

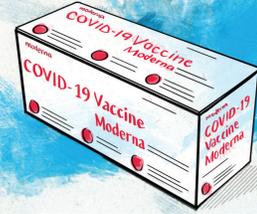
Spikevax dispersion for injection COVID-19 mRNA Vaccine (nucleoside modified)

Storage & Handling

Frozen Storage

Store frozen between
-25°C to -15°C.

Do not store below -50°C
Store in the original carton to protect from light.



Thaw Each Vial Before Use

Vial images for illustrative purposes only

2 hours and 30 minutes in refrigerator

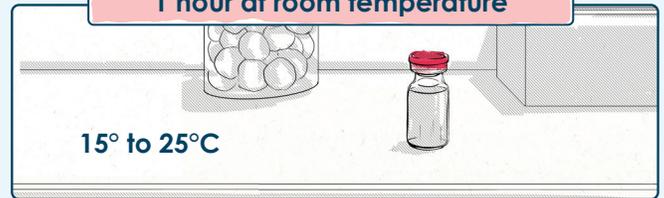
2° to 8°C
(within the 30
days shelf life
at 2°C to 8°C)



OR

1 hour at room temperature

15° to 25°C



Let vial sit at room temperature for 15 minutes before administering

Instructions Once Thawed

Unpunctured Vial

Maximum times

30
days

Refrigerator

2° to 8°C

24
hours

Cool storage up to
room temperature

8° to 25°C



After first dose has been withdrawn

Maximum time

19
hours

Refrigerator or
room temperature

Vial should be held between
2° to 25°C. Record the date and time
of discard on the vial label.

Discard punctured vial after 19 hours.



Withdraw each dose of vaccine from the vial using a new sterile needle and syringe for each injection to prevent transmission of infectious agents from one person to another.
The dose in the syringe should be used immediately.

Once the vial has been punctured to withdraw the initial dose, the vaccine should be used immediately and be discarded after 19 hours.

Any unused vaccine or waste material should be disposed of in accordance with local requirements.

NEVER refreeze thawed vaccine

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Dosing & Administration

Dosing and Schedule

Primary series

Individuals 12 years of age and older

Spikevax is administered as a course of 2 (two) 100 microgram doses (0.5 mL each).

Children 6 through 11 years of age

Spikevax is administered as a course of 2 (two) 50 microgram doses (0.25 mL each, containing 50 micrograms mRNA, which is half of the primary dose for individuals 12 years and older).

It is recommended to administer the second dose 28 days after the first dose.

Severely immunocompromised aged 6 years and older

A third dose may be given at least 28 days after the second dose to individuals 12 years of age and older (0.5 mL, 100 micrograms) and children 6 through 11 years (0.25 mL, 50 micrograms) who are severely immunocompromised.

Booster dose

Individuals 18 years of age and older

A booster dose of Spikevax (0.25 mL, containing 50 micrograms mRNA, which is half of the primary dose) should be given intramuscularly to adults at least 3 months after completion of the primary series.

Spikevax may be used to boost adults who have received a primary series with Spikevax or a primary series comprised of another mRNA vaccine or adenoviral vector vaccine.

Administration

Swirl vial gently after thawing and before each withdrawal.

The vaccine comes ready to use once thawed. **Do not shake or dilute.**

Prior to injection, inspect each dose to:

Confirm liquid is **white to off-white** in colour in both vial and syringe

Verify syringe volume.

The vaccine may contain white or translucent product-related particulates.

If dosage is incorrect, or discolouration and other particulate matter is present, do not administer the vaccine.



Provide a vaccination card to the vaccinee or their caregiver with the date the vaccinee needs to return for **FUTURE DOSES** of Spikevax.

For questions, visit www.modernacovid19global.com and select your country.

INDICATION

Spikevax is indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2 in individuals 6 years of age and older.

The use of this vaccine should be in accordance with official recommendations.

CONTRAINDICATION

Hypersensitivity to the active substance or to any of the excipients.

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