

# New single dose glass prefilled syringes from BioNTech and Pfizer, which are never frozen

## How ordering works

COMIRNATY is now available in a single dose glass prefilled syringe (DO NOT FREEZE) that should never be frozen. COMIRNATY is approved for individuals 12 years of age and older to help protect against COVID-19. To receive this presentation, place an order through Pfizer Prime or a wholesaler. Limited quantities are available.

## Credit for returns on orders

**For orders through Pfizer Prime:** Credit or refund will be issued for returned units of each NDC up to the greater of 1) the direct purchase minimum order quantity units of sale, or 2) 15% of the total doses purchased during the "Season" (as defined in the Returns Goods Policy).

**For orders through wholesalers:** Will be limited to the minimum order quantity required by Pfizer (rather than the wholesaler minimum order quantity). Credit will be issued to the customer's wholesaler account.

Returns in the amount up to the minimum order quantity will be processed as they come in. This means the doses can be returned at any time and credit or refund will be processed, subject to the terms and conditions in the Terms of Sale/Return Goods Policy.\*

## Selected Safety Information

Do not administer COMIRNATY® (COVID-19 Vaccine, mRNA) to individuals with a known history of a severe allergic reaction (e.g., anaphylaxis) to any component of COMIRNATY or to individuals who had a severe allergic reaction (e.g., anaphylaxis) following a previous dose of a Pfizer-BioNTech COVID-19 vaccine.

\*The full Terms of Sale/Return Goods Policy can be viewed at [primevaccines.pfizer.com](https://primevaccines.pfizer.com) under "Terms of Sale."



**Now available to order and stock in your practice**

**Ordering information for COMIRNATY Single Dose  
Glass Prefilled Syringes 2023-2024 Formula  
(DO NOT FREEZE)**

**For 12 Years of Age and Older  
A single dose is 0.3 mL**

**Carton of 10 Single Dose Glass Prefilled Syringes:**  
NDC 0069-2377-10

**Minimum order:**  
Direct—20 (2 boxes x 10 glass prefilled syringes)  
Wholesalers—Contact wholesaler for info

- During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.
- The vaccine should not be used after the expiration date printed on the prefilled syringes and cartons.

**COMIRNATY®**  
(COVID-19 Vaccine, mRNA)

## Frequently asked questions

### 1 What is the formulation and dosing for the single dose glass prefilled syringe (PFS) (NDC 0069-2377-10)?

All presentations of COMIRNATY, including the single dose glass PFS (DO NOT FREEZE), are formulated to contain 30 mcg (0.3 mL) of modRNA encoding Omicron variant lineage XBB.1.5 (Omicron XBB.1.5). Because the single dose glass PFS is never frozen, its requirements for storage and handling differ from the single dose plastic PFS.

### 2 How do I store the single dose glass PFS (DO NOT FREEZE)?

Product must never be frozen and should be stored refrigerated at 2 °C to 8 °C (35 °F to 46 °F). Do not freeze single dose glass PFS. If single dose glass PFS have been frozen, discard.

### 3 How will product ship to the customer?

Product will ship from Pfizer Prime or wholesalers at 2 °C to 8 °C (35 °F to 46 °F). There will not be a relabel on this product with an updated expiry. The expiry indicated on the carton reflects the product expiry (6 months from date of manufacture). Once the customer receives the product, it must be stored at 2 °C to 8 °C (35 °F to 46 °F) and cannot be put into the freezer or ULT storage. **DO NOT FREEZE.**

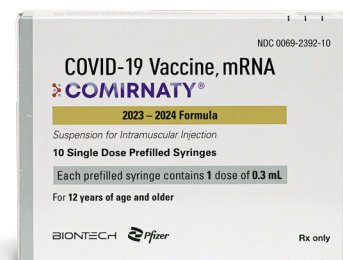
### 4 What is the product expiry?

A single dose glass PFS (DO NOT FREEZE) is refrigerator stable for up to 6 months from date of manufacture not to exceed the expiration date printed on the carton and syringe labels.

### 5 How can I tell the difference between the single dose plastic PFS and the single dose glass PFS (DO NOT FREEZE)?

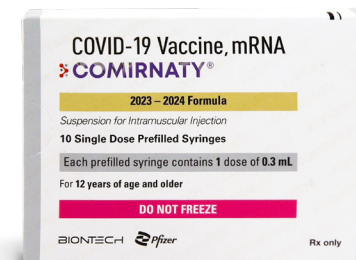
Below is a picture of both the single dose plastic and glass PFS cartons for you to review. There is a pink highlighted bar on the single dose glass PFS carton that states **"DO NOT FREEZE."** Once the barcode is scanned, the expiry date of the product will be displayed. The single dose glass PFS is also shorter and wider than the single dose plastic PFS.

Single dose  
plastic prefilled syringes



NDC 0069-2392-10  
NDC 0069-2392-01

Single dose  
glass prefilled syringes



NDC 0069-2377-10  
NDC 0069-2377-01

### 6 Will the barcode have an expiry date?

Yes, the barcode will have the expiry date, and there is no need for relabeling or updating expiry. Note, expiry could fall within a future month. Please review the expiry date on each carton to ensure product stability.

### 7 What are the carton dimensions?

Carton dimensions are 3.9 in x 3.9 in x 2.1 in.

PFS=prefilled syringe; ULT=ultra-low temperature.

**See Important Safety Information and Indication on page 3.**  
**Please click for [COMIRNATY Full Prescribing Information](#) and [Patient Information](#).**

**COMIRNATY<sup>®</sup>**  
(COVID-19 Vaccine, mRNA)

# Important Safety Information and Indication

## IMPORTANT SAFETY INFORMATION

Do not administer COMIRNATY® (COVID-19 Vaccine, mRNA) to individuals with a known history of a severe allergic reaction (e.g., anaphylaxis) to any component of COMIRNATY or to individuals who had a severe allergic reaction (e.g., anaphylaxis) following a previous dose of a Pfizer-BioNTech COVID-19 vaccine.

### Management of Acute Allergic Reactions

Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of COMIRNATY.

### Myocarditis and Pericarditis

Postmarketing data with authorized or approved mRNA COVID-19 vaccines demonstrate increased risks of myocarditis and pericarditis, particularly within the first week following vaccination. For COMIRNATY, the observed risk is highest in males 12 through 17 years of age.

Although some cases required intensive care support, available data from short-term follow-up suggest that most individuals have had resolution of symptoms with conservative management. Information is not yet available about potential long-term sequelae.

The Centers for Disease Control and Prevention (CDC) has published considerations related to myocarditis and pericarditis after vaccination, including for vaccination of individuals with a history of myocarditis or pericarditis (<https://www.cdc.gov/vaccines/covid-19/clinical-considerations/myocarditis.html>).

**Please click for COMIRNATY Full Prescribing Information and Patient Information.**



Manufactured for  
BioNTech Manufacturing GmbH  
An der Goldgrube 12  
55131 Mainz, Germany  
Marketing Authorization Holder

Manufactured by  
Pfizer Inc.  
New York, NY 10001

COVID-19 vaccines from BioNTech and Pfizer, which are based on BioNTech proprietary mRNA technology, were developed by both BioNTech and Pfizer.

## Syncope

Syncope (fainting) may occur in association with administration of injectable vaccines, including COMIRNATY. Procedures should be in place to avoid injury from fainting.

## Altered Immunocompetence

Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to COMIRNATY.

## Limitation of Vaccine Effectiveness

COMIRNATY may not protect all vaccine recipients.

## Adverse Reactions

The most commonly reported adverse reactions ( $\geq 10\%$ ) after a dose of COMIRNATY were pain at the injection site (up to 90.5%), fatigue (up to 77.5%), headache (up to 75.5%), chills (up to 49.2%), muscle pain (up to 45.5%), joint pain (up to 27.5%), fever (up to 24.3%), injection site swelling (up to 11.8%), and injection site redness (up to 10.4%).

To report SUSPECTED ADVERSE REACTIONS, contact Pfizer Inc. at 1-800-438-1985 or <https://www.pfizersafetyreporting.com> or VAERS at 1-800-822-7967 or <http://vaers.hhs.gov>

## INDICATION

COMIRNATY® (COVID-19 Vaccine, mRNA) is a vaccine indicated for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 12 years of age and older.

 **COMIRNATY®**  
(COVID-19 Vaccine, mRNA)