

FACT SHEET FOR RECIPIENTS AND CAREGIVERS

EMERGENCY USE AUTHORIZATION (EUA) OF THE JANSSEN COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19) IN INDIVIDUALS 18 YEARS OF AGE AND OLDER

You are being offered the Janssen 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 receiving the Janssen COVID-19 Vaccine, which you may receive because there is currently a pandemic of COVID-19.

The Janssen COVID-19 Vaccine 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 Janssen COVID-19 Vaccine. Talk to the vaccination provider if you have questions. It is your choice to receive the Janssen COVID-19 Vaccine.

The Janssen COVID-19 Vaccine is administered as a **single dose**, into the muscle.

The Janssen COVID-19 Vaccine may not protect everyone.

This Fact Sheet may have been updated. For the most recent Fact Sheet, please visit www.janssencovid19vaccine.com.

WHAT YOU NEED TO KNOW BEFORE YOU GET THIS VACCINE

WHAT IS COVID-19?

COVID-19 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. Common 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 JANSSEN COVID-19 VACCINE?

The Janssen 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 Janssen COVID-19 Vaccine to prevent COVID-19 in individuals 18 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 JANSSEN 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 JANSSEN COVID-19 VACCINE?

FDA has authorized the emergency use of the Janssen COVID-19 Vaccine in individuals 18 years of age and older.

WHO SHOULD NOT GET THE JANSSEN COVID-19 VACCINE?

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

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

WHAT ARE THE INGREDIENTS IN THE JANSSEN COVID-19 VACCINE?

The Janssen COVID-19 Vaccine includes the following ingredients: recombinant, replication-incompetent adenovirus type 26 expressing the SARS-CoV-2 spike protein, citric acid monohydrate, trisodium citrate dihydrate, ethanol, 2-hydroxypropyl- β -cyclodextrin (HBCD), polysorbate-80, sodium chloride.

HOW IS THE JANSSEN COVID -19 VACCINE GIVEN?

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

The Janssen COVID-19 Vaccine vaccination schedule is a **single dose**.

HAS THE JANSSEN COVID-19 VACCINE BEEN USED BEFORE?

The Janssen COVID-19 Vaccine is an unapproved vaccine. In an ongoing clinical trial, 21,895 individuals 18 years of age and older have received the Janssen COVID-19 Vaccine.

WHAT ARE THE BENEFITS OF THE JANSSEN COVID-19 VACCINE?

In an ongoing clinical trial, the Janssen COVID-19 Vaccine has been shown to prevent COVID-19 following a single dose. The duration of protection against COVID-19 is currently unknown.

WHAT ARE THE RISKS OF THE JANSSEN COVID-19 VACCINE?

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

- Injection site reactions: pain, redness of the skin and swelling.
- General side effects: headache, feeling very tired, muscle aches, nausea, and fever.

There is a remote chance that the Janssen 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 Janssen 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.

These may not be all the possible side effects of the Janssen COVID-19 Vaccine. Serious and unexpected effects may occur. The Janssen 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 “Janssen COVID-19 Vaccine EUA” in the first line of box #18 of the report form.

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

| e-mail | Fax number | Telephone numbers |
|--------------------------|-------------------|---|
| JNJvaccineAE@its.jnj.com | 215-293-9955 | US Toll Free: 1-800-565-4008 US Toll: (908) 455-9922 |

You may also be given an option to enroll in **v-safe**. **V-safe** is a new voluntary smartphone-based tool that uses text messaging and web surveys to check in with people who have been vaccinated to identify potential side effects after COVID-19 vaccination. **V-safe** asks questions that help CDC monitor the safety of COVID-19 vaccines. **V-safe** also provides live telephone follow-up by CDC if participants report a significant health impact following COVID-19 vaccination. For more information on how to sign up, visit: www.cdc.gov/vsafe.

WHAT IF I DECIDE NOT TO GET THE JANSSEN COVID-19 VACCINE?

It is your choice to receive or not receive the Janssen 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 JANSSEN COVID-19 VACCINE?

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

CAN I RECEIVE THE JANSSEN COVID-19 VACCINE WITH OTHER VACCINES?

There is no information on the use of the Janssen 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 JANSSEN COVID-19 VACCINE GIVE ME COVID-19?

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

KEEP YOUR VACCINATION CARD

When you receive the Janssen COVID-19 Vaccine, you will get a vaccination card to document the name of the vaccine and date of when you received the vaccine.

ADDITIONAL INFORMATION

If you have questions or to access the most recent Janssen COVID-19 Vaccine Fact Sheets, scan the QR code using your device, visit the website or call the telephone numbers provided below.

| QR Code | Fact Sheets Website | Telephone numbers |
|---|--|---|
|  | www.janssencovid19vaccine.com | US Toll Free: 1-800-565-4008 US Toll: (908) 455-9922 |

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. For more information about IISs visit: <https://www.cdc.gov/vaccines/programs/iis/about.html>.

WHAT IS THE COUNTERMEASURE 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 for 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 or call 1-855-266-2427.

WHAT IS AN EMERGENCY USE AUTHORIZATION (EUA)?

The United States FDA has made the Janssen 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 Janssen 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, and 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 during the COVID-19 pandemic.

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

Manufactured by:
Janssen Biotech, Inc.
a Janssen Pharmaceutical Company of Johnson & Johnson
Horsham, PA 19044, USA



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For more information, call US Toll Free: 1-800-565-4008, US Toll: (908) 455-9922 or go to www.janssencovid19vaccine.com

Revised: Feb/27/2021



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

Barcode Date: 02/2021

Understanding the Vaccine Adverse Event Reporting System (VAERS)

➤ For more information on vaccines, vaccine-preventable diseases, and vaccine safety:
<http://www.cdc.gov/vaccines/conversations>

Last updated February 2013

- The Vaccine Adverse Event Reporting System (VAERS) is one component of the United States' comprehensive vaccine safety monitoring system.
- VAERS reports are monitored carefully by the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA).
- Reports of adverse events (possible side effects) after vaccination do not mean that the reported problem was caused by a vaccine. Reports are signals that alert scientists of possible cause-and-effect relationships that need to be investigated.
- Anyone can submit a report to VAERS including health care professionals, vaccine manufacturers, vaccine recipients, and parents or family members of people who have received a vaccine.

monitoring VAERS, conducting studies, and sharing findings, appropriate actions are taken to protect the public's health.

For example, if VAERS identifies a mild adverse event that is verified as a side effect in a focused study, this information is reviewed by CDC, FDA, and vaccine policy makers. In this situation, the vaccine may continue to be recommended if the disease-prevention benefits from vaccination outweigh the risks of a newly found side effect.

Information about newly found side effects is added to the vaccine's package insert that lists safety information. Newly found side effects also are added to the Vaccine Information Statement (VIS) for that vaccine. If serious side effects are found, and if the risks of the vaccine side effect outweigh the benefits, the recommendation to use the vaccine is withdrawn.

Vaccine Information Statements (VISs) are information sheets produced by the Centers for Disease Control and Prevention (CDC) that explain to vaccine recipients, their parents, or their legal representatives both the benefits and risks of a vaccine. Federal law requires that VISs be handed out whenever (before each dose) certain vaccinations are given.

| questions and answers |

What is VAERS?

VAERS is a national vaccine safety surveillance program overseen by CDC and FDA. VAERS collects and analyzes reports of adverse events that happen after vaccination. Each year, VAERS receives around 30,000 reports. Most of these reports describe known, mild side effects such as fever. Scientists at CDC and FDA monitor VAERS reports closely to identify reported adverse events that need to be studied further. Sometimes, it is only after a vaccine has been approved and used broadly that rare side effects can be detected by monitoring systems such as VAERS.

How are the VAERS data used?

VAERS scientists look for unusually high numbers of reports of an adverse event after a particular vaccine or a new pattern of adverse events. If scientists see either of these situations, focused studies in other systems are done to determine if the adverse event is or is not a side effect of the vaccine. Information from VAERS and vaccine safety studies is shared with the public. Throughout the process of

Adverse events reported to VAERS are not necessarily side effects caused by vaccination. An **adverse event** is a health problem that happens after vaccination that may or may not be caused by a vaccine. These events may require further investigation. By definition, a **side effect** has been shown to be linked to a vaccine by scientific studies.

Before the FDA licenses (approves) a vaccine for use, the vaccine must be tested with volunteers during clinical trials to make sure it is safe and effective. Sometimes side effects show up in clinical trials. Most often side effects found in clinical trials are minor, such as possible pain at the injection site, and the vaccine is licensed because the disease-prevention benefits outweigh the risk of getting the side effect.

As part of the United States' comprehensive vaccine safety monitoring system, VAERS detects rare vaccine adverse events, signaling to scientists that focused studies are needed to determine whether the adverse event is a side effect or if there is no medical link.



Vaccines are tested before they are used, so why are there possible unknown side effects?

When vaccines are ready for tests in humans, they are tested on thousands to tens of thousands of volunteers. However, even this large number is not always enough to find rare side effects, such as a one-in-a-million side effect. So, VAERS is needed to constantly look for possible side effects that might not have been detected previously.

Are all events reported to VAERS caused by vaccinations?

VAERS data alone usually cannot be used to answer the question, “Does a certain vaccine cause a certain side effect?” This is mainly because adverse events reported to VAERS may or may not be caused by vaccines. There are reports in VAERS of common conditions that are found shortly after vaccination, often related by chance alone, and investigations find no medical link between vaccination and the condition.

To know if a vaccine causes a side effect, scientists must know whether the adverse event is occurring after vaccination with a particular vaccine more often than would be expected without vaccination. They also need to consider whether the association between the vaccine and the adverse event is consistent with existing medical knowledge about how vaccines work in the body.

Who can report to VAERS?

Anyone can submit a report to VAERS including parents, patients, and health care professionals. Vaccine manufacturers who receive reports of adverse events also report the information to VAERS. FDA and CDC encourage anybody who experiences any adverse event after vaccination to report to VAERS. Individuals completing a report can work with a health care professional to make sure they fill out the report form completely. By working together, health care professionals and patients/parents can provide FDA and CDC with data that will be most useful and accurate for examining possible trends.

Why should I report to VAERS?

Reporting to VAERS gives valuable information that helps CDC and FDA ensure that vaccines are very safe. If a previously unknown adverse event does come up, timely reports will help scientists find it and determine how to best address the issue.

How do I report to VAERS?

Reports can be submitted online, by fax, or by mail. To report to VAERS online, go to <https://vaers.hhs.gov/esub/step1> and follow the 5 steps. Or, to print out the form to return it by fax or mail, go to https://vaers.hhs.gov/resources/vaers_form.pdf. To request a form by phone, call 1-800-822-7967. Forms may be returned by fax to 1-877-721-0366 or mailed to VAERS, P.O. Box 1100, Rockville, MD 20849-1100. VAERS staff may call for more information.

What events should I report to VAERS?

VAERS encourages the reporting of all adverse events that occur after administration of any vaccine licensed in the United States.

How do I find out if a vaccine adverse event has been reported to VAERS?

VAERS data is available to the public for download at <http://vaers.hhs.gov/data/index>. You may also request information about adverse events reported to VAERS by sending a fax to 301-443-1726, by calling 301-827-6500, or by writing to: Food and Drug Administration, Freedom of Information Staff (HF1-35), 5600 Fishers Lane, Rockville, MD 20857.

Remember, just because an adverse event or condition has been reported does not prove that the adverse event is caused by vaccination. Parents who are concerned about vaccine side effects should talk to their child's health care professional.

| the science |

These articles tell more about VAERS and provide examples of the important role it serves as part of the U.S. vaccine safety monitoring system.

An Overview of the Vaccine Adverse Event Reporting System (VAERS) as a Surveillance System by J.A. Singleton et al. *Vaccine*. July 1999. Vol 17: pages 2908-2917. http://www.sciencedirect.com/science?_ob=MIimg&_imagekey=B6TD4-3WRB2MG-R-9&_cdi=5188&_user=856389&_pii=S0264410X99001322&_origin=search&_coverDate=07%2F16%2F1999&_sk=999829977&view=c&wchp=dGLzVlz-zSkzV&md5=a46c65b0b00e73287cf51d7ed0ec2aa9&ie=/sdarticle.pdf

Intussusception among Recipients of Rotavirus Vaccine—United States, 1998–1999 in CDC's *MMWR*. July 1999. Vol 48: pages 577-581. <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm4827a1.htm>

Intussusception among Infants Given an Oral Rotavirus Vaccine by T.V. Murphy et al. *New England Journal of Medicine*. February 2001. Vol 344: pages 564-572. <http://content.nejm.org/cgi/reprint/344/8/564.pdf>

The Role of the Vaccine Adverse Event Reporting System (VAERS) in Monitoring Vaccine Safety by John Iskander et al. *Pediatric Annals*. September 2004. Vol 33: pages 599-606. <http://www.ncbi.nlm.nih.gov/pubmed/15462575> (abstract only)

Postlicensure Safety Surveillance for Quadrivalent Human Papillomavirus Recombinant Vaccine by Barbara Slade et al. *Journal of the American Medical Association*. August 2009. Vol 302: pages 750-757. <http://jama.ama-assn.org/cgi/content/full/302/7/750>

For more information on vaccines call 800-CDC-INFO (800-232-4636) or visit <http://www.cdc.gov/vaccines>.



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 2pm 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.*

*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. These measures comply, where applicable, with the following federal laws, including the Privacy Act of 1974; standards enacted that are consistent with the Health Insurance Portability and Accountability Act of 1996 (HIPAA); the Federal Information Security Management Act, and the Freedom of Information Act.



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

OR

Aim your smartphone's camera at this code

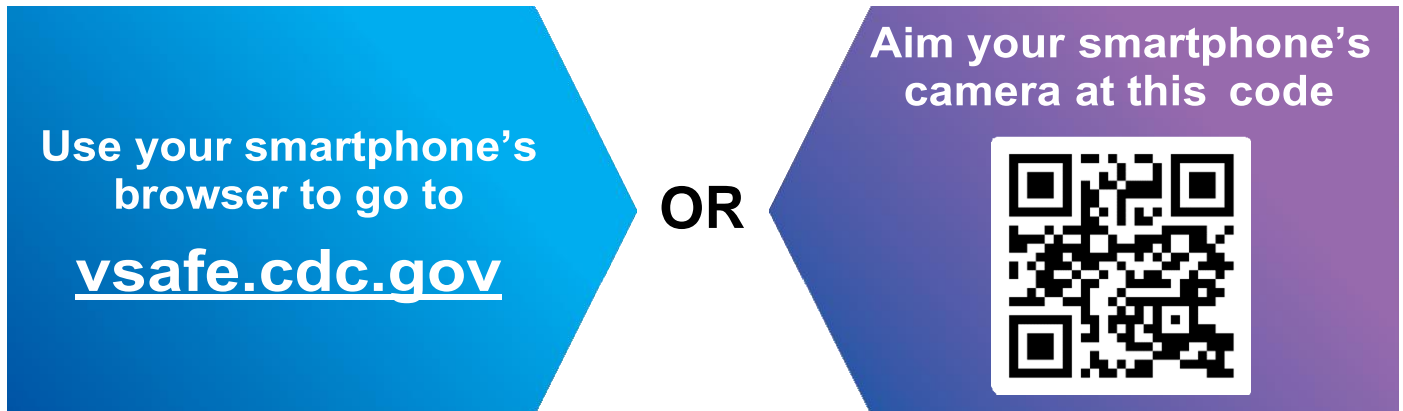


How to register and use v-safe

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 your COVID-19 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 2pm local time, **v-safe** will start your initial health check-in around 2pm that day. If you register after 2pm, **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 2pm 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



Assessing symptoms for post COVID-19 vaccination

Side effects are expected with this vaccine. Some will be difficult to tell whether they are a side effect of the vaccination versus a new onset infection of COVID-19. If you are experiencing any of the following symptoms, please contact your Primary Care Physician.

Symptoms likely due to NEW SARS-CoV-2 INFECTION



Cough



Shortness of Breath



Nasal Congestion



Sore Throat



Loss of Taste/Smell

Symptoms DIFFICULT TO TELL whether side effect vs. new infection



Fever



Fatigue



Chills



Headache



Joint Pain