Johnson & Johnson Updates U.S. COVID-19 Vaccine Fact Sheet

May 05, 2022

NEW BRUNSWICK, NJ, May 5, 2022 - Our number one priority is the safety and well-being of those who use the Johnson & Johnson COVID-19 vaccine. Johnson & Johnson, in close coordination with the U.S. Food and Drug Administration (FDA), has updated its U.S. COVID-19 Vaccine Fact Sheet to increase awareness about the risk of thrombosis with thrombocytopenia syndrome (TTS), a rare but potentially life-threatening condition. Language about the risk of TTS has been added to the first page of the Fact Sheet to increase its prominence.

Following the update to the Fact Sheet, the Johnson & Johnson COVID-19 vaccine is now authorized in the U.S. for use in individuals 18 years of age and older for whom other FDA-authorized or approved COVID-19 vaccines are not accessible or clinically appropriate, as well as for individuals 18 years of age and older who elect to receive the Johnson & Johnson COVID-19 vaccine because they would otherwise not receive a COVID-19 vaccine. This is consistent with the Advisory Committee on Immunization Practices (ACIP) recommendations by the U.S. Centers for Disease Control and Prevention (CDC) in December 2021 that express a clinical preference for individuals to receive an mRNA COVID-19 vaccine.

Data continue to support a favorable benefit-risk profile for the Johnson & Johnson COVID-19 vaccine in adults, when compared with no vaccine.

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the pandemic where people are most in need.

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AUTHORIZATION OF USE

The Janssen COVID-19 Vaccine is authorized for use under an Emergency Use Authorization (EUA) for active immunization to prevent Coronavirus Disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 18 years of age and older for whom other FDA-authorized or approved COVID-19 vaccines are not accessible or clinically appropriate, and in individuals 18 years of age and older who elect to receive the Janssen COVID-19 Vaccine because they would otherwise not receive a COVID-19 vaccine.

· Primary vaccination regimen for the Janssen COVID-19 Vaccine is a single-dose (0.5 mL).
· A single Janssen COVID-19 Vaccine booster dose (0.5 mL) may be administered at least 2 months after the primary vaccination with the Janssen COVID-19 Vaccine.
· A single booster dose of the Janssen COVID-19 Vaccine (0.5 mL) may be administered as a heterologous booster dose following completion of primary vaccination with another authorized or approved COVID-19 vaccine. The dosing interval for the heterologous booster dose is the same as that authorized for a booster dose of the vaccine used for primary vaccination.

IMPORTANT SAFETY INFORMATION

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
· have ever had a low level of platelets (blood cells that help your body stop bleeding)
· 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
· have ever fainted in association with an injection

WHO SHOULD NOT GET THE JANSSEN COVID-19 VACCINE?

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

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HOW IS THE JANSSEN COVID-19 VACCINE GIVEN?
The Janssen COVID-19 Vaccine will be given to you as an injection into the muscle.

Primary Vaccination: The Janssen COVID-19 Vaccine is administered as a single dose.

Booster Dose:
· A single booster dose of the Janssen COVID-19 Vaccine may be administered at least two months after primary vaccination with the Janssen COVID-19 Vaccine.
· A single booster dose of the Janssen COVID-19 Vaccine may be administered after completing primary vaccination with a different authorized or approved COVID-19 vaccine. Please check with your health care provider regarding timing of the booster dose.

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, fever.
· Swollen lymph nodes.
· Blood clots.
· Unusual feeling in the skin (such as tingling or a crawling feeling) (paresthesia), decreased feeling or sensitivity, especially in the skin (hypoesthesia).
· Persistent ringing in the ears (tinnitus).
· Diarrhea, vomiting.

Severe Allergic Reactions
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

Blood Clots with Low Levels of Platelets
Blood clots involving blood vessels in the brain, lungs, abdomen, and legs along with low levels of platelets (blood cells that help your body stop bleeding), have occurred in some people who have

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right away if you have any of the following symptoms after receiving the 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 beyond the site of the injection.

Immune Thrombocytopenia (ITP)
Immune Thrombocytopenia (ITP) is a disorder that can cause easy or excessive bruising and bleeding due to very low levels of platelets. ITP has occurred in some people who have received the Janssen COVID-19 Vaccine. In most of these people, symptoms began within 42 days following receipt of the Janssen COVID-19 Vaccine. The chance of having this occur is very low. If you have ever had a diagnosis of ITP, talk to your vaccination provider before you get the Janssen COVID-19 Vaccine. You should seek medical attention right away if you develop any of the following symptoms after receiving the Janssen COVID-19 Vaccine:
· Easy or excessive bruising or tiny blood spots under the skin beyond the site of the injection,
· Unusual or excessive bleeding.

Guillain Barré Syndrome
Guillain Barré syndrome (a neurological disorder in which the body's immune system damages nerve cells, causing muscle weakness and sometimes paralysis) has occurred in some people who have received the Janssen COVID-19 Vaccine. In most of these people, symptoms began within 42 days following receipt of the Janssen COVID-19 Vaccine. The chance of having this occur is very low. You should seek medical attention right away if you develop any of the following symptoms after receiving the Janssen COVID-19 Vaccine:
· Weakness or tingling sensations, especially in the legs or arms, that's worsening and spreading to other parts of the body.
· Difficulty walking.
· Difficulty with facial movements, including speaking, chewing, or swallowing.
· Double vision or inability to move eyes.
· Difficulty with bladder control or bowel function.

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.

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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 1-800-565-4008.

CAN I RECEIVE THE JANSSEN COVID-19 VACCINE AT THE SAME TIME AS OTHER VACCINES?
Data have not yet been submitted to FDA on administration of the Janssen COVID-19 Vaccine at the same time as other vaccines. If you are considering receiving the Janssen COVID-19 Vaccine with other vaccines, discuss your options with your healthcare provider.

Please read Emergency Use Authorization (EUA) Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) including full EUA Prescribing Information available at: www.JanssenCOVID19Vaccine.com/EUA-factsheet.

Cautions Concerning Forward-Looking Statements
This media statement contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding the development, manufacture and distribution of the Johnson & Johnson COVID-19 vaccine. The reader is cautioned not to rely on these forward-looking statements. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or known or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Janssen Pharmaceuticals, Inc., the Janssen Pharmaceutical Companies, and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: the potential that the expected benefits and opportunities of the agreement may not be realized or may take longer to realize than expected; challenges and uncertainties inherent in product research and development, including the uncertainty of clinical success and of obtaining regulatory approvals; uncertainty of commercial success; manufacturing difficulties and delays; competition, including technological advances, new products and patents attained by competitors; challenges to patents; product efficacy or safety concerns resulting in product recalls or regulatory action; changes in behavior and spending patterns of purchasers of health care products and services; changes to applicable laws and regulations, including global health care reforms; and trends toward health care cost containment. A further list and descriptions of these risks, uncertainties and other factors can be found in Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended January 2, 2022, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in Johnson & Johnson's subsequent Quarterly Report on Form 10-Q and other filings with the Securities and Exchange Commission. Copies of these filings are available

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