




# COMIRNATY COVID-19 mRNA Vaccine (nucleoside modified) Formulations Guide



A quick reference to dosing, dilution, and storage information for formulations for individuals 12 years and older

Formulation and Name of the Medicinal Product	12 years and older, Ready to use, Omicron XBB.1.5 30 micrograms/dose dispersion for injection	12 years and older, Ready to use, Original/Omicron BA.4-5 (15/15 micrograms)/dose dispersion for injection	12 years and older, Ready to use, Original/Omicron BA.1 (15/15 micrograms)/dose dispersion for injection
Vial Cap Colour	Grey <b>Omicron XBB.1.5</b> 	Grey <b>Original/Omicron BA.4-5</b> 	Grey <b>Original/Omicron BA.1 BOOSTER ONLY</b> 
Dosage	30 mcg of raxtozinameran	15 mcg of tozinameran and 15 mcg of famtozinameran	15 mcg of tozinameran and 15 mcg of riltozinameran
Injection Volume per Dose	0.3 mL	0.3 mL	0.3 mL
Dilution	<b>NO DILUTION</b>	<b>NO DILUTION</b>	<b>NO DILUTION</b>
Amount of Diluent Needed per Vial*	<b>NO DILUTION</b>	<b>NO DILUTION</b>	<b>NO DILUTION</b>
Doses per Vial	Single dose vial contains 1 dose OR Multi-dose vial contains 6 doses	Single dose vial contains 1 dose OR Multi-dose vial contains 6 doses	6 doses per vial
Fill Volume per Vial	2.25 mL for multi-dose vial	2.25 mL for multi-dose vial	2.25 mL
ULT Freezer (-90 °C to -60 °C)	18 months (shelf life) <sup>†</sup>	2 years (shelf life) <sup>†</sup>	2 years (shelf life) <sup>†</sup>
Freezer Storage Time (-25 °C to -15 °C)	<b>DO NOT STORE</b>	<b>DO NOT STORE</b>	<b>DO NOT STORE</b>
Refrigeration Storage Time (2 °C to 8 °C)	10 weeks	10 weeks	10 weeks
Room Temperature (8 °C to 30 °C)	12 hours prior to first puncture (including any thaw time)	12 hours prior to first puncture (including any thaw time)	12 hours prior to first puncture (including any thaw time)
After First Puncture (2 °C to 30 °C)	Discard after 12 hours	Discard after 12 hours	Discard after 12 hours

Additional formulations for individuals 12 years and older included on the next page. →

# COMIRNATY COVID-19 mRNA Vaccine (nucleoside modified) Formulations Guide




A quick reference to dosing, dilution, and storage information for formulations for individuals 12 years and older

Formulation and Name of the Medicinal Product	12 years and older, Ready to use, 30 micrograms/dose dispersion for injection	Dilute to use, 12 years and older, 30 micrograms/dose concentrate for dispersion for injection
Vial Cap Colour	Grey 	Purple 
Dosage	<b>30 mcg</b>	<b>30 mcg</b>
Injection Volume per Dose	0.3 mL	0.3 mL
Dilution	<b>NO DILUTION</b>	Dilution required
Amount of Diluent Needed per Vial*	<b>NO DILUTION</b>	1.8 mL
Doses per Vial	Single dose vial contains 1 dose OR Multi-dose vial contains 6 doses	6 doses per vial (after dilution)
Fill Volume per Vial	2.25 mL for multi-dose vial	0.45 mL
ULT Freezer (-90 °C to -60 °C)	2 years (shelf life) <sup>†</sup>	2 years (shelf life) <sup>†</sup>
Freezer Storage Time (-25 °C to -15 °C)	<b>DO NOT STORE</b>	2 weeks
Refrigeration Storage Time (2 °C to 8 °C)	10 weeks	1 month
Room Temperature (8 °C to 30 °C)	12 hours prior to first puncture (including any thaw time)	2 hours prior to dilution (including any thaw time)
After First Puncture (2 °C to 30 °C)	Discard after 12 hours	Discard after 6 hours

Continue on to the next page for formulations for children 5 to 11 years old. →

# COMIRNATY COVID-19 mRNA Vaccine (nucleoside modified) Formulations Guide



A quick reference to dosing, dilution, and storage information for formulations for children 5 to 11 years old

Formulation and Name of the Medicinal Product	5 to 11 years old, Dilute to use, Omicron XBB.1.5 10 micrograms/dose concentrate for dispersion for injection	5 to 11 years old, Dilute to use, Original/Omicron BA.4-5 (5/5 micrograms)/dose concentrate for dispersion for injection	5 to 11 years old, Dilute to use 10 micrograms/dose concentrate for dispersion for injection	5 to 11 years old, Ready to use, Omicron XBB.1.5 10 micrograms/dose dispersion for injection
Vial Cap Colour	Orange Omicron XBB.1.5 	Orange Original/Omicron BA.4-5 	Orange 	Blue Omicron XBB.1.5 
Dosage	10 mcg of raxtozinameran	5 mcg of tozinameran and 5 mcg of famtozinameran	10 mcg	10 mcg of raxtozinameran
Injection Volume per Dose	0.2 mL	0.2 mL	0.2 mL	0.3 mL
Dilution	Dilution required	Dilution required	Dilution required	<b>NO DILUTION</b>
Amount of Diluent Needed per Vial*	1.3 mL	1.3 mL	1.3 mL	<b>NO DILUTION</b>
Doses per Vial	10 doses per vial (after dilution)	10 doses per vial (after dilution)	10 doses per vial (after dilution)	Single dose vial contains 1 dose OR Multi-dose vial contains 6 doses
Fill Volume per Vial	1.3 mL	1.3 mL	1.3 mL	2.25 mL for multi-dose vial
ULT Freezer (-90 °C to -60 °C)	18 months (shelf life) <sup>†</sup>	2 years (shelf life) <sup>†</sup>	2 years (shelf life) <sup>†</sup>	12 months (shelf life) <sup>†</sup>
Freezer Storage Time (-25 °C to -15 °C)	<b>DO NOT STORE</b>	<b>DO NOT STORE</b>	<b>DO NOT STORE</b>	<b>DO NOT STORE</b>
Refrigeration Storage Time (2 °C to 8 °C)	10 weeks	10 weeks	10 weeks	10 weeks
Room Temperature (8 °C to 30 °C)	2 hours prior to dilution (including any thaw time)	2 hours prior to dilution (including any thaw time)	12 hours prior to dilution (including any thaw time)	12 hours prior to first puncture (including any thaw time)
After First Puncture (2 °C to 30 °C)	Discard after 12 hours	Discard after 12 hours	Discard after 12 hours	Discard after 12 hours

Continue on to the next page for formulations for infants and children 6 months to 4 years old. →

# COMIRNATY COVID-19 mRNA Vaccine (nucleoside modified) Formulations Guide

A quick reference to dosing, dilution, and storage information for formulations for infants and children 6 months to 4 years old

Formulation and Name of the Medicinal Product	6 months to 4 years old, Dilute to use, Omicron XBB.1.5 3 micrograms/dose concentrate for dispersion for injection	6 months to 4 years old, Dilute to use Original/Omicron BA.4-5 (1.5/1.5 micrograms)/dose concentrate for dispersion for injection	6 months to 4 years old, Dilute to use 3 micrograms/dose concentrate for dispersion for injection
Vial Cap Colour	Maroon Omicron XBB.1.5 	Maroon Original/Omicron BA.4-5 	Maroon 
Dosage	3 mcg of raxtozinameran	1.5 mcg of tozinameran and 1.5 mcg of famtozinameran	3 mcg
Injection Volume per Dose	0.2 mL	0.2 mL	0.2 mL
Dilution	Dilution required	Dilution required	Dilution required
Amount of Diluent Needed per Vial*	2.2 mL	2.2 mL	2.2 mL
Doses per Vial	10 doses per vial (after dilution)	10 doses per vial (after dilution)	10 doses per vial (after dilution)
Fill Volume per Vial	0.4 mL	0.4 mL	0.4 mL
ULT Freezer (-90 °C to -60 °C)	18 months (shelf life) <sup>†</sup>	18 months (shelf life) <sup>†</sup>	2 years (shelf life) <sup>†</sup>
Freezer Storage Time (-25 °C to -15 °C)	<b>DO NOT STORE</b>	<b>DO NOT STORE</b>	<b>DO NOT STORE</b>
Refrigeration Storage Time (2 °C to 8 °C)	10 weeks	10 weeks	10 weeks
Room Temperature (8 °C to 30 °C)	12 hours prior to dilution (including any thaw time)	12 hours prior to dilution (including any thaw time)	12 hours prior to dilution (including any thaw time)
After First Puncture (2 °C to 30 °C)	Discard after 12 hours	Discard after 12 hours	Discard after 12 hours

Additional information about all formulations included on the next page. →

### A Marketing Authorisation has been granted in the EU:

- for the product COMIRNATY Omicron XBB.1.5 COVID-19 mRNA Vaccine (nucleoside modified) for active immunisation to prevent COVID-19 caused by SARS-CoV-2, in infants and children aged 6 months to 4 years (3 micrograms/dose), in children aged 5 to 11 years (10 micrograms/dose), and in individuals 12 years of age and older (30 micrograms/dose)
- for the product COMIRNATY Original/Omicron BA.4-5 COVID-19 mRNA Vaccine (nucleoside modified) for active immunisation to prevent COVID-19 caused by SARS-CoV-2, in infants and children aged 6 months to 4 years [(1.5/1.5 micrograms)/dose], in children aged 5 to 11 years [(5/5 micrograms)/dose], and in individuals 12 years of age and older [(15/15 micrograms)/dose]
- for the product COMIRNATY Original/Omicron BA.1 COVID-19 mRNA Vaccine (nucleoside modified) for active immunisation to prevent COVID-19 caused by SARS-CoV-2, in individuals 12 years of age and older [(15/15 micrograms)/dose] who have previously received at least a primary vaccination course against COVID-19
- for the product COMIRNATY COVID-19 mRNA Vaccine (nucleoside modified) (Pfizer-BioNTech COVID-19 Vaccine in several countries) for active immunisation to prevent COVID-19 caused by SARS-CoV-2, in infants and children aged 6 months to 4 years of age (3 micrograms/dose), in children aged 5 to 11 years (10 micrograms/dose), and in individuals 12 years of age and older (30 micrograms/dose)

Before administering COMIRNATY, please refer to the Summary of Product Characteristics for each formulation available at [www.COMIRNATYeducation.xyz](http://www.COMIRNATYeducation.xyz).

\*Diluent: sterile sodium chloride 9 mg/mL (0.9%) solution for injection. Bacteriostatic saline or other diluents must NOT be used.

†In consequence of the extension of the shelf life, the handling of the EU-serialization for medicinal products according to the delegated Regulation (EU) 2016/161 must also be considered. Please be aware that during the verification/decommissioning of the unique identifier an alert for the effected batches will appear that the package has expired. The labelled expiration date on the product and the stored data in the NMVS repository is not taking the extended shelf life into account. Kindly share this information with the central pharmacy, wholesalers and persons authorised or entitled to supply COMIRNATY. For more specific expiry date information, please refer to [the Dear Healthcare Professional Letter distributed on <date> or the detailed expiry date information disseminated by <Country Healthcare Authority> on <date>](#).

NMVS=National Medicines Verification System.



For more information on COMIRNATY, please visit [www.COMIRNATYeducation.xyz](http://www.COMIRNATYeducation.xyz)

**BIONTECH**



Marketing Authorisation  
Holder: BioNTech  
Manufacturing GmbH

COMIRNATY COVID-19 mRNA Vaccine (nucleoside modified), which is based on BioNTech proprietary mRNA technology, was developed by both BioNTech and Pfizer.

**COMIRNATY™**  
COVID-19 mRNA Vaccine (nucleoside modified)

PP-CMR-GLB-0512  
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