Y6	Canada	Third Schedule
Apo-Celecoxib (Celecoxib) Capsules 200 mg	do.	do.	do.
BORTEZOMIB (Bortezomib for Injection) 3.5 mg Vial	do.	do.	do.
Myatro Eye Drops 0.01% w/v	Hanuchem Laboratories Plot No. 13, Sec. 5, Industrial Area Parwanoo, Dist. Solan, Himachal Pradesh - 173220	India	do.
Myatro-XL Eye Drops 0.05% w/v	do.	do.	do.
4 Quin TM Eye Drops	do.	do.	do.

Dated this 15th day of June, 2026.

L. BODOE
Minister of Health