

## **FACT SHEET FOR RECIPIENTS AND CAREGIVERS**

### **INTERIM AUTHORIZATION OF THE PFIZER-BIONTECH COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19) IN INDIVIDUALS 12 YEARS OF AGE AND OLDER**

You are being offered the Pfizer-BioNTech COVID-19 Vaccine to prevent Coronavirus Disease 2019 (COVID-19) caused by SARS-CoV-2. This Fact Sheet contains information to help you understand the risks and benefits of the Pfizer-BioNTech COVID-19 Vaccine, which you may receive because there is currently a pandemic of COVID-19.

The Pfizer-BioNTech COVID-19 Vaccine is a vaccine and may prevent you from getting COVID-19. There is currently no Health Sciences Authority (HSA) approved vaccine to prevent COVID-19.

Read this Fact Sheet for information about the Pfizer-BioNTech COVID-19 Vaccine. Talk to the vaccination provider if you have questions. It is your choice to receive the Pfizer-BioNTech COVID-19 Vaccine.

The Pfizer-BioNTech COVID-19 Vaccine is administered as a primary 2-dose series, 3 weeks apart, into the muscle.

A booster dose of Pfizer-BioNTech COVID-19 Vaccine may be given after the second dose.

The Pfizer-BioNTech COVID-19 Vaccine may not protect everyone.

This Fact Sheet may have been updated. For the most recent Fact Sheet, please see [www.cvdvaccine.com](http://www.cvdvaccine.com).

### **WHAT YOU NEED TO KNOW BEFORE YOU GET THIS VACCINE**

#### **WHAT IS COVID-19?**

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 had a wide range of symptoms reported, ranging from mild symptoms to severe illness. Symptoms may appear 2 to 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 THE PFIZER-BIONTECH COVID-19 VACCINE?**

The Pfizer-BioNTech COVID-19 Vaccine is an unapproved vaccine that may prevent COVID-19. There is no HSA-approved vaccine to prevent COVID-19.

The HSA has granted interim authorization of the Pfizer-BioNTech COVID-19 Vaccine to prevent COVID-19 in individuals 12 years of age and older under the Pandemic Special Access Route (PSAR).

For more information on Interim Authorization under PSAR, visit HSA at <https://www.hsa.gov.sg/therapeutic-products/register/special-access-routes/psar-emergency-therapeutic-product>.

## **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 feeling nervous about the vaccination process or have ever fainted in association with an injection

## **WHO SHOULD GET THE PFIZER-BIONTECH COVID-19 VACCINE?**

HSA has authorized the emergency use of the Pfizer-BioNTech COVID-19 Vaccine in individuals 12 years of age and older.

## **WHO SHOULD NOT GET THE PFIZER-BIONTECH COVID-19 VACCINE?**

You should not get the Pfizer-BioNTech COVID-19 Vaccine if you:

- had a severe allergic reaction after a previous dose of this vaccine
- had a severe allergic reaction to any ingredient of this vaccine.

## **WHAT ARE THE INGREDIENTS IN THE PFIZER-BIONTECH COVID-19 VACCINE?**

The Pfizer-BioNTech COVID-19 Vaccine includes the following ingredients: mRNA, lipids ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 2 [(polyethylene glycol)-2000]-N,N-ditetradecylacetamide, 1,2-Distearoyl-sn-glycero-3-phosphocholine, and cholesterol), potassium chloride, monobasic potassium phosphate, sodium chloride, dibasic sodium phosphate dihydrate, and sucrose.

## **HOW IS THE PFIZER-BIONTECH COVID-19 VACCINE GIVEN?**

The Pfizer-BioNTech COVID-19 Vaccine will be given to you as an injection into the muscle.

The Pfizer-BioNTech COVID-19 Vaccine primary vaccination series is 2 doses given 3 weeks apart.

If you receive one dose of the Pfizer-BioNTech COVID-19 Vaccine, you should receive a second dose of this same vaccine 3 weeks later to complete the primary vaccination series.

A booster dose of Pfizer-BioNTech COVID-19 Vaccine may be given after the second dose.

### **HAS THE PFIZER-BIONTECH COVID-19 VACCINE BEEN USED BEFORE?**

The Pfizer-BioNTech COVID-19 Vaccine is an unapproved vaccine. In clinical trials, approximately 23,000 individuals 12 years of age and older have received at least 1 dose of the Pfizer-BioNTech COVID-19 Vaccine.

### **WHAT ARE THE BENEFITS OF THE PFIZER-BIONTECH COVID-19 VACCINE?**

In an ongoing clinical trial, the Pfizer-BioNTech COVID-19 Vaccine has been shown to prevent COVID-19 following the 2-dose primary series given 3 weeks apart. The duration of protection against COVID-19 is currently unknown.

### **WHAT ARE THE RISKS OF THE PFIZER-BIONTECH COVID-19 VACCINE?**

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. For this reason, your vaccination provider may ask you to stay at the place where you received your vaccine for monitoring after vaccination. 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 avoid strenuous physical activity for two weeks after vaccination. 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

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

- severe allergic reactions
- non-severe allergic reactions such as rash, itching, hives, or swelling of the face

- myocarditis (inflammation of the heart muscle)
- pericarditis (inflammation of the lining outside the heart)
- injection site pain
- tiredness
- headache
- muscle pain
- chills
- joint pain
- increase in body temperature including fever
- injection site swelling
- injection site redness
- nausea
- feeling unwell
- enlarged lymph nodes (more frequently observed after the booster dose)
- feeling weak or lack of energy/sleepy
- decreased appetite
- excessive sweating
- night sweats
- diarrhea
- vomiting
- arm pain (more frequently observed after the booster dose)
- a skin reaction that causes red spots or patches on the skin, that may look like a target or “bulls-eye” with a dark red center surrounded by paler red rings (erythema multiforme)
- unusual feeling in the skin, such as tingling or a crawling feeling (paresthesia)
- decreased feeling or sensitivity, especially in the skin (hypoesthesia)

These may not be all the possible side effects of the Pfizer-BioNTech COVID-19 Vaccine. Serious and unexpected side effects may occur. Pfizer-BioNTech COVID-19 Vaccine is still being studied in clinical trials.

**WHAT SHOULD I DO ABOUT SIDE EFFECTS?**

If you experience a severe allergic reaction, call 995, or 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.

Report vaccine side effects to **Pfizer Singapore** at the contact information provided below. Please include “Pfizer-BioNTech COVID-19 Vaccine Interim Authorization” in the report.

Email	Fax number	Telephone number
<a href="mailto:SGP.AEReporting@pfizer.com">SGP.AEReporting@pfizer.com</a>	8001012817 (local toll free)	+65 6403 8888

**WHAT IF I DECIDE NOT TO GET THE PFIZER-BIONTECH COVID-19 VACCINE?**

It is your choice to receive or not receive the Pfizer-BioNTech COVID-19 Vaccine. Should you decide not to receive it, it will not change your standard medical care.

**ARE OTHER CHOICES AVAILABLE FOR PREVENTING COVID-19 BESIDES PFIZER-BIONTECH COVID-19 VACCINE?**

Currently, there is no approved alternative vaccine available for prevention of COVID-19. Other vaccines to prevent COVID-19 may be available under Interim Authorization.

**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 IF I AM PREGNANT OR BREASTFEEDING?**

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

**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.


**KEEP YOUR VACCINATION CARD**

When you get your first dose, you will get a vaccination card to show you when to return for your next dose of Pfizer-BioNTech COVID-19 Vaccine. Remember to bring your card when you return.

**ADDITIONAL INFORMATION**

If you have questions, visit the website or call the telephone number provided below.

To access the most recent Fact Sheets, please scan the QR code provided below.

Global website	Telephone number
<a href="http://www.cvdvaccine.com">www.cvdvaccine.com</a> 	+65 6403 8888

Should you have any medical information enquires, you may submit it at <https://pmiform.com/HCP/SG>.

Alternatively, you may send them to [MedicalInformationSingapore@pfizer.com](mailto:MedicalInformationSingapore@pfizer.com).

## HOW CAN I LEARN MORE?

- Ask the vaccination provider.
- Visit HSA at <https://www.hsa.gov.sg/therapeutic-products/register/special-access-routes/psar-emergency-therapeutic-product>.
- Contact your local or state public health department.

## WHERE WILL MY VACCINATION INFORMATION BE RECORDED?

The vaccination provider may include your vaccination information in your state/local jurisdiction's Immunization Information System (IIS) or other designated system. This will ensure that you receive the same vaccine when you return for the next dose.

## BIONTECH

Manufactured for  
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Reference label: CDS version 10.0

Revised: 03 August 2022