

Patient Information Sheet

Johnson & Johnson/Janssen COVID-19 Vaccine



The purpose of COVID-19 vaccination is to reduce the risk of becoming sick from the virus that causes Coronavirus Disease 2019 (COVID-19).

There are currently three COVID-19 vaccines: two mRNA vaccines (Pfizer-BioNTech and Moderna) and one viral vector vaccine (Johnson & Johnson **(J&J)/Janssen**) (collectively the “EUA Vaccines”) authorized by the Food and Drug Administration (“FDA”) under Emergency Use Authorization (“EUA”). The FDA may issue an EUA based on a declaration by the Secretary of the Department of Health and Human Services that circumstances justify the emergency use of drugs and biological products during the COVID-19 pandemic if certain criteria are met. The criteria for the COVID-19 J&J/Janssen vaccine you are being offered today is explained in more detail in the EUA Fact Sheets linked below.

Please review the EUA Fact Sheet for Recipients and Caregivers online for complete details on the vaccine and possible side effects: www.janssencovid19vaccine.com

You should not receive the J&J/Janssen COVID-19 vaccine if you have a history of severe allergy (anaphylaxis) or immediate reaction of any kind (e.g., anaphylaxis, difficulty breathing, hives, swelling around the mouth, throat or eyes) to any component of the vaccine (such as polysorbate).

Reasons to Delay Vaccination:

- If you have a fever (temperature of 100.4 degrees or higher), chills or any symptoms of COVID-19 infection, contact your primary health care provider for COVID-19 testing prior to vaccination.
- If you were recently diagnosed with COVID-19 or are on quarantine due to an exposure, you should wait until your primary health care provider recommends ending isolation or quarantine prior to vaccination.
- In the very rare instance you have been diagnosed with Multisystem Inflammatory Syndrome (MIS) following COVID-19 infection, we recommend that you wait 90 days after diagnosis to be vaccinated.
- If you have received (or may have received in a clinical trial) a monoclonal antibody or convalescent plasma for COVID-19 treatment or prevention: you should wait 90 days after the treatment date before getting vaccinated so that the vaccine will be as effective as possible.

Other Considerations Prior to Vaccination:

- If you are pregnant, lactating (breastfeeding) or planning to become pregnant, we recommend that you have a conversation with your primary health care provider about whether vaccination is right for you.
- **If you have a history of immediate allergic reaction (such as anaphylaxis, difficulty breathing, hives, or swelling around the mouth, throat or eyes) to any other vaccine or injectable (intramuscular, intravenous or subcutaneous) medication in the past, you must inform us so that the appropriate longer post-vaccination monitoring (30 minutes) may be performed.**

Precaution for Women Aged 18-49:

Due to a rare risk of blood clots related to a condition called thrombosis with thrombocytopenia (TTS) associated with the use of the J&J/Janssen vaccine, BILH recommends that while alternate options are available, women aged 18-49 should be offered an mRNA vaccine (Pfizer-BioNTech or Moderna) as a first choice at our vaccination sites. If a single-dose vaccine is preferred or receipt of an mRNA vaccine is not feasible (due to a history of allergy), you may proceed with vaccination with the J&J/Janssen vaccine but should be informed of the rare risk of blood clots.

Precaution for Patients with a History of Heparin-Induced Thrombocytopenia:

Until more information becomes available, we currently recommend that patients with a history of heparin-induced thrombocytopenia (HIT) receive an mRNA vaccine. If a single-dose vaccine is preferred or receipt of an mRNA vaccine is not feasible (due to a history of allergy), we recommend evaluation by a hematologist prior to use of the J&J/Janssen vaccine.

[Continued on other side](#)

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Information About the Rare Risk of Blood Clots:

Blood clots involving blood vessels in the brain, abdomen, and legs along with low levels of platelets (blood cells that help your body stop bleeding), have occurred in some people who have received the J&J/Janssen vaccine.

Most people who developed these blood clots and low levels of platelets were females ages 18-49 years, with symptoms beginning approximately one to two weeks following vaccination.

You should seek medical attention right away if you have any of the following symptoms after receiving J&J/Janssen COVID-19 vaccine: shortness of breath, chest pain, leg swelling, persistent abdominal pain, severe or persistent headaches or blurred vision, easy bruising or tiny blood spots under the skin other than at the site of the injection.

Information About the Rare Risk of Guillain-Barré Syndrome (GBS):

A small number of cases of vaccine-associated GBS (a neurological disorder in which the body's immune system damages nerve cells, causing muscle weakness and sometimes paralysis) have been seen after receipt the J&J/Janssen vaccine. If you have had a history of GBS related to a vaccine or other causes, we recommend a discussion with your primary physician prior to receipt of the J&J/Janssen vaccine.

Required Post-Vaccination Observation Period:

You will be monitored for any signs of an allergic reaction immediately after the vaccination (minimum 15 minutes, 30 minutes if prior severe allergic reaction). Some symptoms of allergic reaction are rash, wheezing, difficulty breathing, dizziness and fainting, swelling around the mouth, throat, or eyes. This is not an exhaustive list. Please notify us immediately if you notice any of these symptoms or have any other concerns.

What to Expect After Your COVID-19 Vaccination:

The vaccines may cause side effects in some people, like sore muscles, feeling tired, or mild fever. These reactions mean the vaccine is working to help teach your body how to fight COVID-19 if you are exposed.

For most people, these side effects will last no longer than a day or two. **Having these types of side effects does NOT mean that you have COVID-19.** If you have questions about your health after your vaccination, call your primary health care provider. As with any medicine, it is rare but possible to have a serious reaction, such as not being able to breathe. It is very unlikely that this will happen, but if it does, call 911 or go to the nearest emergency room.

Please report all vaccine side effects to the FDA/CDC Vaccine Adverse Event Reporting System (VAERS) online, vaers.hhs.gov/reportevent.html, or the VAERS toll-free number (1-800-822-7967). You may also report to the CDC v-safe online tool (vsafe.cdc.gov).

Even after you get your vaccine, you will need to keep wearing a mask that covers your nose and mouth in certain situations as outlined in the Massachusetts Mask Order (www.mass.gov/info-details/mask-up-massachusetts) and to clean your hands often. This gives you and others the best protection from catching the virus.

Only one dose of the J&J/Janssen vaccine is recommended. You do not need to book additional appointments after your vaccination is completed. We are following the current FDA and CDC guidance for vaccination and are not recommending booster doses at this time due to limited data on safety and efficacy.

Reminder - The vaccine you receive will be listed on a vaccination card provided to you. Please keep this card for your COVID-19 Vaccination Record.

Consider enrolling in the CDC v-safe Tool (vsafe.cdc.gov) - a smartphone after vaccination health checker for people who receive COVID-19 vaccines.

If you have any questions about side effects, please consult with your primary health care provider.

As of 7/16/21

COVID-19 Vaccination Record Card			
Please keep this record card, which includes medical information about the vaccines you have received.			
Por favor, guarde esta tarjeta de registro, que incluye información médica sobre las vacunas que ha recibido.			
Last Name		First Name	MI
Date of birth		Patient number (medical record or IIS record number)	
Vaccine	Product Name/Manufacturer Lot Number	Date	Healthcare Professional or Clinic Site
1 st Dose COVID-19		mm dd yy	
2 nd Dose COVID-19		mm dd yy	
Other		mm dd yy	
Other		mm dd yy	