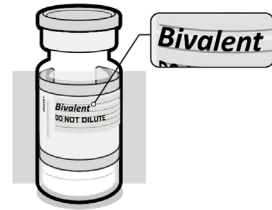


## Vaccine recipient guide for grey cap vials

### For persons vaccinated with PFIZER-BIONTECH COVID-19 VACCINE, BIVALENT (ORIGINAL ANDOMICRON BA.4/BA.5) BOOSTER DOSE FOR 12 YEARS OF AGE AND OLDER



You are being offered the PFIZER-BIONTECH COVID-19 VACCINE, BIVALENT to prevent Coronavirus Disease 2019 (COVID-19) caused by SARS-CoV-2.

**This guide** contains information that may help you understand the risks and benefits of the PFIZER-BIONTECH COVID-19 VACCINE, BIVALENT.

Read all this guide carefully before you receive this vaccine because it contains what important you should know before getting vaccinated.

- Keep this guide; you may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This guide also includes any possible side effects.

**This document is approved by The Executive Directorate of Pharmacovigilance at SFDA.**

#### What is Covid-19 disease?

- COVID-19 disease is caused by a coronavirus called SARS-CoV-2. You can get COVID-19 through contact with another mild symptoms to severe illness.
- Symptoms may appear 2-14 days after exposure to the virus, including fever or chills; cough; shortness of breath; fatigue; muscle or body aches; headache; loss of taste or smell; sore throat; congestion or runny nose; nausea or vomiting; diarrhea.

#### What is PFIZER-BIONTECH COVID-19 VACCINE, BIVALENT?

Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5) is used for active immunization to prevent COVID-19 disease caused by SARS-CoV-2 virus.

For adolescents 12 years of age and older, PFIZER-BIONTECH COVID-19 VACCINE, BIVALENT is authorized. Pfizer-BioNTech COVID-19 Vaccine, Bivalent, Bivalent is made in the same way as Pfizer-BioNTech COVID-19 Vaccine but it also contains an Omicron component to help prevent COVID-19 caused by the Omicron variant of SARS-CoV-2.

The Pfizer-BioNTech COVID-19 Vaccine, Bivalent is provided either:

- A single booster dose to individuals 12 years of age and older at least **2 months after completion of primary vaccination** with any authorized or approved monovalent COVID-19 vaccine
- A single booster dose to individuals 12 years of age and older **at least 2 months after receipt of the most recent booster dose** with any authorized or approved monovalent COVID-19 vaccine.

#### What should you know before taking the vaccine?

COVID-19 Vaccine should not be given in case of allergy to the active substance or any of the other ingredients of this medicine.

Signs of an allergic reaction may include itchy skin rash, shortness of breath and swelling of the face or tongue.

Contact your doctor or healthcare professional immediately or go to the nearest hospital emergency room right away in case of an allergic reaction. It can be life threatening.

## What should you mention to your vaccination provider before you get the PFIZER-BIONTECH COVID-19 VACCINE, BIVALENT?

Tell the vaccination provider about all of your medical condition, including:

- Any allergies
- Have had myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining outside the heart)
- Fever
- immunocompromised or are on a medicine that affects the immune system
- Have received another COVID-19 vaccine
- Have recently received any other vaccine
- Using, have recently used or might use any other medicines
- Have a bleeding disorder or is on a blood thinner
- Have ever fainted in association with an injection

### How is the vaccine given?

The Pfizer-BioNTech COVID-19 Vaccine, BIVALENT is administered intramuscularly in the upper arm as a single booster dose (0.3 mL) at least 2 months after completion of primary vaccination or receipt of the most recent booster dose with any authorized or approved monovalent COVID-19 vaccine.

### What are the ingredients of the vaccine?

Pfizer-BioNTech COVID-19 Vaccine, Bivalent for individuals 12 years of age and older contains the following additional ingredients: **tromethamine, tromethamine hydrochloride and sucrose.**

### What should I do after vaccination?

You will be monitored for 15 minutes after vaccination, with a longer observation period when indicated after clinical assessment. There is a remote chance that the Pfizer-BioNTech COVID-19, BIVALENT Vaccine could cause a severe allergic reaction.

A severe allergic reaction would usually occur within a few minutes to one hour after getting a dose of the Pfizer-BioNTech COVID-19 Vaccine.

### Signs of severe allergic reactions

- Difficulty breathing, swelling of your face and throat.
- A fast heartbeat, a bad rash all over your body.
- Dizziness and weakness.

You should also seek medical attention right away if you have any of the following symptoms after receiving the Pfizer-BioNTech COVID-19 Vaccine, BIVALENT:

- Chest pain
- Shortness of breath
- Feelings of having a fast beating, fluttering, or pounding heart

### What if I am pregnant or breastfeeding?

If you are pregnant or breastfeeding, discuss your options with your healthcare provider.

### What if I am immunocompromised?

Individuals 12 years of age and older may receive a booster dose with Pfizer-BioNTech COVID-19 Vaccine, Bivalent. Vaccinations may not provide full immunity to COVID-19 in people who are immunocompromised, and you should continue to maintain physical precautions to help prevent COVID-19. Your close contacts should be vaccinated as appropriate

#### Can I receive the Pfizer-BioNTech COVID-19 vaccine, BIVALENT with other vaccines?

If you are considering to receive the Pfizer-BioNTech COVID-19 Vaccine, BIVALENT with other vaccines, discuss the options with your healthcare provider.

There is no information on the use of the Pfizer BioNTech COVID-19 Vaccine, BIVALENT with other vaccines.

#### What are the possible side effects of the Pfizer-BioNTech COVID-19 vaccine, BIVALENT?

Like all vaccines, Pfizer BioNTech COVID-19 Vaccine can cause side effects, although not everybody gets them.

Side effects that have been reported with the Pfizer BioNTech COVID-19 Vaccine are:

Very common side effects: may affect more than 1 in 10 people

- injection site: pain, swelling
- Tiredness
- Headache
- muscle pain
- Chills
- joint pain
- Diarrhea
- Fever

Common side effects: may affect up to 1 in 10 people

- injection site redness
- Nausea
- Vomiting

Uncommon side effects: may affect up to 1 in 100 people

- enlarged lymph nodes (more frequently observed after the booster dose)
- feeling unwell
- arm pain
- injection site itching
- allergic reactions such as rash or itching
- feeling weak or lack of energy/sleepy
- decreased appetite

Rare side effects: may affect up to 1 in 1,000 people

- temporary one-sided facial drooping
- allergic reactions such as hives or swelling of the face

Not known (cannot be estimated from the available data)

- severe allergic reaction

- inflammation of the heart muscle (myocarditis) or inflammation of the lining outside the heart (pericarditis) which can result in breathlessness, palpitations or chest pain
- extensive swelling of the vaccinated limb
- swelling of the face (swelling of the face may occur in patients who have had facial dermatological fillers)

These may not be all the possible side effects of the vaccine. Serious and unexpected side effects may occur. The possible side effects of the vaccine are still being studied in clinical trials.

#### **How to manage the side effects?**

Most side effects are mild or moderate and go away within a few days of appearing. If side effects such as pain and/or fever are troublesome, they can be treated by medicines for pain and fever such as paracetamol.

If you experience a severe allergic reaction, go to the nearest hospital.

Call the vaccination provider or your healthcare provider if you have any Side effects that bother you or do not go away.

#### **WILL THE PFIZER-BIONTECH COVID-19 VACCINE, BIVALENT GIVE ME COVID-19?**

No. The Pfizer-BioNTech COVID-19 Vaccine, BIVALENT does not contain SARS-CoV-2 and cannot give COVID-19.

#### **Call for reporting**

As a reminder, there is a need to report any suspected adverse reactions to the National Pharmacovigilance Center (NPC):

#### **Saudi Food and Drug Authority (SFDA) The National Pharmacovigilance Centre (NPC)**

SFDA call center: [19999](tel:19999)

E-mail: [npc.drug@sfda.gov.sa](mailto:npc.drug@sfda.gov.sa) Website:

<http://ade.sfda.gov.sa/>

**Pharmacovigilance department in Pfizer Mobile:** +966 53 906-9565

**E-mail:** [SAU.AEReporting@pfizer.com](mailto:SAU.AEReporting@pfizer.com)

**Tel:** +966 12 229-3633