

The Janssen COVID-19 Vaccine

Step-by-Step Guide: How To Check Expiration

The Janssen COVID-19 Vaccine has not been approved or licensed by the U.S. Food and Drug Administration (FDA), but has been authorized by FDA through an Emergency Use Authorization (EUA) for active immunization to prevent Coronavirus Disease 2019 (COVID-19) in individuals 18 years of age and older. The emergency use of this product is authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of the medical product under Section 564(b)(1) of the FD&C Act, unless the declaration is terminated or authorization revoked sooner.

Dynamic Expiration Dates

Janssen is conducting ongoing stability assessment studies for the Janssen COVID-19 Vaccine. Expiry dates may be updated as data from these studies become available. Therefore, no expiry date appears on the carton or vial.

Expiry Update

The US FDA has authorized an extension of the shelf life for the Janssen COVID-19 Vaccine. **Prior to discarding any doses of the Janssen COVID-19 Vaccine, vaccination providers should validate the expiration date to determine if the vaccine can still be used.**

Three Methods to Check The Expiration Date of the Janssen COVID-19 Vaccine



1. Scan the Quick Response (QR) code on the back of the carton using a mobile device camera.



2. On the web: [VaxCheck.jnj](https://www.vaxcheck.jnj.com)



3. By phone: 1-800-565-4008 (US Toll Free) or 1-908-455-9922 (US Toll)



To view a video detailing the process of checking the Janssen COVID-19 Vaccine expiry information, please visit <https://www.janssencovid19vaccine.com/hcp/check-expiration.html>.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

Do not administer the Janssen COVID-19 Vaccine to individuals with a known history of a severe allergic reaction (e.g., anaphylaxis) to any component of the Janssen COVID-19 Vaccine.

Please read additional Important Safety Information throughout.

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.

The Janssen COVID-19 Vaccine



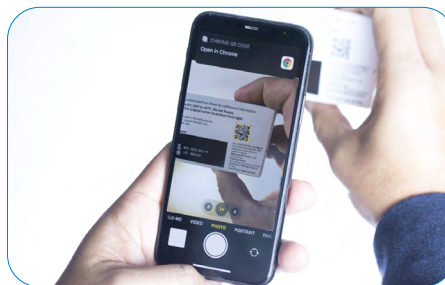
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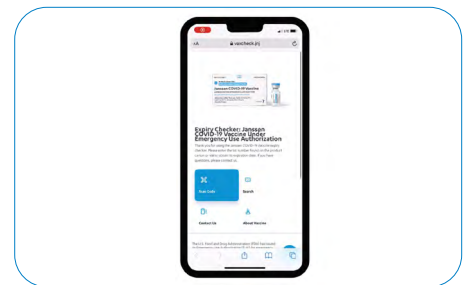
Use your mobile device to access [VaxCheck.jnj](https://www.vaxcheck.jnj) to check vaccine expiry.



To access [VaxCheck.jnj](https://www.vaxcheck.jnj) and check the expiration date for each vaccine lot, locate the QR Code (as indicated) on the back of the Janssen COVID-19 Vaccine carton.



Access your device's camera and direct it at the QR code at the back of the carton. Follow the screen prompts to connect to [VaxCheck.jnj](https://www.vaxcheck.jnj).

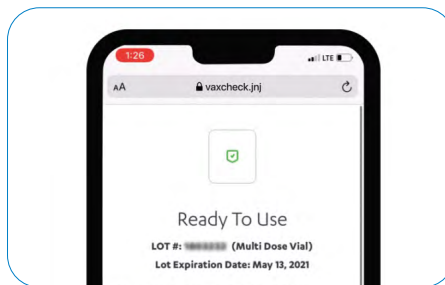


Once on the [VaxCheck.jnj](https://www.vaxcheck.jnj) website, you can choose to either use your device's camera to scan the vaccine *lot tag* or enter the vaccine *lot number* manually.



When scanning the vaccine *lot tag*, allow access to your device's camera and point it at the vaccine *lot tag* on the back of the carton (do NOT scan the lot tag on the vial).

The vaccine lot tag is the second code within the large black rectangle.



The site will provide the expiration date and indicate that either the product is Ready To Use or Restricted Do Not Use.

If you receive an error message, contact a specialist by phone: [1-800-565-4008](tel:1-800-565-4008) (US Toll Free) or [1-908-455-9922](tel:1-908-455-9922) (US Toll)

ALTERNATIVELY

- You can also check this information **online** by typing [VaxCheck.jnj](https://www.vaxcheck.jnj) into your mobile or desktop browser and following the screen prompts provided.
- Or you can check by phone: [1-800-565-4008](tel:1-800-565-4008) (US Toll Free) or [1-908-455-9922](tel:1-908-455-9922) (US Toll)

IMPORTANT SAFETY INFORMATION (CONT.)

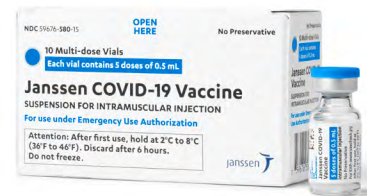
WARNINGS AND PRECAUTIONS

- Management of Acute Allergic Reactions:** Appropriate medical treatment to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of the Janssen COVID-19 Vaccine.

Monitor Janssen COVID-19 Vaccine recipients for the occurrence of immediate adverse reactions according to the Centers for Disease Control and Prevention guidelines (<https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html>).

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IMPORTANT SAFETY INFORMATION (CONT.)

WARNINGS AND PRECAUTIONS (CONT.)

- **Thrombosis with Thrombocytopenia:** Reports of adverse events following use of the Janssen COVID-19 Vaccine under emergency use authorization suggest an increased risk of thrombosis involving the cerebral venous sinuses and other sites (including but not limited to the large blood vessels of the abdomen and the veins of the lower extremities) combined with thrombocytopenia and with onset of symptoms approximately one to two weeks after vaccination. The reporting rate of thrombosis with thrombocytopenia following the administration of the Janssen COVID-19 Vaccine has been highest in females ages 18 through 49 years; some cases have been fatal. The clinical course of these events shares features with autoimmune heparin-induced thrombocytopenia. Specific risk factors for thrombosis with thrombocytopenia following administration of the Janssen COVID-19 Vaccine and the level of potential excess risk due to vaccination are under investigation. Based on currently available evidence, a causal relationship between thrombosis with thrombocytopenia and the Janssen COVID-19 Vaccine is plausible.

Healthcare professionals should be alert to the signs and symptoms of thrombosis with thrombocytopenia in individuals who receive the Janssen COVID-19 Vaccine. In individuals with suspected thrombosis with thrombocytopenia following administration of the Janssen COVID-19 Vaccine, the use of heparin may be harmful and alternative treatments may be needed. Consultation with hematology specialists is strongly recommended. The American Society of Hematology has published considerations relevant to the diagnosis and treatment of thrombosis with thrombocytopenia following administration of the Janssen COVID-19 Vaccine (<https://www.hematology.org/covid-19/vaccine-induced-immune-thrombotic-thrombocytopenia>).

Recipients of Janssen COVID-19 Vaccine should be instructed to seek immediate medical attention if they develop shortness of breath, chest pain, leg swelling, persistent abdominal pain, neurological symptoms (including severe or persistent headaches or blurred vision), or petechiae beyond the site of vaccination.

- **Guillain-Barré Syndrome:** Reports of adverse events following use of the Janssen COVID-19 Vaccine under emergency use authorization suggest an increased risk of Guillain-Barré syndrome during the 42 days following vaccination.
- **Altered Immunocompetence:** Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the Janssen COVID-19 Vaccine.
- **Syncope:** Syncope (fainting) may occur in association with administration of injectable vaccines. Procedures should be in place to avoid injury from fainting.
- **Limitations of Vaccine Effectiveness:** The Janssen COVID-19 Vaccine may not protect all vaccinated individuals.

ADVERSE REACTIONS

Adverse Reactions in Clinical Trials

Adverse reactions reported in a clinical trial following administration of the Janssen COVID-19 Vaccine include injection site pain, headache, fatigue, myalgia, nausea, fever, injection site erythema and injection site swelling. In clinical studies, severe allergic reactions, including anaphylaxis, have been reported following the administration of the Janssen COVID-19 Vaccine.

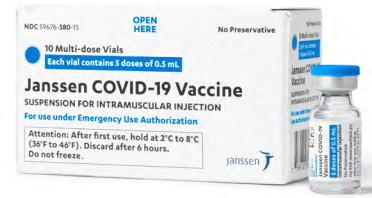
Adverse Reactions Identified during Post Authorization Use

Severe allergic reactions (including anaphylaxis), thrombosis with thrombocytopenia, Guillain-Barré syndrome, and capillary leak syndrome have been reported following administration of the Janssen COVID-19 Vaccine during mass vaccination outside of clinical trials.

Additional adverse reactions, some of which may be serious, may become apparent with more widespread use of the Janssen COVID-19 Vaccine.

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IMPORTANT SAFETY INFORMATION (CONT.)

ADVERSE REACTIONS (CONT.)

Reporting Adverse Events and Vaccine Administration Error

The vaccination provider enrolled in the federal COVID-19 Vaccination Program is responsible for mandatory reporting of the listed events following Janssen COVID-19 Vaccine administration to the Vaccine Adverse Event Reporting System (VAERS):

- Vaccine administration errors whether or not associated with an adverse event,
- Serious adverse events (irrespective of attribution to vaccination),
- Cases of Multisystem Inflammatory Syndrome (MIS) in adults,
- Cases of COVID-19 that result in hospitalization or death.

Instructions for Reporting to VAERS

The vaccination provider enrolled in the federal COVID-19 Vaccination Program should complete and submit a VAERS form to FDA using one of the following methods below. Reports should include the words “Janssen COVID-19 Vaccine EUA” in the description section of the report as the first line.

- Complete and submit the report online: <https://vaers.hhs.gov/reportevent.html>, or
- If you are unable to submit this form electronically, you may fax it to VAERS at 1-877-721-0366. If you need additional help submitting a report you may call the VAERS toll free information line at 1-800-822-7967 or send an email to info@vaers.org

Report adverse events to Janssen Biotech, Inc. by calling 1-800-565-4008 or provide a copy of the VAERS form by faxing 1-215-293-9955.

PREGNANCY AND LACTATION

- **Pregnancy:** Available data on Janssen COVID-19 Vaccine administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy.
- **Lactation:** Data are not available to assess the effects of Janssen COVID-19 Vaccine on the breastfed infant or on milk production/excretion.

DOSING AND SCHEDULE

The Janssen COVID-19 Vaccine is administered intramuscularly as a single dose (0.5 mL). There are no data available on the use of the Janssen COVID-19 Vaccine to complete a vaccination series initiated with another COVID-19 vaccine.

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