

LEGAL NOTICE No. 196

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
Kesimpta™ 20mg Solution for injection in pre-filled pen	Novartis Pharma Stein AG, Stein, Switzerland For: Novartis Pharma AG, Basel, Switzerland	Switzerland	Third Schedule (Specialist Use Only)
Symbicort Rapihaler 160/4.5µg/inhalation Pressurised inhalation suspension for oral inhalation	AstraZeneca Dunkerque Production (AZDP), Dunkerque, France For: AstraZeneca AG, Switzerland	France	Third Schedule
Pifeltro®100 mg Film Coated Tablets	MSD International GMBH Clonmel, Ireland Packaged by: Merck Sharp & Dohme B.V., Haarlem, The Netherlands	The Netherlands	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Delstrigo®100mg/300mg/ 300mg Film coated tablets	MSD International GMBH Clonmel, Ireland Packaged by: Merck Sharp & Dohme B.V., Haarlem, The Netherlands	The Netherlands	Third Schedule
Tylenol® Cold + Flu Severe Caplets for Adults	Janssen Cilag SpA, Italy Distributed by: Johnson & Johnson Consumer Inc., USA	Italy	Freely
Colgate® Enamel Strength Sparkling Fresh Mint Anticavity Protection Fluoride Mouthwash	Colgate-Palmolive Company, U.S.A.	United States of America	Freely
Vastarel® OD 80mg prolonged-release hard capsule	EGIS Pharmaceuticals PLC, Hungary For: Les Laboratoires Servier- France	Hungary	Third Schedule
Carivalan™ 6.25mg/5mg film-coated tablets	Les Laboratoires Servier Industrie, France For: Les Laboratoires Servier, France	France	Third Schedule
Carivalan™ 6.25mg/7.5mg film-coated tablets	do.	do.	do.
Carivalan™ 12.5mg/5mg film-coated tablets	do.	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Carivalan™ 12.5mg/7.5mg film-coated tablets	Les Laboratoires Servier Industrie, France For: Les Laboratoires Servier, France	France	Third Schedule
Carivalan™ 25mg/5mg film-coated tablets	do.	do.	do.
Carivalan™ 25mg/7.5mg film-coated tablets	do.	do.	do.
Saizen® 6mg (5.83mg/mL) injectable solution in pre-filled cartridge	Merck Serono S.p.A., Via Delle Magnolie, Italy For: Merck S.A., Guatemala	Italy	Third Schedule (Specialist Use Only)
Saizen® 12mg (8mg/mL) injectable solution in pre-filled cartridge	do.	do.	do.
Gliclazide 60mg MR modified release tablets	Les Laboratoires Servier Industrie, France For: Les Laboratoires Servier, France	France	Third Schedule
Oncaspar 750U/ml powder for solution for Injection/Infusion	Lyophilization Services Of New England INC., USA Packaged by: Exelead Inc., Indianapolis, Indiana, USA For: Les Laboratoires Servier, France	United States of America	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Lipocomb 10mg/10mg hard capsule	EGIS Pharmaceuticals PLC, Körmend-Hungary Packaged by: EGIS Pharmaceuticals PLC, Budapest- Hungary For: Servier Centro América y Caribe S.A.	Hungary	Third Schedule
Lipocomb 20mg/10mg hard capsule	do.	do.	do.
Fasenra™ 30mg/1ml solution for injection in Pen	Manufacturer and Primary Packager: Catalent Indiana, LLC, USA Assembled and Packaged by: Amylin Ohio LLC, USA For: AstraZeneca AB, Sweden	United States of America	Third Schedule (Specialist Use Only)
Fasenra™ 30mg/1ml solution for injection in pre- filled syringe	do.	do.	do.
Betaserc® 16mg Tablets	Mylan Laboratories S.A.S., France Packaged by: Abbott Laboratories de México, S.A. de C.V., México For: Abbott Laboratories de México, S.A. de C.V., México	Mexico	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Betaserc® 24mg Tablets	Mylan Laboratories S.A.S., France Packaged by: Abbott Laboratories de México, S.A. de C.V., México For: Abbott Laboratories de México, S.A. de C.V., México	Mexico	Third Schedule
Primovist® 0.25mmol/mL Solution for Injection in prefilled syringe	Bayer AG, Germany	Germany	Third Schedule
Rozlytrek® 100mg Hard capsules	Mayne Pharma Inc., Greenville, North Carolina, USA Packaged by: F.Hoffmann-La Roche Ltd., Kaiseraugst, Switzerland For: F.Hoffmann-La Roche Ltd., Basel, Switzerland	Switzerland	Third Schedule (Specialist Use Only)
Rozlytrek® 200mg Hard capsules	do.	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Tecentriq® 840mg/14ml concentrate for solution for infusion	F.Hoffmann-La Roche Ltd., Kaiseraugst, Switzerland Packaged by F.Hoffmann-La Roche Ltd., Kaiseraugst, Switzerland For: F.Hoffmann-La Roche Ltd., Basel, Switzerland	Switzerland	Third Schedule (Specialist Use Only)
Esbriet® 267mg film-coated tablets	Delpharm Milano S.r.l., Segrate (MI), Italy Packaged by: Delpharm Milano S.r.l., Segrate (MI), Italy For: F.Hoffmann-La Roche Ltd, Basel, Switzerland	Italy	Third Schedule (Specialist Use Only)
Esbriet® 801mg film-coated tablets	do.	do.	do.
Beriplex® P/N 500 Lyophilized powder for solution for injection	CSL Behring GmbH, Germany	Germany	Third Schedule (Specialist Use Only)
Viagra® 25mg Film-coated tablets	Fareva Amboise, France For: Upjohn EESV, Netherlands	France	Third Schedule
Adempas® 0.5mg film-coated tablets	Bayer AG, Germany	Germany	Third Schedule (Specialist Use Only)

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Adempas® 1mg film-coated tablets	Bayer AG, Germany	Germany	Third Schedule (Specialist Use Only)
Adempas® 1.5mg film-coated tablets	do.	do.	do.
Adempas® 2mg film-coated tablets	do.	do.	do.
Adempas® 2.5mg film-coated tablets	do.	do.	do.
Gavreto® 100mg Capsules	Catalent CTS, LLC, United States Packaged by: AndersonBrecon Inc., United States For: F.Hoffmann-La Roche Ltd., Basel, Switzerland	United States of America	Third Schedule (Specialist Use Only)
Verzenio™ 150mg film-coated tablets	Lilly del Caribe, Inc., Carolina, Puerto Rico (PR) 00985, USA Packaged by: Lilly, S.A., Madrid, Spain.	Spain	Third Schedule (Specialist Use Only)
AlbuRx™ 25 Human albumin 25% Solution	CSL Behring LLC, USA	United States of America	Third Schedule (Specialist Use Only)

Dated this 30th day of September, 2022.

T. DEYALSINGH  
*Minister of Health*