

Package leaflet: Information for the user

Spikevax 0.2 mg/mL dispersion for injection Spikevax 0.1 mg/mL dispersion for injection Spikevax 50 micrograms dispersion for injection in pre-filled syringe COVID-19 mRNA Vaccine (nucleoside modified) elasomeran

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

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 caused by SARS-CoV-2. It is given to adults and children aged 6 months 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 a very weak or compromised immune system
- you have ever fainted following any needle injection.
- you have a bleeding disorder
- you have a high fever or severe infection; however, you can have your vaccination if you have a mild fever or upper airway infection like a cold
- you have any serious illness
- if you have anxiety related to injections

There is an increased risk of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) after vaccination with Spikevax (see section 4).

These conditions can develop within just a few days after vaccination and have primarily occurred within 14 days. They have been observed more often after the second dose compared to the first dose, and more often in younger males.

Following vaccination, you should be alert to signs of myocarditis and pericarditis, such as breathlessness, palpitations and chest pain, and seek immediate medical attention should these occur.

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.

Capillary leak syndrome (CLS) flare-ups

A few cases of capillary leak syndrome flare-ups (causing fluid leakage from small blood vessels (capillaries) resulting in rapid swelling of the arms and legs, sudden weight gain and feeling faint, low blood pressure) have been reported following vaccination with Spikevax. If you have previously had episodes of CLS, talk to a doctor before you are given Spikevax.

Duration of protection

As with any vaccine, the primary 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

Spikevax is not recommended for children aged under 6 months.

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.

Immunocompromised individuals

If you are immunocompromised, you may receive a third dose of Spikevax. The efficacy of Spikevax even after a third dose may be lower in people who are immunocompromised. In these cases, you should continue to maintain physical precautions to help prevent COVID-19. In addition, your close contacts should be vaccinated as appropriate. Discuss appropriate individual recommendations with your doctor.

Pregnancy and breast-feeding

If you are pregnant or think you may be pregnant, tell your doctor, nurse or pharmacist before you receive this vaccine. Spikevax can be used during pregnancy. A large amount of information from pregnant women vaccinated with Spikevax during the second and third trimester have not shown negative effects on the pregnancy or the newborn baby. While information on effects on pregnancy or the newborn baby after vaccination during the first trimester is limited, no change to the risk for miscarriage has been seen.

Spikevax can be given during breastfeeding.

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

This medicine 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

Table 1. Spikevax dosing for primary series, a third dose in severely immunocompromised and booster doses

Vaccination	Spikevax 0.2 mg/mL dispersion for injection	Spikevax 0.1 mg/mL dispersion for injection and Spikevax 50 micrograms dispersion for injection in pre-filled syringe*
Primary series It is recommended to get the second dose of the same vaccine 28 days after the first dose to complete the vaccination course.	Individuals 12 years of age and older two 0.5 mL injections	Not applicable†
	Children 6 years through 11 years of age two 0.25 mL injections	Children 6 years through 11 years of age two 0.5 mL injections
	Not applicable	Children 6 months through 5 years of age two 0.25 mL injections*
Third dose in severely immunocompromised individuals at least 1 month after the second dose	Individuals 12 years of age and older 0.5 mL	Not applicable‡

	Children 6 years through 11 years of age 0.25 mL	Children 6 years through 11 years of age 0.5 mL
	Not applicable	Children 6 months through 5 years of age two 0.25 mL injections*
Booster dose may be given at least 3 months after the second dose	Individuals 12 years of age and older 0.25 mL	Individuals 12 years of age and older 0.5 mL

*Do not use the pre-filled syringe to deliver a partial volume of 0.25 mL.

†For primary series for individuals 12 years of age and older, the 0.2 mg/mL strength vial should be used.

‡For the third dose in severely immunocompromised patients 12 years of age and older, the 0.2 mg/mL strength vial should be used.

If you miss an appointment for your primary 2nd dose of Spikevax

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

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

After each injection of the vaccine, your doctor, pharmacist or nurse will watch over you for at least **15 minutes** to monitor for signs of an allergic reaction.

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/tenderness in the underarm
- decreased appetite (observed in 6 month to 5 year olds)
- irritability/crying (observed in 6 month to 5 year olds)
- headache
- sleepiness (observed in 6 month to 5 year olds)
- nausea
- vomiting
- muscle ache, joint aches, and stiffness
- pain or swelling at the injection site
- redness at the injection site (some of which may occur approximately 9 to 11 days after the injection)
- feeling very tired
- chills
- fever

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

- diarrhoea
- rash
- rash or hives at the injection site (some of which may occur approximately 9 to 11 days after the injection)

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

- itchiness at the injection site
- dizziness

- stomach pain

Rare (may affect up to 1 in 1 000 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.)
- decreased sense of touch or sensation
- unusual feeling in the skin, such as tingling or a crawling feeling (paraesthesia)

Very rare (may affect up to 1 in 10 000 people)

- inflammation of the heart muscle (myocarditis) or inflammation of the lining outside the heart (pericarditis) which can result in breathlessness, palpitations or chest pain

Frequency unknown

- severe allergic reactions with breathing difficulties (anaphylaxis)
- reaction of increased sensitivity or intolerance by the immune system (hypersensitivity)
- a skin reaction that causes red spots or patches on the skin that may look like a target or “bulls-eye” with a dark red centre surrounded by paler red rings (erythema multiforme)
- extensive swelling of the vaccinated limb

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. You can also report side effects directly via the national reporting system listed below. By reporting side effects you can help provide more information on the safety of this vaccine.

Ireland

HPRA Pharmacovigilance

Website: www.hpra.ie

Malta

ADR Reporting Website: www.medicinesauthority.gov.mt/adrportal

United Kingdom (Northern Ireland)

Yellow Card Scheme

Website: <https://coronavirus-yellowcard.mhra.gov.uk/> or search for MHRA Yellow Card in the Google Play or Apple App Store

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

Table 2. Composition by container type

Strength	Container	Dose(s)	Composition
Spikevax 0.2 mg/mL dispersion for injection	Multidose vial	Maximum 10 doses of 0.5 mL each	One dose (0.5 mL) contains 100 micrograms of elasomeran, a COVID-19 mRNA Vaccine (embedded in SM-102 lipid nanoparticles).
		Maximum 20 doses of 0.25 mL each	One dose (0.25 mL) contains 50 micrograms of elasomeran, a

Strength	Container	Dose(s)	Composition
			COVID-19 mRNA Vaccine (embedded in SM-102 lipid nanoparticles).
Spikevax 0.1 mg/mL dispersion for injection	Multidose vial	5 doses of 0.5 mL each Maximum 10 doses of 0.25 mL each	One dose (0.5 mL) contains 50 micrograms of elasomeran, a COVID-19 mRNA Vaccine (embedded in SM-102 lipid nanoparticles). One dose (0.25 mL) contains 25 micrograms of elasomeran, a COVID-19 mRNA Vaccine (embedded in SM-102 lipid nanoparticles).
Spikevax 50 micrograms dispersion for injection in pre-filled syringe	Pre-filled syringe	1 dose of 0.5 mL For single-use only. Do not use the pre-filled syringe to deliver a partial volume of 0.25 mL.	One dose (0.5 mL) contains 50 micrograms of elasomeran, a COVID-19 mRNA Vaccine (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 SM-102 (heptadecan-9-yl 8-((2-hydroxyethyl)[6-oxo-6-(undecyloxy)hexyl]amino)octanoate), 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 0.2 mg/mL dispersion for injection

Spikevax is a white to off white dispersion supplied in a 5 mL glass vial with a rubber stopper and red flip-off plastic cap with aluminium seal.

Pack size: 10 multidose vials

Spikevax 0.1 mg/mL dispersion for injection

Spikevax is a white to off white dispersion supplied in a 2.5 mL glass vial with a rubber stopper and blue flip-off plastic cap with aluminium seal.

Pack size: 10 multidose vials

Spikevax 50 micrograms dispersion for injection in pre-filled syringe

Spikevax is a white to off white dispersion supplied in a pre-filled syringe (cyclic olefin polymer) with plunger stopper and a tip cap (without needle).

The pre-filled syringe is packaged in 5 clear blisters containing 2 pre-filled syringes in each blister.

Pack size: 10 pre-filled syringes

Marketing Authorisation Holder

MODERNA BIOTECH SPAIN, S.L.
Calle del Príncipe de Vergara 132 Plt 12
Madrid 28002
Spain

Manufacturer

For multidose vials

Rovi Pharma Industrial Services, S.A.
Paseo de Europa, 50

28703. San Sebastián de los Reyes
Madrid, Spain

Recipharm Monts
18 Rue de Montbazon
Monts, France 37260

Moderna Biotech Spain S.L.
Calle del Príncipe de Vergara 132 Plt 12
Madrid 28002
Spain

For pre-filled syringe

Rovi Pharma Industrial Services, S.A.
Calle Julián Camarillo n°35
28037 Madrid Spain

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

Ireland

Tel: 1800 800 354

Malta

Tel: 8006 5066

United Kingdom (Northern Ireland)

Tel: 0800 085 7562

This leaflet was last revised in 11/2022.

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



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

Detailed information on this vaccine is available on the European Medicines Agency web site: <http://www.ema.europa.eu>.

This leaflet is available in all EU/EEA languages on the European Medicines Agency website.

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.

Storage and preparation for administration

Spikevax should be administered by a trained healthcare professional.

The vaccine comes ready to use once thawed.

Do not shake or dilute.

The vaccine should be inspected visually for particulate matter and discolouration prior to administration.

Spikevax is a white to off-white dispersion. It may contain white or translucent product-related particulates. Do not administer if vaccine is discoloured or contains other particulate matter.

Vials and pre-filled syringes are stored frozen between -50°C to -15°C.

Frozen Storage

**Store frozen between
-50°C to -15°C**

Keep the vial and pre-filled syringe in the outer carton to protect from light.



Spikevax 0.2 mg/mL dispersion for injection (multidose vials with a red flip-off cap)

Ten (10) doses (of 0.5 mL each) or a maximum of twenty (20) doses (of 0.25 mL each) can be withdrawn from each multidose vial.


Pierce the stopper preferably at a different site each time. Do not puncture the red-cap vial more than 20 times.

Thaw each vial before use

Images for illustrative purposes only

2 hours and 30 minutes in refrigerator


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



OR

1 hour at room temperature

15° to 25°C



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.



*When stored for 12 months at -50°C to -15°C provided that once thawed and stored at 2°C to 8°C, protected from light, the vial should be used up within a maximum of 14 days (instead of 30 days, when stored at -50°C to -15°C for 9 months), but not exceeding a total storage time of 12 months.

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

Spikevax 0.1 mg/mL dispersion for injection (multidose vials with a blue flip-off cap)

Five (5) doses (of 0.5 mL each) or a maximum of ten (10) doses (of 0.25 mL each) can be withdrawn from each multidose vial.

Pierce the stopper preferably at a different site each time.


Thaw each vial before use

Images for illustrative purposes only

Within the period of 9 months, after removal from the freezer

2 hours and 30 minutes in refrigerator


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



*When stored for 12 months at -50°C to -15°C provided that once thawed and stored at 2°C to 8°C, protected from light, the vial should be used up within a maximum of 14 days (instead of 30 days, when stored at -50°C to -15°C for 9 months), but not exceeding a total storage time of 12 months.

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

Spikevax 50 micrograms dispersion for injection in pre-filled syringe

Do not shake or dilute the contents of the pre-filled syringe.

Each pre-filled syringe is for single use only. The vaccine comes ready to use once thawed.

One (1) dose of 0.5 mL can be administered from each pre-filled syringe. Do not use the pre-filled syringe to deliver a partial volume of 0.25 mL.

Spikevax is supplied in a single-dose, pre-filled syringe (without needle) containing 0.5 mL (50 micrograms) mRNA and must be thawed prior to administration.

During storage, minimise exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.

Thaw each pre-filled syringe before use following the instructions below. Syringes may be thawed in the blister packs (each blister containing 2 pre-filled syringes) or in the carton itself, either in the refrigerator or at room temperature (Table 3).

Table 3. Thawing instructions for pre-filled syringes and cartons before use

Configuration	Thaw instructions and duration			
	Thaw Temperature (in a refrigerator) (°C)	Thaw Duration (minutes)	Thaw Temperature (at room temperature) (°C)	Thaw Duration (minutes)
Pre-filled syringe in blister pack	2 – 8	55	15 – 25	45
Carton	2 – 8	155	15 – 25	140

Verify that the product name of the pre-filled syringe is Spikevax 50 micrograms dispersion for injection in pre-filled syringe. If the product name is Spikevax bivalent Original/Omicron BA.1 25 micrograms/25 micrograms dispersion for injection in pre-filled syringe, please make reference to the Summary of Product Characteristics for that formulation.

Handling instructions for the pre-filled syringes

- Let each pre-filled syringe stand at room temperature (15°C to 25°C) for 15 minutes before administering.
- Do not shake.
- Pre-filled syringe should be inspected visually for particulate matter and discolouration prior to administration.
- Spikevax is a white to off-white dispersion. It may contain white or translucent product-related particulates. Do not administer if vaccine is discoloured or contains other particulate matter.
- Needles are not included in the pre-filled syringe cartons.
- Use a sterile needle of the appropriate size for intramuscular injection (21-gauge or thinner needles).
- Remove tip cap from syringe by twisting in a counter-clockwise direction.
- Attach the needle by twisting in a clockwise direction until the needle fits securely on the syringe.
- Uncap the needle when ready for administration.
- Administer the entire dose intramuscularly.
- After thawing, do not refreeze.

Disposal

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

Dosing and schedule

Table 4. Spikevax dosing for primary series, a third dose in severely immunocompromised and booster doses

Vaccination	Spikevax 0.2 mg/mL dispersion for injection	Spikevax 0.1 mg/mL dispersion for injection and Spikevax 50 micrograms dispersion for injection in pre-filled syringe*
Primary series It is recommended to get the second dose of the same vaccine 28 days after the first dose to complete the vaccination course.	Individuals 12 years of age and older two 0.5 mL injections	Not applicable†
	Children 6 years through 11 years of age two 0.25 mL injections	Children 6 years through 11 years of age two 0.5 mL injections
	Not applicable	Children 6 months through 5 years of age two 0.25 mL injections*
Third dose in severely immunocompromised at least 1 month after the second dose	Individuals 12 years of age and older 0.5 mL	Not applicable‡
	Children 6 years through 11 years of age 0.25 mL	Children 6 years through 11 years of age 0.5 mL
	Not applicable	Children 6 months through 5 years of age 0.25 mL*
Booster dose may be given at least 3 months after the second dose	Individuals 12 years of age and older 0.25 mL	Individuals 12 years of age and older 0.5 mL

* Do not use the pre-filled syringe to deliver a partial volume of 0.25 mL.

†For primary series for individuals 12 years of age and older, the 0.2 mg/mL strength vial should be used.

‡For the third dose in severely immunocompromised patients 12 years of age and older, the 0.2 mg/mL strength vial should be used.

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 15 minutes after vaccination.

High-dose quadrivalent influenza vaccine can be concomitantly administered with Spikevax. Spikevax must not be mixed with other vaccines or medicinal products in the same syringe.

Administration

The vaccine must be administered intramuscularly. The preferred site is the deltoid muscle of the upper arm or in infants and young children, the anterolateral aspect of the thigh. Do not administer this vaccine intravascularly, subcutaneously or intradermally.

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.

An illustration of a person from the chest up, wearing a white t-shirt and a blue surgical mask. A syringe is shown in the foreground, pointing towards the person's right shoulder, indicating the injection site. The background is a light blue gradient.

Pre-filled syringes

Use a sterile needle of the appropriate size for intramuscular injection (21-gauge or thinner). Remove tip cap from pre-filled syringe by twisting in a counter-clockwise direction. Attach the needle by twisting in a clockwise direction until the needle fits securely on the syringe. Uncap the needle when ready for administration. Administer the entire dose intramuscularly. Discard syringe after use. For single-use only.