

LEGAL NOTICE No. 55

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 |
|---|---|-------------------|--|
| TOZINAMERAN COVID-19mRNA Vaccine (nucleoside modified) COMIRNATY® Concentrate for dispersion, for injection (Tris/Sucrose 10µg per dose) 2.6ml/ Multidose Vial | Baxter Oncology GmbH Kantstraße 2, 33790 Halle/Westfalen, Germany | Germany | Pandemic Use/ Emergency Use Authorization/ Children 5-11 years |
| TOZINAMERAN COVID-19mRNA Vaccine (nucleoside modified) COMIRNATY® Concentrate for dispersion, for injection (Tris/Sucrose 10µg per dose) 2.6ml/ Multidose Vial | Pfizer Manufacturing Belgium NV Rijksweg 12, 2870 Puurs, Belgium | Belgium | Pandemic Use/ Emergency Use Authorization/ Children 5-11 years |
| TOZINAMERAN COVID-19mRNA Vaccine (nucleoside modified) COMIRNATY® Concentrate for dispersion, for injection (Tris/Sucrose 10µg per dose) 2.6ml/ Multidose Vial | Novartis Pharma Stein AG Schaffhauserstrasse, 4332 Stein, Switzerland | Switzerland | Pandemic Use/ Emergency Use Authorization/ Children 5-11 years |

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| TOZINAMERAN COVID-19mRNA Vaccine (nucleoside modified) COMIRNATY® Concentrate for dispersion, for injection (Tris/Sucrose 10µg per dose) 2.6ml/ Multidose Vial | Mibe GmbH Arzneimittel Münchener Straße 15, 06796 Brehna, Germany | Germany | Pandemic Use/ Emergency Use Authorization/ Children 5-11 years |
| TOZINAMERAN COVID-19mRNA Vaccine (nucleoside modified) COMIRNATY® Concentrate for dispersion, for injection (Tris/Sucrose 10µg per dose) 2.6ml/ Multidose Vial | BioNTech Manufacturing GmbH Kupferbergterrasse 17 - 19, 55116 Mainz, Germany | Germany | Pandemic Use/ Emergency Use Authorization/ Children 5-11 years |
| TOZINAMERAN COVID-19mRNA Vaccine (nucleoside modified) COMIRNATY® Concentrate for dispersion, for injection (Tris/Sucrose 10µg per dose) 2.6ml/ Multidose Vial | Delpharm Saint-Remy Rue de L'Isle, 28380 Saint Remy sur Avre, France | Germany | Pandemic Use/ Emergency Use Authorization/ Children 5-11 years |
| TOZINAMERAN COVID-19mRNA Vaccine (nucleoside modified) COMIRNATY® Concentrate for dispersion, for injection (Tris/Sucrose 10µg per dose) 2.6ml/ Multidose Vial | Sanofi-Aventis Deutschland GmbH Bereich Handelsprodukte, Industriepark Hoechst, Brueningstrasse 50, H500, H590, H600, H750, H785, H790, 65926 Frankfurt am Main, Germany | Germany | Pandemic Use/ Emergency Use Authorization/ Children 5-11 years |
| TOZINAMERAN COVID-19mRNA Vaccine (nucleoside modified) COMIRNATY® Concentrate for dispersion, for injection (Tris/Sucrose 10µg per dose) 2.6ml/ Multidose Vial | Siegfried Hameln GmbH, Langes Feld 13, 31789 Hameln, Germany | Germany | Pandemic Use/ Emergency Use Authorization/ Children 5-11 years |

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| TOZINAMERAN COVID-19mRNA Vaccine (nucleoside modified) COMIRNATY® Concentrate for dispersion, for injection (Tris/Sucrose 10µg per dose) 2.6ml/ Multidose Vial | Patheon Italia S.p.A., Viale G.B. Stucchi, 110, 20900 - Monza (MB), Italy | Italy | Pandemic Use/ Emergency Use Authorization/ Children 5-11 years |
| Pfizer-BioNTech COVID-19 Vaccine Tozinameran COVID-19 mRNA Vaccine (nucleoside modified) Concentrate for dispersion, for injection (Tris/Sucrose 10µg per dose) 2.6ml/ Multidose Vial | Pharmacia & Upjohn Company LLC 7000 Portage Road Kalamazoo, MI 49001, United States of America | United States of America | Pandemic Use/ Emergency Use Authorization/ Children 5-11 years |
| Pfizer-BioNTech COVID-19 Vaccine Tozinameran COVID-19 mRNA Vaccine (nucleoside modified) Concentrate for dispersion, for injection (Tris/Sucrose 10µg per dose) 2.6ml/ Multidose Vial | Hospira Inc., a Pfizer Company 1776 Centennial Drive, McPherson, Kansas 67460, United States of America | United States of America | Pandemic Use/ Emergency Use Authorization/ Children 5-11 years |
| Pfizer-BioNTech COVID-19 Vaccine Tozinameran COVID-19 mRNA Vaccine (nucleoside modified) Concentrate for dispersion, for injection (Tris/Sucrose 10µg per dose) 2.6ml/ Multidose Vial | Exelead, Inc. 6925 Guion Road, Indianapolis, IN 46268, United States of America | United States of America | Pandemic Use/ Emergency Use Authorization/ Children 5-11 years |

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| <p>TOZINAMERAN COVID-19mRNA Vaccine (nucleoside modified) COMIRNATY® Concentrate for dispersion, for injection (Tris/Sucrose 30µg per dose) 2ml/ Multidose Vial</p> | <p>Baxter Oncology GmbH Kantstraße 2, 33790 Halle/Westfalen, Germany</p> | Germany | <p>Pandemic Use/ Emergency Use Authorization/ Individual 12 years and above</p> <p>New Indication Pregnant Women (second and third trimester)</p> |
| <p>TOZINAMERAN COVID-19mRNA Vaccine (nucleoside modified) COMIRNATY® Concentrate for dispersion, for injection (Tris/Sucrose 30µg per dose) 2ml/ Multidose Vial</p> | <p>Pfizer Manufacturing Belgium NV Rijksweg 12, 2870 Puurs, Belgium</p> | Belgium | <p>Pandemic Use/ Emergency Use Authorization/ Individual 12 years and above</p> <p>New Indication Pregnant Women (second and third trimester)</p> |
| <p>TOZINAMERAN COVID-19mRNA Vaccine (nucleoside modified) COMIRNATY® Concentrate for dispersion, for injection (Tris/Sucrose 30µg per dose) 2ml/ Multidose Vial</p> | <p>Novartis Pharma Stein AG Schaffhauserstrasse, 4332 Stein, Switzerland</p> | Switzerland | <p>Pandemic Use/ Emergency Use Authorization/ Individual 12 years and above</p> <p>New Indication Pregnant Women (second and third trimester)</p> |

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Dated this 2nd day of March, 2022.

T. DEYALSINGH
Minister of Health