

**Important Safety Information on
Janssen COVID-19 Vaccine
and the Risk of Thrombosis with Thrombocytopenia**



2021/04/26

IMPORTANT: Janssen COVID-19 Vaccine and the risk of thrombosis in combination with thrombocytopenia

Please note: Important safety information on the importation of Janssen COVID-19 Vaccine with two types of English-only vial and carton labels was also published on April 26, 2021

Audience

Healthcare professionals including infectious disease physicians, family physicians, emergency room physicians, hematologists, neurologists, pharmacists, public health officials, nurses and nurse practitioners, and healthcare professionals at the identified points of use.

Key messages

- **Very rare cases of thrombosis in combination with thrombocytopenia, in some cases accompanied by bleeding, have been observed following vaccination with Janssen COVID-19 Vaccine. A causal relationship with the vaccine is considered plausible.**
- **Health Canada has assessed the available data on the reported events and has determined that the benefits of Janssen COVID-19 Vaccine outweigh the risks of thrombosis and thrombocytopenia.**
- **Healthcare professionals are advised to:**
 - **be alert to the signs and symptoms of thrombosis and thrombocytopenia in individuals.**
 - **instruct those being vaccinated to seek immediate medical attention if they develop signs and symptoms of thrombosis and/or thrombocytopenia following vaccination (see the Information for healthcare professionals section).**

- consult with current [guidance](#) and hematologic specialists to diagnose and treat this post-vaccine event.
- Health Canada has worked with Janssen Inc. to update the Product Monograph for Janssen COVID-19 Vaccine to include this new safety information.
- Health Canada continues to work closely with international regulators to review data as it becomes available on these very rare events and will make further updates to product labelling or take other actions as needed.

What is the issue?

Janssen COVID-19 Vaccine was authorized for use in Canada on March 5, 2021 in accordance with the [Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19](#). Since the time of authorization, there have been very rare reports of thrombosis with thrombocytopenia following administration of Janssen COVID-19 Vaccine.

Products affected

Janssen COVID-19 Vaccine (5 × 10¹⁰ virus particles/0.5 mL) suspension for intramuscular injection, multiple dose vials. Each vial contains 5 doses (each dose is 0.5 mL).

DIN: 02513153

Manufacturer, Importer and Distributor: Janssen Inc.
Logistics Services Provider: Innomar Strategies Inc.

Background information

Janssen COVID-19 Vaccine is indicated for active immunization for the prevention of coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2 virus in individuals 18 years of age and older.

Very rare cases of thrombosis in combination with thrombocytopenia, in some cases accompanied by bleeding, have been observed following vaccination with Janssen COVID-19 Vaccine. This includes severe cases presenting in unusual sites such as cerebral venous sinus thrombosis (CVST) and splanchnic vein thrombosis, as well as arterial thrombosis, concomitant with thrombocytopenia. The majority of cases occurred within three weeks following vaccination. Some cases had a fatal outcome. No specific risk factors have been identified at this time.

Health Canada has assessed the available data on the reported events and has determined that the benefits of Janssen COVID-19 Vaccine outweigh the risks of thrombosis and thrombocytopenia.

Janssen COVID-19 Vaccine is expected to be distributed and administered in Canada in early May 2021.

Information for consumers

A combination of blood clots with low levels of platelets (elements in the blood that help it to clot), in some cases together with bleeding, has been observed very rarely following vaccination with Janssen COVID-19 Vaccine. For the majority of people who developed these blood clots and low levels of platelets, symptoms began one to three weeks following vaccination.

Patients should seek immediate medical attention if they develop any of the following symptoms within the first month after receiving Janssen COVID-19 Vaccine:

- New severe headaches, worsening or persistent headaches, blurred vision, confusion or seizures;
- Shortness of breath, chest pain, leg swelling, leg pain or persistent abdominal pain;
- Unusual skin bruising or pinpoint round spots under the skin beyond the site of injection.

The benefits of Janssen COVID-19 Vaccine in protecting Canadians from COVID-19 continue to outweigh the risks. Canadians are encouraged to get immunized with any of the COVID-19 vaccines that are offered to them.

Information for healthcare professionals

The Janssen COVID-19 Vaccine Product Monograph has been updated to include the risk of thrombosis with thrombocytopenia.

Healthcare professionals are advised to:

- be alert to the signs and symptoms of thrombosis and thrombocytopenia and report cases through their respective jurisdiction's Adverse Events Following Immunization (AEFI) surveillance system.
- instruct individuals vaccinated with Janssen COVID-19 Vaccine to seek immediate medical attention if they develop symptoms such as shortness of breath, chest pain, leg pain or swelling, or progressive abdominal pain following vaccination. Additionally, anyone with neurological symptoms including sudden onset of severe headaches, persistent or worsening headaches, blurred vision, confusion or seizure after vaccination, or who experiences unusual skin bruising or petechiae beyond the site of vaccination after a few days, should seek prompt medical attention.
- consult with current [guidance](#) and hematologic specialists to diagnose and treat this post-vaccine event.

Action taken by Health Canada

Health Canada has worked closely with international regulators and reviewed the available data. Health Canada will continue to gather Canadian and international information from the manufacturer, international regulators, and other experts, and will communicate any new information as needed.

Health Canada worked with the manufacturer to update the Product Monograph for Janssen COVID-19 Vaccine to reflect current knowledge of this safety issue in a timely manner. Further updates will be made or other actions will be taken, if required, based on emerging evidence.

Health Canada has worked with Janssen Inc. to prepare this alert. Health Canada is communicating this important safety information to healthcare professionals and Canadians via the [Recalls and Safety Alerts Database](#) on the Healthy Canadians Web Site. This communication will be further distributed through the MedEffect™ e-Notice email notification system, as well as through social media channels, including LinkedIn and Twitter.

Report health or safety concerns

Managing marketed health product-related side effects depends on healthcare professionals and consumers reporting them. Any serious or unexpected side effects in patients receiving Janssen COVID-19 Vaccine should be reported to your local Health Unit or Janssen Inc.

Janssen Inc.
19 Green Belt Drive
Toronto, ON
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To correct your mailing address or fax number, contact Janssen Inc. at 1-800-565-4008 (toll free) or 1-908-455-9922 (US toll).

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.

For other health product inquiries related to this communication, contact Health Canada at:

Biologic and Radiopharmaceutical Drugs Directorate
E-mail: hc.brdd.dgo.enquiries.sc@canada.ca

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