

INFORMATION FOR MSK PATIENTS RECEIVING THE

# Pfizer-BioNTech COVID-19 Vaccine



Memorial Sloan Kettering  
Cancer Center

# Understanding and Managing COVID-19 Vaccine Side Effects

## Local side effects (injection site swelling, pain, redness)

Local side effects are very common. As many as 4 out of 5 people who receive the vaccine have arm pain, redness, or swelling at the injection site. These side effects generally go away in a few days.

**What you can do:** Applying ice for 15 minutes to the sore injection site 3 to 4 times per day may be helpful. For more severe soreness, you can also take over-the-counter anti-inflammatory medications such as ibuprofen (Motrin®, Advil®) or naproxen (Aleve®), as long as you don't have a medical condition that makes these medications unsafe.

**When to get help:** If the redness, pain, or swelling at the injection site is getting worse after 2 days, you should **contact your primary MSK care team**.

## Systemic side effects (fever, chills, fatigue, headache, muscle aches, joint aches, nausea)

Most people who receive the COVID vaccine have general side effects like fatigue (feeling tired), fever, and aches, especially after the second dose. These side effects are a sign that your immune system is reacting to the vaccine. They generally occur within the first 3 days after vaccination and last only a day or 2.

**What you can do:** Acetaminophen (Tylenol®) may help alleviate headache, muscle or joint aches, fever, chills, and other symptoms. Be sure to drink plenty of liquids – salty liquids like chicken, beef, or vegetable broth might be especially helpful.

**When to get help:** If your symptoms are getting worse or you do not begin to improve after 2 days, **contact your primary MSK care team**.

## Allergic Reactions

Allergic reactions are rare and could occur after you leave the clinic after receiving the vaccine.

**What you can do:** If you experience signs of a severe allergic reaction (hives or a bad rash all over your body, swelling of your face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), **call 911 or go to the nearest emergency room**.

## Symptoms that are unlikely to be due to the vaccine

Please be aware that cough, shortness of breath, a runny nose, sore throat, and loss of taste or smell are not common side effects related to vaccination. If you have any of these symptoms after vaccination, you should stay home and arrange to have a COVID-19 test. For information about COVID-19, visit [www.mskcc.org/coronavirus](http://www.mskcc.org/coronavirus).

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

### **EMERGENCY USE AUTHORIZATION (EUA) OF THE PFIZER-BIONTECH COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19) IN INDIVIDUALS 16 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 no U.S. Food and Drug Administration (FDA) 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 2-dose series, 3 weeks apart, into the muscle.

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 FDA-approved vaccine to prevent COVID-19.

The FDA has authorized the emergency use of the Pfizer-BioNTech COVID-19 Vaccine to prevent COVID-19 in individuals 16 years of age and older under an Emergency Use Authorization (EUA).

For more information on EUA, see the “**What is an Emergency Use Authorization (EUA)?**” section at the end of this Fact Sheet.

### **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 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

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

FDA has authorized the emergency use of the Pfizer-BioNTech COVID-19 Vaccine in individuals 16 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 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 vaccination series.

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

The Pfizer-BioNTech COVID-19 Vaccine is an unapproved vaccine. In clinical trials, approximately 20,000 individuals 16 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 2 doses 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?**

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

- injection site pain
- tiredness
- headache
- muscle pain
- chills
- joint pain
- fever
- injection site swelling
- injection site redness
- nausea
- feeling unwell
- swollen lymph nodes (lymphadenopathy)

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

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 9-1-1, 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 **FDA/CDC Vaccine Adverse Event Reporting System (VAERS)**. The VAERS toll-free number is 1-800-822-7967 or report online to <https://vaers.hhs.gov/reportevent.html>. Please include “Pfizer-BioNTech COVID-19 Vaccine EUA” in the first line of box #18 of the report form.

In addition, you can report side effects to Pfizer Inc. at the contact information provided below.

| Website  | Fax number     | Telephone number |
|--|----------------|------------------|
| <a href="http://www.pfizersafetyreporting.com">www.pfizersafetyreporting.com</a> | 1-866-635-8337 | 1-800-438-1985   |

**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. FDA may allow the emergency use of other vaccines to prevent COVID-19.

**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 second 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  |
|---|---|
| <p data-bbox="315 415 618 443"><a href="http://www.cvdvaccine.com">www.cvdvaccine.com</a></p>  | <p data-bbox="954 464 1214 533">1-877-829-2619<br/>(1-877-VAX-CO19)</p> |

## HOW CAN I LEARN MORE?

- Ask the vaccination provider.
- Visit CDC at <https://www.cdc.gov/coronavirus/2019-ncov/index.html>.
- Visit FDA at <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>.
- 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 second dose. For more information about IISs visit: <https://www.cdc.gov/vaccines/programs/iis/about.html>.

## WHAT IS THE COUNTERMEASURES INJURY COMPENSATION PROGRAM?

The Countermeasures Injury Compensation Program (CICP) is a federal program that may help pay for costs of medical care and other specific expenses of certain people who have been seriously injured by certain medicines or vaccines, including this vaccine. Generally, a claim must be submitted to the CICP within one (1) year from the date of receiving the vaccine. To learn more about this program, visit [www.hrsa.gov/cicp/](http://www.hrsa.gov/cicp/) or call 1-855-266-2427.

## WHAT IS AN EMERGENCY USE AUTHORIZATION (EUA)?

The United States FDA has made the Pfizer-BioNTech COVID-19 Vaccine available under an emergency access mechanism called an EUA. The EUA is supported by a Secretary of Health and Human Services (HHS) declaration that circumstances exist to justify the emergency use of drugs and biological products during the COVID-19 pandemic.

The Pfizer-BioNTech COVID-19 Vaccine has not undergone the same type of review as an FDA-approved or cleared product. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, available alternatives. In addition, the FDA decision is based on the totality of scientific evidence available showing that the product may be effective to prevent COVID-19 during the COVID-19

pandemic and that the known and potential benefits of the product outweigh the known and potential risks of the product. All of these criteria must be met to allow for the product to be used in the treatment of patients during the COVID-19 pandemic.

The EUA for the Pfizer-BioNTech COVID-19 Vaccine is in effect for the duration of the COVID-19 EUA declaration justifying emergency use of these products, unless terminated or revoked (after which the products may no longer be used).



Manufactured by  
Pfizer Inc., New York, NY 10017

**BIONTECH**

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

LAB-1451-0.7

Revised: December 2020



Scan to capture that this Fact Sheet was provided to vaccine recipient for the electronic medical records/immunization information systems.

Barcode Date: 12/2020





# Get vaccinated. Get your smartphone. Get started with v-safe.

## What is v-safe?

**V-safe** is a smartphone-based tool that uses text messaging and web surveys to provide personalized health check-ins after you receive a COVID-19 vaccination. Through **v-safe**, you can quickly tell CDC if you have any side effects after getting the COVID-19 vaccine. Depending on your answers, someone from CDC may call to check on you. And **v-safe** will remind you to get your second COVID-19 vaccine dose if you need one.

Your participation in CDC's **v-safe** makes a difference—it helps keep COVID-19 vaccines safe.

## How can I participate?

Once you get a COVID-19 vaccine, you can enroll in **v-safe** using your smartphone. Participation is voluntary and you can opt out at any time. You will receive text messages from **v-safe** around 2 p.m. local time. To opt out, simply text "STOP" when **v-safe** sends you a text message. You can also start **v-safe** again by texting "START."

## How long do v-safe check-ins last?

During the first week after you get your vaccine, **v-safe** will send you a text message each day to ask how you are doing. Then you will get check-in messages once a week for up to 5 weeks. The questions **v-safe** asks should take less than 5 minutes to answer. If you need a second dose of vaccine, **v-safe** will provide a new 6-week check-in process so you can share your second-dose vaccine experience as well. You'll also receive check-ins 3, 6, and 12 months after your final dose of vaccine.

## Is my health information safe?

Yes. Your personal information in **v-safe** is protected so that it stays confidential and private.\*



Use your smartphone to tell CDC about any side effects after getting the COVID-19 vaccine. You'll also get reminders if you need a second vaccine dose.



Sign up with your smartphone's browser at [vsafe.cdc.gov](https://vsafe.cdc.gov)

OR

Aim your smartphone's camera at this code



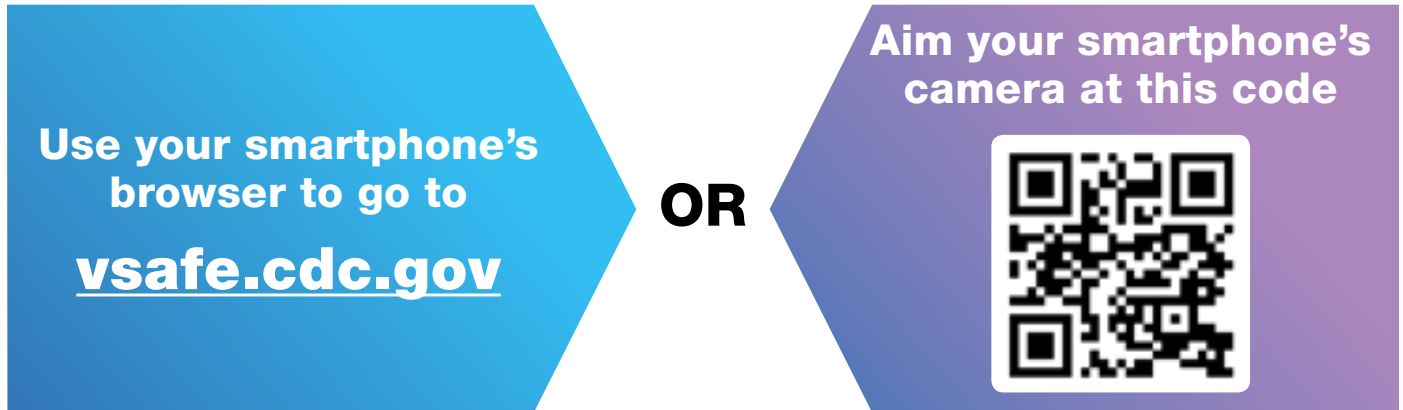
\*To the extent **v-safe** uses existing information systems managed by CDC, FDA, and other federal agencies, the systems employ strict security measures appropriate for the data's level of sensitivity.

## How to register and use v-safe

You will need your smartphone and information about the COVID-19 vaccine you received. This information can be found on your vaccination record card; if you cannot find your card, please contact your healthcare provider.

### Register

1. Go to the **v-safe** website using one of the two options below:



2. Read the instructions. Click **Get Started**.
3. Enter your name, mobile number, and other requested information. Click **Register**.
4. You will receive a text message with a verification code on your smartphone. Enter the code in **v-safe** and click **Verify**.
5. At the top of the screen, click **Enter vaccine information**.
6. Select which COVID-19 vaccine you received (found on your vaccination record card; if you cannot find your card, please contact your healthcare provider). Then enter the date you were vaccinated. Click **Next**.
7. Review your vaccine information. If correct, click **Submit**. If not, click **Go Back**.
8. **Congrats! You're all set!** If you complete your registration before 2 p.m. local time, **v-safe** will start your initial health check-in around 2 p.m. that day. If you register after 2 p.m., **v-safe** will start your initial health check-in immediately after you register—just follow the instructions. You will receive a reminder text message from v-safe when it's time for the next check-in — around 2 p.m. local time. Just click the link in the text message to start the check-in.

### Complete a v-safe health check-in

1. When you receive a **v-safe** check-in text message on your smartphone, click the link when ready.
2. Follow the instructions to complete the check-in.

### Troubleshooting

#### How can I come back and finish a check-in later if I'm interrupted?

- Click the link in the text message reminder to restart and complete your check-in.

#### How do I update my vaccine information after my second COVID-19 vaccine dose?

- **V-safe** will automatically ask you to update your second dose information. Just follow the instructions.

#### Need help with v-safe?

Call 800-CDC-INFO (800-232-4636)

TTY 888-232-6348

Open 24 hours, 7 days a week

Visit [www.cdc.gov/vsafe](https://www.cdc.gov/vsafe)



# New York State COVID-19 Vaccine Form

The New York State Department of Health requires every person who receives a COVID-19 vaccine to self-report information (such as name, race, ethnicity and occupation) prior to vaccine administration. The Department of Health asks for this information so that it can track vaccination progress throughout New York State.

To complete the New York State required COVID-19 vaccine form, go to the following website:

**[vaccineform.health.ny.gov](https://vaccineform.health.ny.gov)**

