Ministry of Health

Ministère de la Santé



Office of Chief Medical Officer of

Health, Public Health

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June 28, 2023

To all COVID-19 Vaccinators.

Janssen Inc. has submitted a voluntary recall to Health Canada for the JCOVDEN (Janssen) COVID-19 vaccine and requested cancellation of the DIN for this product. According to Janssen, the decision to withdraw this product from use in Canada is a business decision and is NOT the result of any health or safety concerns related to the vaccine. As Janssen and Health Canada have indicated post-market surveillance of the product will be discontinued after June 30, 2023, the Ministry recommends an immediate discontinuation of the use of JCOVDEN (Janssen) COVID-19 vaccine and to consider other available COVID-19 vaccines.

For sites that do not have this product on hand, no action is required. Please continue to counsel and provide advice on COVID-19 vaccination. Please note, as a result of this recall, there will be a non-mRNA COVID-19 vaccine supply gap across Canada after June 30, 2023 until the next shipment of Novavax (date TBD).

All remaining JCOVDEN (Janssen) COVID-19 vaccine doses are being repatriated to the federal warehouse for disposal. If there are any pharmacies that have this product in their inventory, please contact us at covid.logistics@ontario.ca to arrange a pick-up of the vaccine. The ministry will be working closely with public health units to repatriate all doses of Janssen COVID-19 vaccines from other locations.

Product details:

Brand Name: JCOVDEN

Company Name: Janssen Inc.

LOT#: 1875739

Expiry date: September 30, 2023

Presentation: 5 doses of 0.5ml

DIN: 02513153

Required Actions:

- Discontinue use of the JCOVDEN (Janssen) COVID-19 vaccine product immediately.
- Label JCOVDEN (Janssen) COVID-19 vaccine product as "DO NOT USE".
- Ensure that any doses on-hand are accurately reflected in COVaxON.
- Due to the planned disposal of this vaccine, routine cold-chain monitoring will not be necessary.

Please email <u>covid.logistics@ontario.ca</u> if you have questions or concerns.

Thank you,

to And

Dr. Kieran Michael Moore, MD, CCFP(EM), FCFP, MPH, DTM&H, FRCPC, FCAHS Chief Medical Officer of Health and Assistant Deputy Minister, Public Health

Elizabeth Walker, Executive Lead
Dr. Daniel Warshafsky, Associate Chief Medical Officer of Health
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