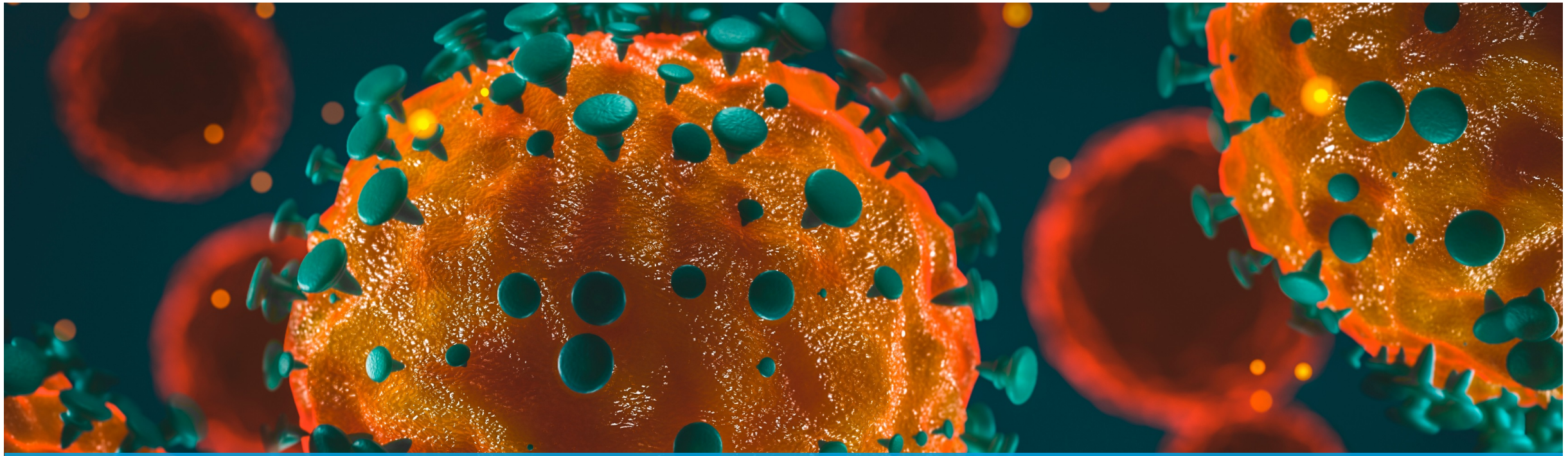


JANSSEN COVID-19 VACCINE

OVERVIEW OF PANDEMIC SUPPLY LOGISTICS

Coronavirus 2019-nCov novel coronavirus

The Janssen COVID-19 Vaccine has not been approved or licensed by the U.S. Food and Drug Administration (FDA), but has been authorized by FDA through an Emergency Use Authorization (EUA) for active immunization to prevent Coronavirus Disease 2019 (COVID-19) in individuals 18 years of age and older. The emergency use of this product is authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of the medical product under Section 564(b)(1) of the FD&C Act, unless the declaration is terminated or authorization revoked sooner.

 02/21 cp-191118v3

janssen | PHARMACEUTICAL COMPANIES OF Johnson & Johnson

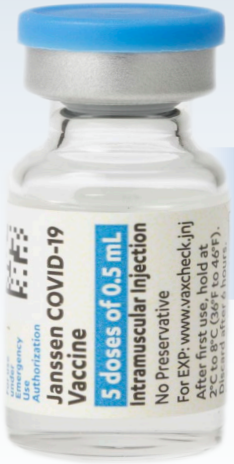
Janssen COVID-19 Vaccine

Supply and Packaging Configuration for Product Authorized for Emergency Use[1]

Primary Packaging

2R glass vial
High volume 5-dose vial for EUA
0.5 mL per dose (5x10^{10} vp)

Blue matte finish (3769) button with silver crimp combination.



- Does not contain preservatives
- No reconstitution required
- No latex in the rubber stopper

10 vials per carton

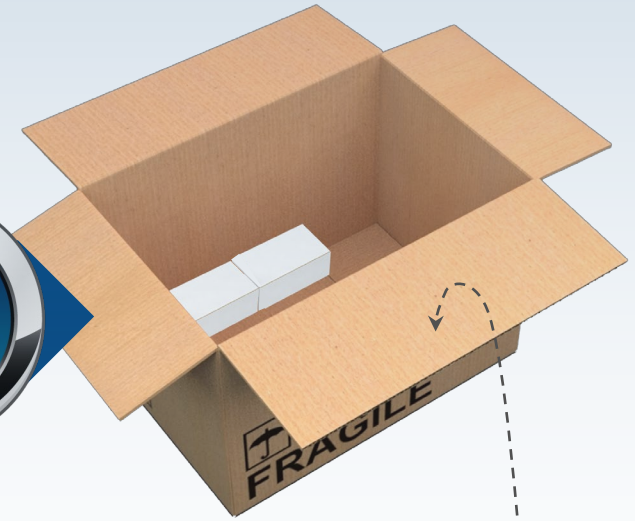
Secondary Packaging

1 product insert per carton

Carton material: solid bleached sulfate (SBS)

48 cartons per case

Tertiary Packaging



Shipping case material: ECT-55 corrugate

DIMENSIONS:

Ht: Overall 35 mm (1.38”)
Ht: Flange 3.6 mm (0.14”)
Int Dia: Finish 7 mm (0.28”)
Ext Dia: Body 16 mm (0.63”)
Ext Dia: Flange 13 mm (0.51”)

DIMENSIONS:

L: 93 mm 3.66” x W: 38 mm 1.50” x D: 54 mm 2.13”

DIMENSIONS:

L: 389 mm 15.31” x W: 243 mm 9.56” x D: 121 mm 4.75”

2R = 2mL injection vial; EUA = emergency use authorization; Ext Dia = exterior diameter; Ht = height; Int Dia = interior diameter; vp = virus particles.

1. Data on file. Janssen Vaccines & Prevention B.V.

Janssen COVID-19 Vaccine

Ancillary Kit Content and Configuration*[1,2]

Needles
22-25G x 1" (Qty 85)

Needles
22-25G x 1.5" (Qty 20)

Syringes
1mL or 3mL (Qty 105)

Alcohol Pads
Sterile, individually sealed (Qty 210)

Pandemic Kit Packaging

DIMENSIONS[2]:

L: 14.1” x W: 13.1” x D: 9.1”

Vaccination card
(Qty 100)

Needle information card
(Qty 1)

Face shield
(Qty 2)

Surgical mask
(Qty 4)

*Kits are supplied by an unrelated third-party distributor under emergency use authorization (EUA).

1. CDC. Accessed February 2, 2021. https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf. 2. Data on file. Janssen Vaccines & Prevention B.V.

Janssen COVID-19 Vaccine

Storage and Handling for Product Authorized for Emergency Use[1]

How Supplied

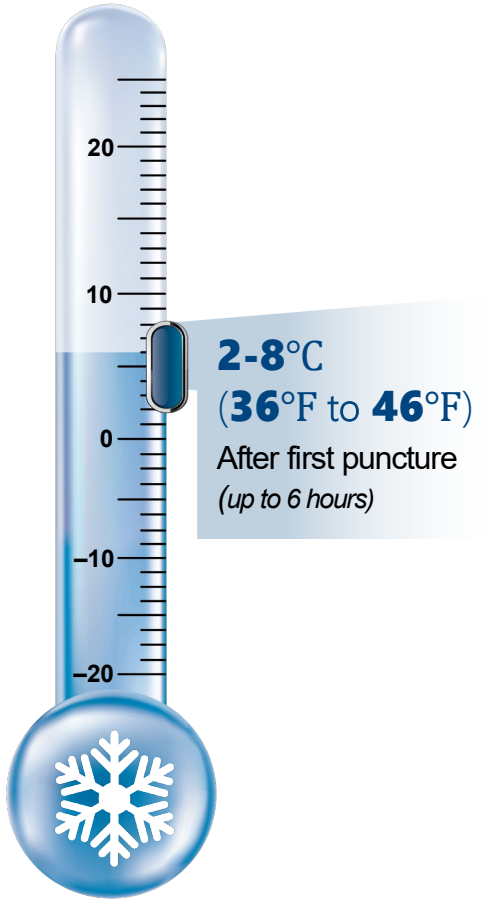
- Janssen COVID-19 Vaccine is supplied in a carton of 10 multi-dose vials. Each vial contains 5 doses. Do not pool vaccine from multiple vials
- The Janssen COVID-19 Vaccine is initially stored frozen by the manufacturer, then shipped at 2°C to 8°C (36°F to 46°F)
- If vaccine is still frozen upon receipt, thaw at 2°C to 8°C (36°F to 46°F). If needed immediately, thaw at room temperature (maximally 25°C/77°F). Do not refreeze once thawed

Storage Prior to First Puncture of the Vaccine Vial

- Store unpunctured multi-dose vials of the Janssen COVID-19 Vaccine at 2°C to 8°C (36°F to 46°F) and protect from light. Do not store frozen
- Unpunctured vials of Janssen COVID-19 Vaccine may be stored between 9°C to 25°C (47°F to 77°F) for up to 12 hours

Storage After First Puncture of the Vaccine Vial

- After the first dose has been withdrawn, the vial may be held at 2°C to 8°C (36°F to 46°F) for up to 6 hours or at room temperature (maximally 25°C or 77°F) for up to 2 hours. Record the date and time of first use on the Janssen COVID-19 Vaccine vial label
- Discard the vial if vaccine is not used within this time



EUA = emergency use authorization.

1. Janssen COVID-19 Vaccine EUA Fact Sheet/USPI.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

Do not administer the Janssen COVID-19 Vaccine to individuals with a known history of a severe allergic reaction (e.g., anaphylaxis) to any component of the Janssen COVID-19 Vaccine.

WARNINGS AND PRECAUTIONS

Management of Acute Allergic Reactions: Appropriate medical treatment to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of the Janssen COVID-19 Vaccine.

Monitor Janssen COVID-19 Vaccine recipients for the occurrence of immediate adverse reactions according to the Centers for Disease Control and Prevention guidelines (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html).

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

Limitations of Vaccine Effectiveness: The Janssen COVID-19 Vaccine may not protect all vaccinated individuals.

ADVERSE REACTIONS

Adverse reactions reported in a clinical trial following administration of the Janssen COVID-19 Vaccine include injection site pain, headache, fatigue, myalgia, nausea, fever, injection site erythema and injection site swelling. In clinical studies, severe allergic reactions, including anaphylaxis, have been reported following the administration of the Janssen COVID-19 Vaccine.

Additional adverse reactions, some of which may be serious, may become apparent with more widespread use of the Janssen COVID-19 Vaccine.

IMPORTANT SAFETY INFORMATION (continued)

Reporting Adverse Events and Vaccine Administration Error

The vaccination provider enrolled in the federal COVID-19 Vaccination Program is responsible for mandatory reporting of the listed events following Janssen COVID-19 Vaccine administration to the Vaccine Adverse Event Reporting System (VAERS):

- Vaccine administration errors whether or not associated with an adverse event,
- Serious adverse events (irrespective of attribution to vaccination),
- Cases of Multisystem Inflammatory Syndrome (MIS) in adults,
- Cases of COVID-19 that result in hospitalization or death.

Instructions for Reporting to VAERS

The vaccination provider enrolled in the federal COVID-19 Vaccination Program should complete and submit a VAERS form to FDA using one of the following methods below. Reports should include the words “Janssen COVID-19 Vaccine EUA” in the description section of the report as the first line.

- Complete and submit the report online: https://vaers.hhs.gov/reportevent.html, or
- If you are unable to submit this form electronically, you may fax it to VAERS at 1-877-721-0366. If you need additional help submitting a report you may call the VAERS toll free information line at 1-800-822-7967 or send an email to info@vaers.org

Report adverse events to Janssen Biotech, Inc. by calling 1-800-565-4008 or provide a copy of the VAERS form by faxing 1-215-293-9955.

IMPORTANT SAFETY INFORMATION (continued)

PREGNANCY AND LACTATION

- **Pregnancy:** Available data on Janssen COVID-19 Vaccine administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy.
- **Lactation:** Data are not available to assess the effects of Janssen COVID-19 Vaccine on the breastfed infant or on milk production/excretion.

DOSING AND SCHEDULE

The Janssen COVID-19 Vaccine is administered intramuscularly as a single dose (0.5 mL).

There are no data available on the use of the Janssen COVID-19 Vaccine to complete a vaccination series initiated with another COVID-19 vaccine.

Please read Emergency Use Authorization (EUA) Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) including full EUA Prescribing Information available at www.JanssenCOVID19vaccine.com/EUA-Factsheet.

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