



Vaccine recipient guide for orange cap vials For Children's parents vaccinated with Pfizer BioNTech COVID-19

Your child is being offered the Pfizer-BioNTech COVID-19 Vaccine 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.

Read all this guide carefully before your child receives this vaccine because it contains what is 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 your child gets 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. Your child can get COVID-19 through contact with another person, 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?

It is a type of COVID-19 mRNA used for active immunization to prevent COVID-19 disease caused by SARS-CoV-2 virus.

It is given to individuals 5 through 11 years of age. Pfizer-BioNTech COVID-19 Vaccine does not include use in individuals younger than 5 years of age.

For adolescents 12 through 17 years of age, a different formulation and a different presentation of this formulation of the Pfizer-BioNTech COVID-19 Vaccine are authorized.

What should you know before your child taking the vaccine?

COVID-19 mRNA 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 take your child 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 your child gets the Pfizer- BioNTech COVID-19 vaccine?

Tell the vaccination provider about all of his/her 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
- Has received another COVID-19 vaccine
- Has recently received any other vaccine
- Using, have recently used or might use any other medicines
- Has a bleeding disorder or is on a blood thinner
- Has ever fainted in association with an injection

How is the vaccine given?

The Pfizer-BioNTech COVID-19 Vaccine is administered intramuscularly in the upper arm as a primary series of 2 doses (0.2 mL each) 3 weeks apart in individuals 5 through 11 years of age.

What should I do after vaccination?

You will monitor your child 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 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 your child has 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 my child receive the Pfizer-BioNTech COVID-19 vaccine with other vaccines?

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

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:

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.

Some of these side effects were slightly more frequent in adolescents 12 to 15 years than in adults.

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 your child experiences a severe allergic reaction, go to the nearest hospital.

Call the vaccination provider or your child's healthcare provider if your child has any

Side effects that bother your child or do not go away.

WILL THE PFIZER-BIONTECH COVID-19 VACCINE GIVE MY CHILD COVID-19?

No. The Pfizer-BioNTech COVID-19 Vaccine 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**

E-mail: 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

Tel: +966 12 229-3633