Vial and carton labels for Janssen COVID-19 Vaccine with English-only labelling

Vial – Version 1

AW_176976	
COVID Vaccin	-19 e Janssen
COVID-1 (Ad26.C (recomb IM injec	pinant))
5 doses	of 0.5 mL
Discard	date/time:
///	///
Lot	////

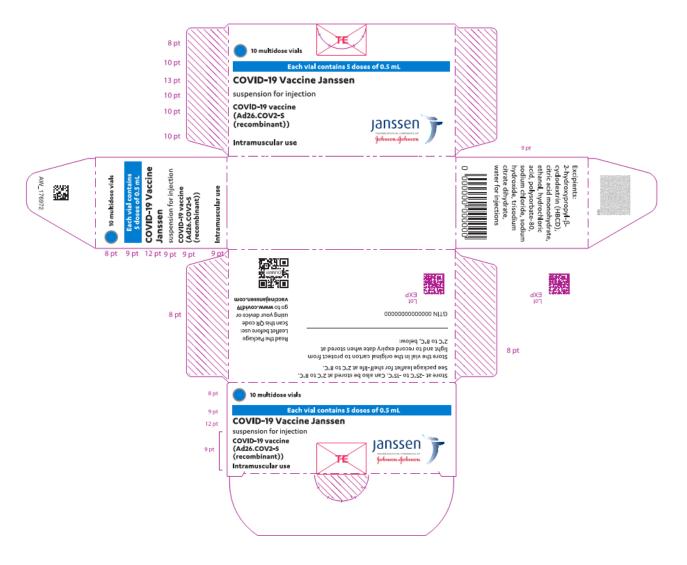
EU White Label: Vial Label

COVID-19 Vaccine Janssen COVID-19 vaccine (Ad26.COV2-S (recombinant)) IM Injection 5 doses of 0.5 mL Discard date/time:

Lot EXP

Carton – Version 1

EU White Label: Carton Label



10 multidose vials Each vial contains 5 doses of 0.5 mL COVID-19 Vaccine Janssen suspension for injection COVID-19 vaccine (Ad26.COV2-S (recombinant)) Intramuscular use

Excipients: 2-hydroxypropyl-β-cyclodextrin (HBCD), citric acid monohydrate, ethanol, hydrochloric acid, polysorbate-80, sodium chloride, sodium hydroxide, trisodium citrate dihydrate, water for injections

Store at -25°C to -15°C. Can also be stored at 2°C to 8°C. See package leaflet for shelf-life at 2°C to 8°C.

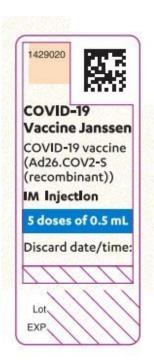
Store vial in the original carton to protect from light and to record expiry date when stored at 2°C to 8°C, below: _____

GTIN XXXXXXXXXXXXXXX Lot EXP

Read the package leaflet before use: Scan this QR code using your device or go to www.covid19vaccinejanssen.com

[QR Code]

EU White Label: Vial label



COVID-19 Vaccine Janssen COVID-19 vaccine (Ad26.COV2-S [recombinant]) IM Injection 5 doses of 0.5 mL Discard date/time:

Lot EXP

Carton – Version 2

EU White Label: Carton label



10 multidose vials Each vial contains 5 doses of 0.5 mL COVID-19 Vaccine Janssen suspension for injection COVID-19 vaccine (Ad26.COV2-S [recombinant]) Intramuscular use

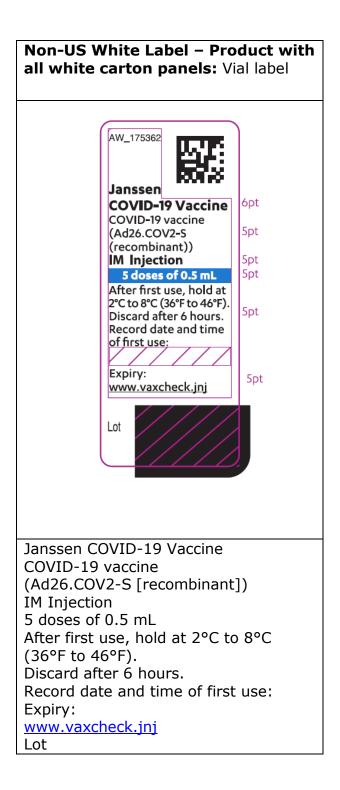
Excipients: 2-hydroxypropyl-β-cyclodextrin (HBCD), citric acid monohydrate, ethanol, hydrochloric acid, polysorbate-80, sodium chloride, sodium hydroxide, trisodium citrate dihydrate, water for injections

Store at -25°C to -15°C. Can also be stored at 2°C to 8°C. See package leaflet for shelf-life at 2°C to 8°C.

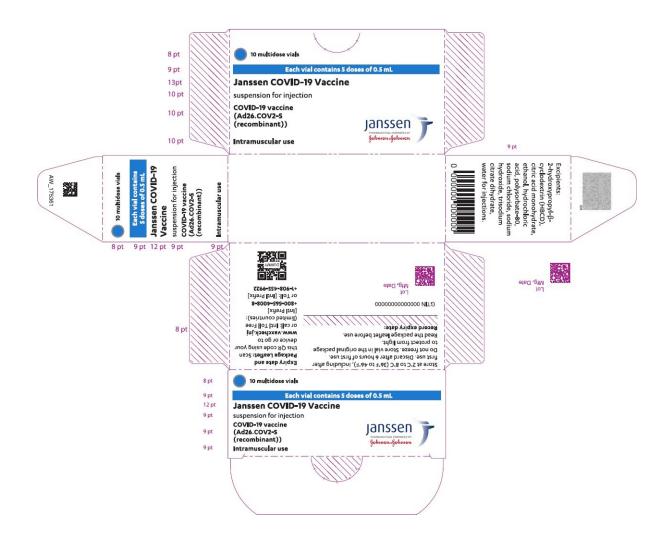
Store vial in the original carton to protect from light and to record expiry date when stored at 2°C to 8°C, below: _____

Read the package leaflet before use: Scan this QR code using your device or go to <u>www.covid19vaccinejanssen.com</u>

SN EXP Lot GTIN



Carton – Version 3



Non-US White - Product with all white carton panels: Carton label

10 multidose vials Each vial contains 5 doses of 0.5 mL Janssen COVID-19 Vaccine Suspension for injection COVID-19 vaccine (Ad26.COV2-S [recombinant]) Intramuscular use 5 doses of 0.5 mL

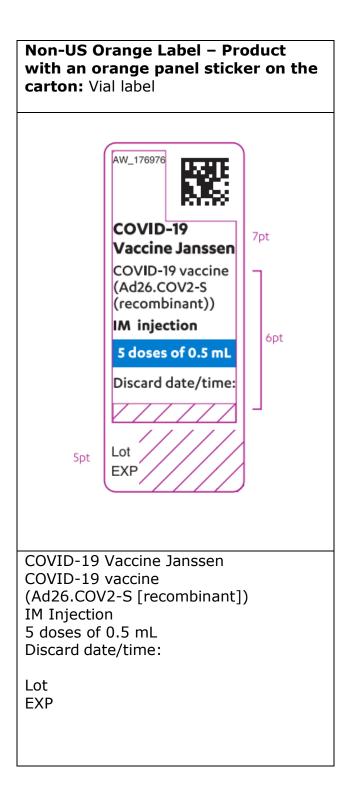
Excipients: 2-hydroxypropyl-β-cyclodextrin (HBCD), citric acid monohydrate, ethanol, hydrochloric acid, polysorbate-80, sodium chloride, sodium hydroxide, trisodium citrate dihydrate, water for injections

Store at 2°C to 8°C (36°F to 46°F), including after first use. Discard after 6 hoursof first use. Do not freeze. Store vial in the original package to protect from light.Read the package leaflet before use.

Record expiry date: _____

GTIN Lot Mfg. Date

Expiry date and package leaflet: Scan this QR code using your device or go to <u>www.vaxcheck.jnj</u> or call Intl toll free (limited countries): [intl prefix] +800-565-4008-8 Or Toll: [Intl prefix] +1-908-455-9922



Non-US Orange Label – Product with an orange panel sticker on the carton: Carton label



10 multidose vials Each vial contains 5 doses of 0.5 mL COVID-19 Vaccine Janssen Suspension for injection COVID-19 vaccine (Ad26.COV2-S [recombinant)]) Intramuscular use

Excipients: 2-hydroxypropyl-β-cyclodextrin (HBCD), citric acid monohydrate, ethanol, hydrochloric acid, polysorbate-80, sodium chloride, sodium hydroxide, trisodium citrate dihydrate, water for injections

Store at 2 to 8°C including after first use. DO NOT FREEZE.

Discard punctured vial after 6h. Store vials in the original carton to protect from light. Retain carton for expiry date.

For complete storage and other product information see Product Monograph at <u>www.janssen.com/canada/products</u> or call 1-800-565-4008 (toll free) or 1-908-455-9922 (US toll) or visit <u>www.janssenmedicalinformation.ca</u>

GTIN Lot: EXP: