

Public advisory

Health Canada is updating the labels of the Janssen and Vaxzevria (AstraZeneca) COVID-19 vaccines

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Summary

Product: Janssen and Vaxzevria (AstraZeneca) COVID-19 vaccines

Issue: Health products » Product safety
COVID

What to do: Seek medical attention immediately if you have any of the following symptoms after vaccination with the Janssen and Vaxzevria COVID-19 vaccines: unexplained bleeding, unexplained bruising, small purplish spots beyond the site of vaccination, shortness of breath, chest pain, leg pain and/or swelling, and persistent abdominal pain.

Issue

Health Canada is informing Canadians and healthcare professionals about changes to the product labels of the Janssen and Vaxzevria (AstraZeneca) COVID-19 vaccines.

The Department is updating the label of the Janssen COVID-19 Vaccine to provide additional information about the very rare risk of immune thrombocytopenia (ITP), an autoimmune condition, and the rare risk of venous thromboembolism (VTE) following vaccination.

Health Canada is also updating the label of the Vaxzevria (AstraZeneca) COVID-19 vaccine to provide additional information about the very rare risk of thrombocytopenia, including the very rare risk of ITP, following vaccination.

Immune thrombocytopenia

Very rare cases of ITP, an autoimmune condition, have been reported internationally after receiving the Janssen COVID-19 vaccine. Similarly, cases of thrombocytopenia including ITP have been reported after receiving Vaxzevria.

ITP is a disorder that can lead to easy or excessive bruising and bleeding. The bleeding results from unusually low levels of platelets the cells that help blood clot. These cases typically occur within the first four weeks after vaccination. Some of these cases occurred in individuals with a history of ITP. Cases with a fatal outcome have been reported abroad.

Individuals should seek immediate medical attention if they develop symptoms, such as unexplained bleeding, unexplained bruising, or small purplish spots beyond the site of vaccination.

Venous thromboembolism

Rare cases of VTE have been reported following vaccination with the Janssen COVID-19 vaccine. VTE is a condition where a blood clot forms in a deep vein, usually in a leg, arm or groin, and may travel to the lungs

causing a blockage of the blood supply, with possible life-threatening consequences.

The risk of VTE should be considered for individuals who are at increased risk for thromboembolism. Healthcare professionals should be alert to the signs and symptoms of VTE. Individuals should seek immediate medical attention if they develop symptoms, such as shortness of breath, chest pain, leg pain, leg swelling, or persistent abdominal pain following vaccination.

The risk of VTE should be considered for individuals who are at increased risk for thromboembolism. Healthcare professionals should be alert to the signs and symptoms of VTE. Individuals should seek immediate medical attention if they develop symptoms, such as shortness of breath, chest pain, leg pain, leg swelling, or persistent abdominal pain following vaccination.

What you should do

If you have received the Janssen or Vaxzevria COVID-19 vaccine:

- Seek prompt medical attention immediately if you have any of the following symptoms after vaccination:
 - unexplained bleeding
 - unexplained bruising
 - small purplish spots beyond the site of vaccination
 - shortness of breath
 - chest pain
 - leg pain and/or swelling
 - persistent abdominal pain
- Talk to your healthcare professional if you have any questions about the Janssen or Vaxzevria COVID-19 vaccines.

- Report any adverse events after immunization to your healthcare professional.

If you are a healthcare professional:

- Be alert to the signs and symptoms of thromboembolism and thrombocytopenia to promptly treat these conditions according to available evidence and clinical guidelines.
- Inform people receiving the vaccine to seek medical attention if they develop any of the following symptoms:
 - ITP symptoms include spontaneous bleeding, unusual bruising or small red, purple or brown spots that appear under the skin.
 - VTE symptoms include shortness of breath, chest pain, leg pain, leg swelling, or persistent abdominal pain following vaccination.
- Consider consultation with a specialist if you suspect the patient has post-vaccine thrombosis.
- If an individual has a history of a thrombocytopenic disorder, such as immune thrombocytopenia, the risk of developing low platelet levels should be considered before administering the vaccine and platelet monitoring is recommended after vaccination.

Additional information

▼ What is being done

Health Canada will continue to work with manufacturers, as well as with international and domestic partners including the Public Health Agency of Canada (PHAC), to gain a better understanding of the potential relationships between COVID-19 vaccines and these adverse events. Health Canada will take further action if necessary.

The Department is also providing Canadians and healthcare professionals with information on the use of the Janssen vaccine in Canada and monitoring for post-vaccination symptoms.

▼ Details

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