

**PACKAGE LEAFLET**

**Package leaflet: Information for the user**  
**INTERIM AUTHORISATION**  
**Spikevax dispersion for injection**  
COVID-19 mRNA Vaccine (nucleoside modified)

The HSA has granted interim authorisation of Spikevax to prevent COVID-19 in individuals 18 years of age and older under the Pandemic Special Access Route (PSAR).

For more information on Interim Authorisation under PSAR, visit HSA at <https://www.hsa.gov.sg/therapeutic-products/register/special-access-routes/psar-emergency-therapeutic-product>.

**Read all of this leaflet carefully before you receive this vaccine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet**

1. What Spikevax is and what it is used for
2. What you need to know before you are given Spikevax
3. How Spikevax is given
4. Possible side effects
5. How to store Spikevax
6. Contents of the pack and other information

**1. What Spikevax is and what it is used for**

Spikevax is a vaccine used to prevent COVID-19 disease caused by SARS-CoV-2. It is given to adults aged 18 years and older. The active substance in Spikevax is mRNA encoding the SARS-CoV-2 Spike protein. The mRNA is embedded in SM-102 lipid nanoparticles.

As Spikevax does not contain the virus, it cannot give you COVID-19.

**How the vaccine works**

Spikevax stimulates the body's natural defences (immune system). The vaccine works by causing the body to produce protection (antibodies) against the virus that causes COVID-19. Spikevax uses a substance called messenger ribonucleic acid (mRNA) to carry instructions that cells in the body can use to make the spike protein that is also on the virus. The cells then make antibodies against the spike protein to help fight off the virus. This will help to protect you against COVID-19.

**2. What you need to know before you are given Spikevax**

**The vaccine must not be given if**

- you are **allergic** to the active substance or any of the other ingredients of this vaccine (listed in section 6).

**Warnings and precautions**

Talk to your doctor, pharmacist or nurse before you are given Spikevax if:

- you have previously had a severe, life-threatening **allergic** reaction after any other vaccine injection or after you were given Spikevax in the past.
- you have any allergies
- you have a very weak or compromised immune system

- you have ever fainted following any needle injection.
- you have a bleeding disorder
- you have a fever
- you are pregnant or plan to be pregnant
- you are breastfeeding
- you have any serious illness
- you have received another COVID-19 vaccine
- if you have anxiety related to injections

Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have occurred in some people who have received Spikevax. In most of these people, symptoms began within a few days following receipt of the second dose of Spikevax. The chance of having this occur is very low. You should avoid strenuous physical activity for one week after vaccination. You should seek medical attention right away if you have any of the following symptoms after receiving Spikevax:

- Chest pain
- Shortness of breath
- Feelings of having a fast-beating, fluttering, or pounding heart

If any of the above apply to you (or you are not sure), talk to your doctor, pharmacist or nurse before you are given Spikevax.

As with any vaccine, the 2-dose vaccination course of Spikevax may not fully protect all those who receive it and it is not known how long you will be protected.

### **Children and adolescents**

Spikevax is not recommended for children aged under 18 years.

### **Other medicines and Spikevax**

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines. Spikevax may affect the way other medicines work, and other medicines may affect how Spikevax works.

### **Driving and using machines**

Do not drive or use machines if you are feeling unwell after vaccination. Wait until any effects of the vaccine have worn off before you drive or use machines.

### **Spikevax contains sodium**

Spikevax contains less than 1 mmol (23 mg) sodium per dose and, that is to say, essentially 'sodium-free'.

## **3. How you will be given Spikevax**

Spikevax will be given to you as two 0.5 mL injections. It is recommended to administer the second dose of the same vaccine 28 days after the first dose to complete the vaccination course.

Your doctor, pharmacist or nurse will inject the vaccine into a muscle (intramuscular injection) in your upper arm.

During and after each injection of the vaccine, your doctor, pharmacist or nurse will watch over you for around 30 minutes to monitor for signs of an allergic reaction.

### **If you miss an appointment for your 2<sup>nd</sup> dose of Spikevax**

- If you miss an appointment, arrange another visit as soon as possible with your doctor, nurse, or pharmacist.
- If you miss a scheduled injection, you may not be fully protected against COVID-19.

If you have any further questions on the use of this vaccine, ask your doctor, pharmacist or nurse.

#### **4. Possible side effects**

Like all medicines, this vaccine can cause side effects, although not everybody gets them.

Get **urgent** medical attention if you get any of the following signs and symptoms of an allergic reaction:

- feeling faint or light-headed;
- changes in your heartbeat;
- shortness of breath;
- wheezing;
- swelling of your lips, face, or throat;
- hives or rash;
- nausea or vomiting;
- stomach pain.

Talk to your doctor or nurse if you develop any other side effects. These can include:

**Very common** (may affect more than 1 in 10 people):

- swelling in the underarm
- headache
- nausea
- vomiting
- muscle ache, joint aches, and stiffness
- pain or swelling at the injection site
- feeling very tired
- chills
- fever

**Common** (may affect up to 1 in 10 people):

- rash
- rash, redness, or hives at the injection site

**Uncommon** (may affect up to 1 in 100 people):

- itchiness at the injection site

**Rare** (may affect up to 1 in 1000 people)

- temporary one-sided facial drooping (Bell's palsy)
- swelling of the face (Swelling of the face may occur in patients who have had facial cosmetic injections.)

**Frequency unknown**

- severe allergic reactions (anaphylaxis)
- hypersensitivity
- inflammation of the heart muscle (myocarditis) or inflammation of the lining outside the heart (pericarditis) which can result in breathlessness, palpitations or chest pain.

#### **Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

#### **5. How to store Spikevax**

Keep this vaccine out of the sight and reach of children.

Do not use this vaccine after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

Information about storage, expiry, and use and handling are described in the section intended for healthcare professionals at the end of the package leaflet.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## **6. Contents of the pack and other information**

### **What Spikevax contains**

- This is a multidose vial which contains 10 doses of 0.5 mL.
- One dose (0.5 mL) contains 100 micrograms of messenger RNA (mRNA) (embedded in SM-102 lipid nanoparticles).
- Single-stranded, 5'-capped messenger RNA (mRNA) produced using a cell-free in vitro transcription from the corresponding DNA templates, encoding the viral spike (S) protein of SARS-CoV-2.
- The other ingredients are lipid SM-102, cholesterol, 1,2-distearoyl-sn-glycero-3-phosphocholine (DSPC), 1,2-Dimyristoyl-rac-glycero-3-methoxypolyethylene glycol-2000 (PEG2000 DMG), trometamol, trometamol hydrochloride, acetic acid, sodium acetate trihydrate, sucrose, water for injections.

### **What Spikevax looks like and contents of the pack**

Spikevax is a white to off white dispersion supplied in a glass vial with a rubber stopper and aluminium seal.

Pack size: 10 multidose vials

#### **Product owner:**

MODERNA BIOTECH SPAIN, S.L.  
Calle Monte Esquinza 30  
28010 Madrid  
Spain

#### **Manufacturer:**

Rovi Pharma Industrial Services, S.A.  
Paseo de Europa, 50  
28703. San Sebastián de los Reyes  
Madrid, Spain

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder.

**This leaflet was last revised in {MM/YYYY}.**

Scan the code with a mobile device to get the package leaflet in different languages.



Or visit the URL <https://www.ModernaCovid19Global.com>

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**The following information is intended for healthcare professionals only:**

Traceability

In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

Spikevax should be administered by a trained healthcare professional. The vaccine comes ready to use once thawed.

Do not shake or dilute.

Spikevax vials are multidose. Ten (10) doses can be withdrawn from each multidose vial. Pierce the stopper preferably at a different site each time.

An additional overfill is included in each vial to ensure that 10 doses of 0.5 mL can be delivered.

Thawed vials and filled syringes can be handled in room light conditions.

Spikevax should be administered as two 0.5 mL doses. It is recommended to administer the second dose 28 days after the first dose.

As with all injectable vaccines, appropriate medical treatment and supervision must always be readily available in the event of an anaphylactic reaction following the administration of Spikevax. Individuals should be observed by a healthcare professional for at least 30 minutes after vaccination.

There are no data to assess the concomitant administration of Spikevax with other vaccines. Spikevax must not be mixed with other vaccines or medicinal products in the same syringe.

The vaccine must be administered intramuscularly. The preferred site is the deltoid muscle of the upper arm. Do not administer this vaccine intravascularly, subcutaneously or intradermally.

## Information about storage and handling

### Frozen Storage

Store frozen between  $-25^{\circ}$  to  $-15^{\circ}\text{C}$   
Do not store on dry ice or below  $-50^{\circ}\text{C}$   
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

$2^{\circ}$  to  $8^{\circ}\text{C}$   
(within the 30 days shelf life at  $2^{\circ}$  to  $8^{\circ}\text{C}$ )



1 hour at room temperature

$15^{\circ}$  to  $25^{\circ}\text{C}$



Let vial sit at room temperature for 15 minutes before administering

### Instructions Once Thawed

#### Unpunctured Vial

Maximum times

30 days

Refrigerator

$2^{\circ}$  to  $8^{\circ}\text{C}$

24 hours

Cool storage up to room temperature

$8^{\circ}$  to  $25^{\circ}\text{C}$



#### After first dose has been withdrawn

Maximum time

19 hours

Refrigerator or room temperature

Vial should be held between  $2^{\circ}$  to  $25^{\circ}\text{C}$ . Record the date and time of discard on the vial label.

Discard punctured vial after 19 hours.



Withdraw each 0.5 mL 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

### 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 of **0.5 mL**

The COVID-19 Vaccine Moderna may contain white or translucent product-related particulates.

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

