Package leaflet: Information for the user

Spikevax LP.8.1
0.1 mg/mL dispersion for injection
mRNA-1273.251

▼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 LP.8.1 is and what it is used for

Spikevax LP.8.1 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 the vaccine is ribonucleic acid (RNA) encoding the SARS-CoV-2 spike protein. The RNA is embedded in SM-102 lipid nanoparticles.

Spikevax LP.8.1 contains messenger ribonucleic acid (mRNA) (mRNA-1273.251) that encodes the spike protein of the LP.8.1 strain of the virus.

As Spikevax LP.8.1 does not contain the virus, it cannot give you COVID-19.

How the vaccine works
Spikevax LP.8.1 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 LP.8.1 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 LP.8.1

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 LP.8.1 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

Myocarditis/pericarditis
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 in younger males, and more often after the second dose compared to the first dose.

Most cases of myocarditis and pericarditis recover. Some cases required intensive care support and fatal cases have been seen.

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 LP.8.1.

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 (original). If you have previously had episodes of CLS, talk to a doctor before you are given Spikevax LP.8.1.

Duration of protection
As with any vaccine, Spikevax LP.8.1 may not fully protect all those who receive it and it is not known how long you will be protected.

Children
Spikevax LP.8.1 is not recommended for children aged under 6 months.

Other medicines and Spikevax LP.8.1
Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines. Spikevax LP.8.1 may affect the way other medicines work, and other medicines may affect how Spikevax LP.8.1 works.

Immunocompromised individuals
The efficacy of Spikevax LP.8.1 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. No data are available yet regarding the use of Spikevax LP.8.1 during pregnancy. However, a large amount of information from pregnant women vaccinated with Spikevax (original) 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 increased risk for miscarriage has been seen. Since differences between the two products are only related to the spike protein in the vaccine, and there are no clinically meaningful differences, Spikevax LP.8.1 can be used during pregnancy.

No data are available yet regarding the use of Spikevax LP.8.1 during breast feeding. However, no effects on the breastfed newborn/infant are anticipated. Data from women who were breastfeeding after vaccination with Spikevax (original) have not shown a risk for side effects in breastfed newborns/infants. Spikevax LP.8.1 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 LP.8.1 contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per dose and, that is to say, essentially 'sodium-free'.

3. How you will be given Spikevax LP.8.1

Table 1. Spikevax LP.8.1 posology

Age(s)	Dose	Additional recommendations
Children 6 months through 4 years of age, without prior vaccination and no known history of SARS-CoV-2 infection	Two doses of 0.25 mL each, given intramuscularly	The second dose should be administered 28 days after the first dose. If a child has received one prior dose of any Spikevax vaccine, one dose of Spikevax LP.8.1 should be administered to complete the two-dose series.
Children 6 months through 4 years of age, with prior vaccination or known history of SARS-CoV-2 infection	One dose of 0.25 mL, given intramuscularly	Spikevax LP.8.1 should be administered at least 3 months after the most recent dose of a COVID-19 vaccine.
Children 5 years through 11 years of age, with or without prior vaccination	One dose of 0.25 mL, given intramuscularly	
Individuals 12 years of age and older, with or without prior vaccination	One dose of 0.5 mL, given intramuscularly	
Individuals 65 years of age and older	One dose of 0.5 mL, given intramuscularly	One additional dose may be administered at least 3 months after the most recent dose of a COVID-19 vaccine.

Table 2. Spikevax LP.8.1 posology for immunocompromised individuals

Age(s)	Dose	Additional recommendations
Immunocompromised children 6 months through 4 years of age, without prior vaccination	Two doses of 0.25 mL, given intramuscularly	A third dose in severely immunocompromised may be given at least 28 days after the second dose.

Age(s)	Dose	Additional recommendations
Immunocompromised children 6 months through 4 years of age, with prior vaccination	One dose of 0.25 mL, given intramuscularly	Additional age-appropriate dose(s) may be administered in severely immunocompromised at least 2 months following the most recent dose of a COVID-19 vaccine at the discretion of the healthcare provider, taking into consideration the individual's clinical circumstances.
Immunocompromised children 5 years through 11 years of age, with or without prior vaccination	One dose of 0.25 mL, given intramuscularly	
Immunocompromised individuals 12 years of age and older, with or without prior vaccination	One dose of 0.5 mL, given intramuscularly	

Your doctor, pharmacist, nurse or healthcare professional 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 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. Most side effects go away within a few days of appearing. If side effects such as pain and/or fever are troublesome, they can be treated by medicines for pain and fever such as paracetamol.

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, tongue 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 of the underarm glands
- 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
- raised, itchy rash (urticaria) (which may occur from the time of injection and up to approximately two weeks after the injection)

Rare (may affect up to 1 in 1,000 people)
- severe allergic reactions with breathing difficulties (anaphylaxis)
- temporary one-sided facial drooping (Bell's palsy)
- swelling of the face (swelling of the face may occur in individuals who have had facial cosmetic injections.)
- 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)
- 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 not known
- reaction of increased sensitivity or intolerance by the immune system (hypersensitivity)
- heavy menstrual bleeding (most cases appeared to be non-serious and temporary in nature)
- extensive swelling of the vaccinated limb
- rash elicited by external stimulus such as firm stroking, scratching, or pressure to the skin (mechanical urticaria)
- raised, itchy rash with a duration of more than six weeks (chronic urticaria)

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. If you are concerned about a side effect it can be reported directly via the Coronavirus Yellow Card reporting site or search for MHRA Yellow Card in the Google Play or Apple App Store and include the vaccine brand and batch/Lot number if available. By reporting side effects you can help provide more information on the safety of this vaccine.

5. How to store Spikevax LP.8.1

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.

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 LP.8.1 contains

This is a multidose vial that contains 5 doses of 0.5 mL or a maximum of 10 doses of 0.25 mL each.

One dose (0.5 mL) contains 50 micrograms of mRNA-1273.251, a COVID-19 mRNA Vaccine (embedded in SM-102 lipid nanoparticles).

One dose (0.25 mL) contains 25 micrograms of mRNA-1273.251, a COVID-19 mRNA Vaccine (embedded in SM-102 lipid nanoparticles).

This vaccine contains polyethylene glycol/macrogol (PEG) as part of PEG2000-DMG.

mRNA-1273.251 is a 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 variant LP.8.1.

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 LP.8.1 looks like and contents of the pack

Multidose vial

Spikevax LP.8.1 is a white to off white dispersion supplied in a glass vial with a rubber stopper and a blue flip-off plastic cap with aluminium seal.

Pack size: 10 multidose vials. Each vial contains 2.5 mL.

Marketing Authorisation Holder
MODERNA BIOTECH SPAIN, S.L.
C/ Julián Camarillo n ° 31
28037 Madrid
Spain

Manufacturers

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

Moderna Biotech Spain S.L.
C/ Julián Camarillo n ° 31
28037 Madrid
Spain

Moderna Technology Centre
Harwell (MTC-H)
Perimeter Road

Harwell Oxford
Didcot
OX11 0GN
United Kingdom

For any information about this medicine, please contact Medical Information telephone on 0800 085 7562.

This leaflet was last revised in February 2026.

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

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

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 LP.8.1
0.1 mg/mL dispersion for injection (multidose vials with a blue flip-off cap)

Spikevax LP.8.1 should be administered by a trained healthcare professional.

Vials are stored in a freezer at -50ºC to -15ºC.

The vaccine comes ready to use once thawed.

Do not shake or dilute. Swirl the vial gently after thawing and before each withdrawal. Pierce the stopper preferably at a different site each time.

Parenteral drug products should be inspected visually for particulate matter and discolouration prior to administration, whenever solution and container permit.

Spikevax LP.8.1 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.

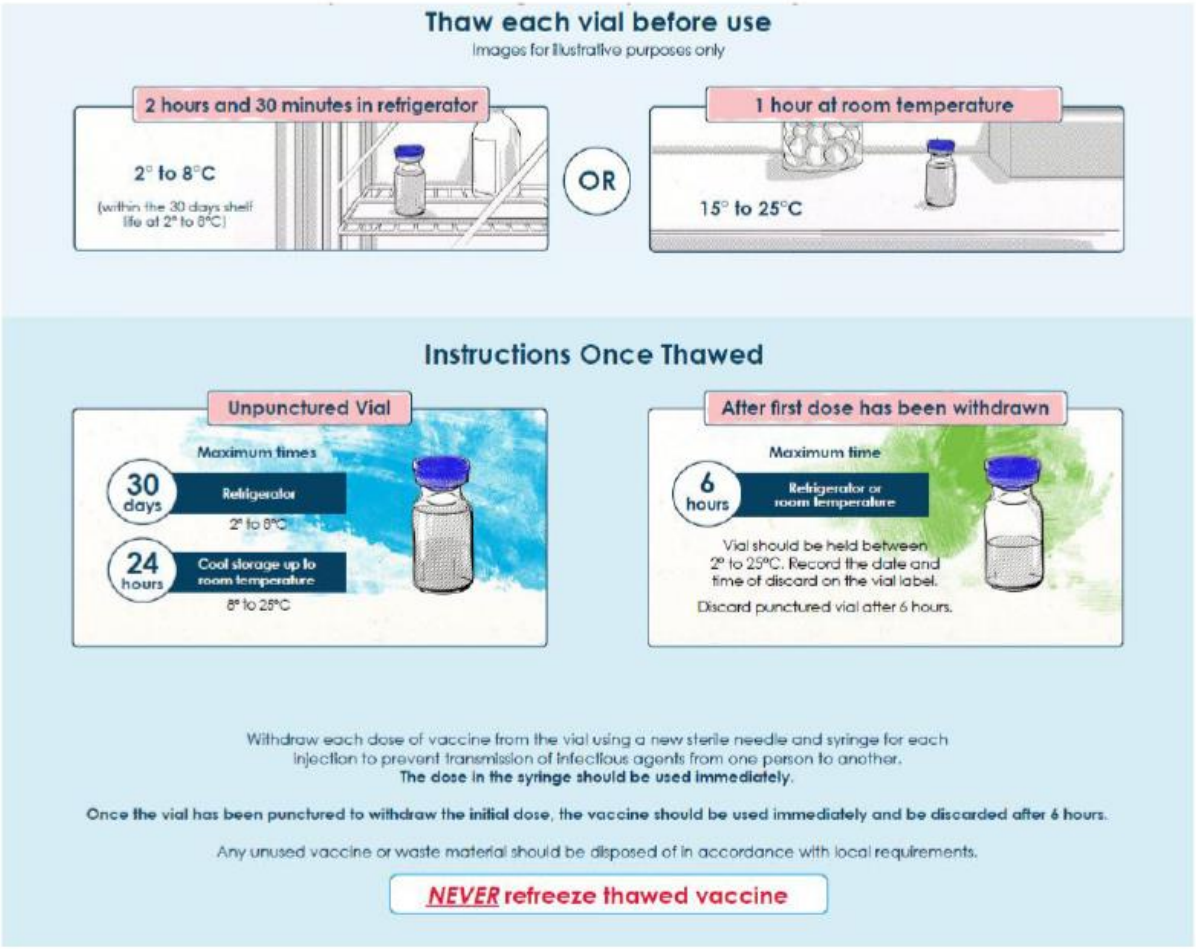
Five (5) doses (of 0.5 mL each) or a maximum of ten (10) doses (of 0.25 mL each) can be withdrawn from each multidose vial. An additional overfill is included in each vial to ensure that 5 doses of 0.5 mL or a maximum of 10 doses of 0.25 mL can be delivered.

Verify that the vial has a blue flip-off cap and the product name is Spikevax LP.8.1.

Thaw each multidose vial before use following the instructions below (Table 3).

Table 3. Thawing instructions for multidose vials before use

Configuration	**Thaw instructions and duration**			
	Thaw temperature (in a refrigerator)	**Thaw duration**	**Thaw temperature (at room temperature)**	**Thaw duration**
Multidose vial	2° – 8°C	2 hours and 30 minutes	15°C – 25°C	1 hour



After thawing, do not refreeze.

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

Dosing and schedule

Table 4. Spikevax LP.8.1 dosing

Age(s)	**Dose**	**Additional recommendations**
Children 6 months through 4 years of age, without prior vaccination and no known history of SARS-CoV-2 infection	Two doses of 0.25 mL each, given intramuscularly	The second dose should be administered 28 days after the first dose. If a child has received one prior dose of any Spikevax vaccine, one dose of Spikevax LP.8.1 should be administered to complete the two-dose series.
Children 6 months through 4 years of age, with prior vaccination or known history of SARS-CoV-2 infection	One dose of 0.25 mL, given intramuscularly	Spikevax LP.8.1 should be administered at least 3 months after the most recent dose of a COVID-19 vaccine and/or a known SARS-CoV-2 infection.
Children 5 years through 11 years of age, with or without prior vaccination	One dose of 0.25 mL, given intramuscularly	

Age(s)	Dose	Additional recommendations
Individuals 12 years of age and older, with or without prior vaccination	One dose of 0.5 mL, given intramuscularly	
Individuals 65 years of age and older	One dose of 0.5 mL, given intramuscularly	One additional dose may be administered at least 3 months after the most recent dose of a COVID-19 vaccine.

Table 5. Spikevax LP.8.1 posology for immunocompromised individuals

Age(s)	Dose	Additional recommendations
Immunocompromised children 6 months through 4 years of age, without prior vaccination	Two doses of 0.25 mL, given intramuscularly	A third dose in severely immunocompromised may be given at least 28 days after the second dose.
Immunocompromised children 6 months through 4 years of age, with prior vaccination	One dose of 0.25 mL, given intramuscularly	Additional age-appropriate dose(s) may be administered in severely immunocompromised at least 2 months following the most recent dose of a COVID-19 vaccine at the discretion of the healthcare provider, taking into consideration the individual's clinical circumstances.
Immunocompromised children 5 years through 11 years of age, with or without prior vaccination	One dose of 0.25 mL, given intramuscularly	
Immunocompromised individuals 12 years of age and older, with or without prior vaccination	One dose of 0.5 mL, given intramuscularly	

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 LP.8.1.

Individuals should be observed by a healthcare professional for at least 15 minutes after vaccination.

Spikevax (including variant formulations) can be concomitantly administered with influenza vaccines (standard and high-dose) and with herpes zoster (shingles) subunit vaccine.

Different injectable vaccines should be given at different injection sites.

Spikevax LP.8.1 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.

Multidose vials