

Vaccine recipient guide

For **Pfizer-BioNTech** vaccine (COVID-19 mRNA Vaccine BNT162b2)



You are being offered the Pfizer-BioNTech COVID-19 Vaccine to prevent Coronavirus Disease 2019 (COVID 19) caused by SARS-CoV-2. This guide contains information to help you understand the risks and benefits of the Pfizer-BioNTech COVID-19 Vaccine.

Read all of this guide carefully before you receive this vaccine because it contains important information for you.

- 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 includes any possible side effects.

• **What is Covid-19 disease?**

COVID-19 disease is caused by a coronavirus called SARS-CoV-2. This type of coronavirus has not been seen before. You can get COVID-19 through contact with another person who has the virus. It is predominantly a respiratory illness that can affect other organs. People with COVID-19 have reported a wide range of symptoms reported, ranging from mild symptoms to severe illness. Symptoms may appear 2-14 days after exposure to the virus. Symptoms may include: fever or chills; cough; shortness of breath; fatigue; muscle or body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea or vomiting; diarrhea

• **What is Pfizer-BioNTech COVID-19 vaccine?**

It is a type of COVID-19 mRNA used for active immunization prevent COVID-19 disease caused by SARS-CoV-2 virus. It is given to adults and adolescents above 12 years.

• **What should you know before taking the vaccine?**

COVID-19 mRNA Vaccine BNT162b2 should not be given if you are allergic 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 if you have 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?**

Tell the vaccination provider about all of your medical conditions, including if you:

- have any allergies

- have had myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining outside the heart)
- have a fever
- have a bleeding disorder or are on a blood thinner
- are immunocompromised or are on a medicine that affects your immune system
- are pregnant or plan to become pregnant
- are breastfeeding
- have received another COVID-19 vaccine
- are using, have recently used or might use any other medicines or have recently received any other vaccine.

Special population:

- Children and adolescents:

COVID-19 mRNA Vaccine BNT162b2 is not recommended for children under 12 years.

- WHAT IF I AM PREGNANT OR BREASTFEEDING ?

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

- Geriatric: Clinical studies of Pfizer-BioNTech COVID-19 Vaccine include participants 65 years of age and older and their data contributes to the overall assessment of safety and efficacy.

How the vaccine is given

The Pfizer BioNTech COVID-19 Vaccine will be given to you as an injection into the muscle of your upper arm. You will receive 2 injections, given 21 days apart.

If you receive one dose of COVID-19 mRNA Vaccine you should receive a second dose of the same vaccine 21 days later to complete the vaccination series.

Protection against COVID-19 disease may not be effective until at least 7 days after the second dose. If you have any further questions on the use of COVID-19 mRNA Vaccine BNT162b2, ask your doctor, pharmacist or nurse.

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 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 a severe allergic reaction can include:

- Difficulty breathing
- Swelling of your face and throat
- A fast heartbeat
- A bad rash all over your body
- Dizziness and weakness

- Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have occurred in some people who have received the **Pfizer-BioNTech COVID-19 Vaccine**. In most of these people, symptoms began within a few days following receipt of the second dose of the **Pfizer-BioNTech COVID-19 Vaccine**. The chance of having this occur is very low. you should seek medical attention right away if you have any of the following symptoms after receiving the **Pfizer-BioNTech COVID-19 Vaccine**:

chest pain

Shortness of breath

Feelings of having a fast beating, fluttering, or pounding heart

- Can I receive the Pfizer-biontech COVID-19 vaccine with other vaccines?

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

- **What is the possible side effects of the Pfizer-biontech COVID-19 vaccine?**

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:

- injection site pain
- injection site swelling
- redness at injection site
- tiredness
- headache
- muscle pain
- chills
- joint pain
- fever
- Nausea
- Diarrhea
- Feeling unwell
- Swollen lymph nodes (lymphadenopathy)
- Myocarditis (inflammation of the heart muscle)
- Pericarditis (inflammation of the lining outside the heart)

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.

WILL THE PFIZER-BIONTECH COVID-19 VACCINE GIVE ME COVID-19?

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

Call for Reporting

You can report any side effects of COVID-19 mRNA Vaccine BNT162b2 (Pfizer-biontech)via:

1. The National Pharmacovigilance Centre (NPC):

Website <https://ade.sfda.gov.sa>

Email: npc.drug@sfda.gov.sa

Call center number: 19999

2. Pharmacovigilance department in Pfizer:

Mobile: +966 53 9069565

Email : SAU.AEReporting@pfizer.com Tel: + 966

2 2293633

Approved by Saudi Food & Drug Authority, 07/21. Version-2