Janssen COVID-19 Vaccine

Storage and Expiry

The use of Janssen COVID-19 Vaccine is permitted under an interim authorization delivered in accordance with section 5 of the Interim Order (IO) Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19.* Patients should be advised of the nature of the authorization. The interim authorization is associated with Terms and Conditions to ascertain the continued quality, safety and efficacy of the product. For further information on authorization under this pathway, please refer to Health Canada's IO Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19.

Janssen COVID-19 Vaccine is indicated for active immunization for the prevention of COVID-19 caused by SARS-CoV-2 virus in individuals 18 years of age and older.

* Available at Health Canada at www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/drugs-vaccines-treatments/interim-order-import-sale-advertising-drugs.html.

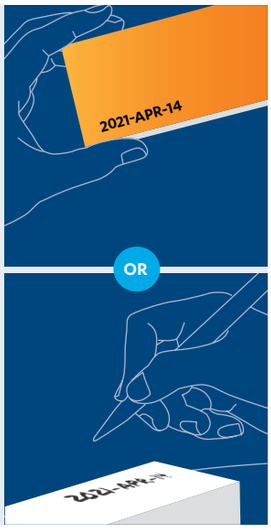
Expiry Date

If the expiry date has passed, the vaccine should not be administered. Any unused product and waste material should be disposed of in accordance with local requirements.

→ **Non-US Carton with Orange Label:** The expiry date can be found printed on the orange label on the carton containing ten multi-dose vials. Store the vials in the carton to keep track of the expiry date and to protect them from light.

→ **Non-US Carton with White Label:** The expiry date is not printed on the white carton. Access the expiry date and record it on the carton. As the expiry date approaches, check the date again to determine if it has been extended.

Expiry date can be obtained a number of different ways:
- Scan the QR code on the carton or carton leaflet using a smart device
- Visit the dedicated **vaxcheck.jnj** website
- Call **1-800-565-4008** (toll-free) or **1-908-455-9922** (US toll)



Refrigerator Storage

2°C to 8°C

- Store unopened vials at 2°C to 8°C until the expiry date*
- **DO NOT FREEZE**
- Store in the original carton to protect from direct sunlight and ultraviolet light
- During vaccination day the vials can be exposed to normal light conditions

* See instructions above on how to access expiry date information.

Shelf Life

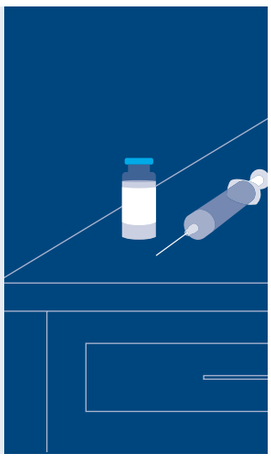
UNPUNCTURED VIAL

Until the expiry date Refrigerator	2°C to 8°C
12 hours max. Room temperature	9°C to 25°C

FOR PUNCTURED VIALS/FILLED SYRINGES

6 hours max. Refrigerator	2°C to 8°C
OR	
3 hours max. Room temperature	9°C to 25°C

The method of recording date and time on the vial label differs with the type of label. Follow instructions on vial label: record either discard date/time OR date and time of first use on vial accordingly. Discard if vaccine is not used within the appropriate time.



NEVER freeze the vaccine

janssen | PHARMACEUTICAL COMPANIES OF Johnson & Johnson

Janssen COVID-19 Vaccine

Dosage and Administration

The Janssen COVID-19 Vaccine is supplied in a multi-dose Type I glass vial (containing five doses of 0.5 mL) with a latex-free rubber stopper, aluminum seal and blue plastic cap.

Administration

Swirl vial gently in an upright position for 10 seconds. **Do not shake or dilute.**

Prior to injection:

1. Inspect the vial to check for particulate matter and discolouration; the vaccine is a colourless to slightly yellow and clear to very opalescent suspension.
2. Check the vial for cracks or any abnormalities, such as evidence of tampering.
3. Verify a syringe volume of 0.5 mL.

If any discolouration or particulate matter is present, or if the vial has any cracks or abnormalities, do no administer the vaccine.

Dosing

- An injection of **0.5 mL** should be administered by intramuscular injection only; the preferred site is the deltoid muscle of the upper arm.
- **Up to five doses of 0.5 mL** can be withdrawn from one multi-dose vaccine vial.

Janssen COVID-19 Vaccine should be administered as a single dose.

There are no data available on the use of the Janssen COVID-19 Vaccine to complete a two-dose vaccination series (either as the first or second dose) in combination with another COVID-19 Vaccine.

For medical information inquiries or for assistance with real-time product expiry, please call **1-800-565-4008** (toll-free) or **1-908-455-9922** (US toll), or visit **www.janssenmedicalinformation.ca**.

IMPORTANT SAFETY INFORMATION

Contraindications

Janssen COVID-19 Vaccine is contraindicated in individuals who are hypersensitive to the active ingredient or to any ingredients in the formulation, including any non-medicinal ingredient, or component of the container.

Warnings and Precautions

Thrombosis and Thrombocytopenia: A combination of thrombosis and thrombocytopenia, in some cases accompanied by bleeding, has been observed very rarely following vaccination. Since medical management of a post-vaccine thrombosis with thrombocytopenia may be different than medical management of other thromboses, if patients present with thrombosis with thrombocytopenia, healthcare professionals should consult with current guidance and hematologic specialists to diagnose and treat this post-vaccine event.

Hypersensitivity and Anaphylaxis: As with all vaccines, training for immunizers, and appropriate medical treatment and supervision after immunization should always be readily available in case of rare anaphylactic reactions following administration of this vaccine. Vaccine recipients should be kept under observation for at least 15 minutes after immunization; 30 minutes is a preferred interval when there is a specific concern about a possible vaccine reaction.

Altered Immunocompetence: Immunocompromised individuals including those receiving substantial immunosuppressant therapy may have a diminished immune response to Janssen COVID-19 Vaccine.

Limitations of Vaccine Effectiveness: The Janssen COVID-19 Vaccine may not protect all vaccine recipients.

Adverse Reactions

Adverse reactions reported in a clinical trial following administration of the Janssen COVID-19 Vaccine include pain at the injection site, headache, fatigue, muscle aches, nausea, fever, redness and swelling at the injection site, chills and joint pain.

Reporting Suspected Side Effects for Vaccines

If a patient experiences a side effect following immunization, please complete the Adverse Events Following Immunization (AEFI) Form appropriate for your province/territory (https://www.canada.ca/en/public-health/services/immunization/reporting-adverse-events-following-immunization/form.html) and send it to your local Health Unit.

Pregnant Women and Breastfeeding

The safety and efficacy of the Janssen COVID-19 Vaccine in pregnant women have not yet been established. It is not known whether the components of Janssen COVID-19 Vaccine or antibodies induced by Janssen COVID-19 Vaccine are excreted in human milk. Human data are not available to assess the impact of Janssen COVID-19 Vaccine on milk production or its effects on the breastfed child.
The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for immunization against COVID-19.

For more information:

Consult the Product Monograph at https://www.janssen.com/canada/sites/www_janssen_com_canada/files/prod_files/live/covid_19_vaccine_cpm.pdf for contraindications, warnings, precautions, adverse reactions, drug interactions, dosing and administration instructions and conditions of clinical use.
The Product Monograph is also available by calling Janssen Inc. at 1-800-565-4008 (toll-free) or 1-908-455-9922 (US toll).

Reference: Janssen COVID-19 Vaccine Product Monograph. Janssen Inc.

Janssen Inc. | 19 Green Belt Drive
Toronto, Ontario | M3C 1L9
www.janssen.com/canada

Janssen
PHARMACEUTICAL COMPANIES OF
Johnson & Johnson