World Health Organization

WHO - Prequalification of Medical Products (IVDs, Medicines, Vaccines and Immunization Devices, Vector Control)

WHO recommendation Tozinameran – COVID-19 mRNA vaccine (nucleoside modified) – COMIRNATY®

WHO assessed theTozinameran - COVID-19 mRNA vaccine (nucleoside modified) - COMIRNATY® submitted by Pfizer under the Emergency Use Listing (EUL). The vaccine is expected to be an important tool in response to the COVID-19 pandemic. Based on the available evidence assessed, WHO find that sufficient data is available on the Tozinameran - COVID-19 mRNA vaccine (nucleoside modified) - COMIRNATY® for an EUL recommendation.

Tozinameran - COVID-19 mRNA vaccine (nucleoside modified) - COMIRNATY® is a vaccine for preventing coronavirus disease 2019 (COVID-19) in individuals aged 16 years and older. The vaccine contains a molecule called messenger RNA (mRNA) with instructions for producing a protein from SARS-CoV-2, the virus that causes COVID-19. Novel Covid-19 mRNA vaccine does not contain the virus itself and cannot cause COVID-19.

The use of Tozinameran - COVID-19 mRNA vaccine (nucleoside modified) - COMIRNATY® under an emergency situation has been also endorsed by the European Medicines Agency (EMA), the Food and Drug Administration of the United States of America and Health Canada and other regulatory authorities (including Bahrain, Israel, Kuwait, Mexico, Oman, Qatar, Saudi Arabia, Singapore and the United Kingdom).

TOZINAMERAN - COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) - COMIRNATY®

	Product Overview		
Vaccine type:	Tozinameran - COVD-19 mRNA Vaccine		
Commercial name:	COMIRNATY®		
Manufacturer:	BioNTech Manufacturing GmbH		
Country:	Germany		
URL:	https://biontech.de/ [https://biontech.de/]		
Responsible NRA:	European Medicines Agency		
Country:	The Netherlands		
URL:	https://www.ema.europa.eu/en [https://www.ema.europa.eu/en]		
	WHO Recommendation		
Effective date:	31 December 2020		
	Product Description		
Pharmaceutical form:	Concentrate for dispersion for injection		

form:	injection		
Presentation:	Vial		
Number of doses:	6 doses		
Diluent:	Sodium Chloride Inj USP 0.9%		
Route of administration	Intramuscular		
Shelf-life:	6 months	**at storage temperature:**	- 90°C to - 60°C
Vaccine vial monitor:	None		
Secondary packaging:			
Vaccine:	Carton holding 195 vials (1170 doses). Dimensions: 22.9 x 22.9 x 4.0 cm		
Diluent:	Carton containing 25 diluent vials (10 ml vial). Dimensions: 13.5 x 15 x 5.6 cm		
Tertiary packaging:			
Vaccine:	Insulated box containing 5 secondary cartons with a total of 975 vials (5850doses). External Dimensions: 40 X 40 X 56 cm		
Diluent:	Box containing 16 secondary cartons with a total of 400 vials. External Dimensions: 29.5 x 29.0 x 24.5 cm. The pallet holds 60 boxes containing 16 secondary cartons with a total of 24 000 vials. Pallet dimensions: 121.92 x 101.6 x 137.16 cm.		
Cold chain volume:	1.8	**cm3 (in secondary packaging)**	
Preservative:	None	with concentration:	N/A
Handling of opened	WHO recommends that opened vials of this vaccine should be discarded 6 hours after opening or at the end of		

Remarks:	Each vaccine vial has to be diluted with 1.8 mL of diluent. The remaining volume of diluent cannot be used for the dilution of other vaccine vials and therefore, must be discarded.		

RECOMMENDATION AND PRODUCT INSERT

Recommendation for an Emergency Use Listing (EUL) of Tozinameran (COVID-19mRNA Vaccine (Nucleoside Modified)) submitted by BioNTech Manufacturing GmbH (Published: 31 December 2020) [/pqweb/key-resources/documents/recommendation-emergency-use-listing-eul-covid-19-mrna-vaccine-nucleoside]

Package Insert Tozinameran [/pqweb/key-resources/documents/package-insert-tozinameran]

USPI Tozinameran [/pqweb/key-resources/documents/uspi-tozinameran]

Product Information [/pqweb/key-resources/documents/comirnaty-product-information]