

## Package leaflet: Information for the user

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

▼ 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 COVID-19 Vaccine Moderna is and what it is used for
2. What you need to know before you are given COVID-19 Vaccine Moderna
3. How COVID-19 Vaccine Moderna is given
4. Possible side effects
5. How to store COVID-19 Vaccine Moderna
6. Contents of the pack and other information

#### 1. What COVID-19 Vaccine Moderna is and what it is used for

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

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

#### How the vaccine works

COVID-19 Vaccine Moderna 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. COVID-19 Vaccine Moderna 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 COVID-19 Vaccine Moderna

**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 COVID-19 Vaccine Moderna if:

- you have previously had a severe, life-threatening **allergic** reaction after any other vaccine injection or after you were given COVID-19 Vaccine Moderna 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

Very rare cases of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have been reported after vaccination with COVID-19 Vaccine Moderna. The cases have primarily occurred within two weeks following vaccination, more often after the second vaccination, and more often occurred in younger men. 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 COVID-19 Vaccine Moderna.

As with any vaccine, the 2-dose vaccination course of COVID-19 Vaccine Moderna may not fully protect all those who receive it and it is not known how long you will be protected.

### **Children and adolescents**

COVID-19 Vaccine Moderna is not recommended for children aged under 18 years.

### **Other medicines and COVID-19 Vaccine Moderna**

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines. COVID-19 Vaccine Moderna may affect the way other medicines work, and other medicines may affect how COVID-19 Vaccine Moderna works.

### **Pregnancy and breast-feeding**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, tell your doctor, pharmacist or nurse before being vaccinated.

### **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.

### **COVID-19 Vaccine Moderna contains sodium**

COVID-19 Vaccine Moderna contains less than 1 mmol (23 mg) sodium per dose and, that is to say, essentially 'sodium-free'.

## **3. How you will be given COVID-19 Vaccine Moderna**

COVID-19 Vaccine Moderna 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.

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

### **If you miss an appointment for your 2<sup>nd</sup> dose of COVID-19 Vaccine Moderna**

- 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.

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 with breathing difficulties (anaphylaxis)
- reaction of increased sensitivity or intolerance by the immune system (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.

**Call for reporting**

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

**There is a need to report any suspected adverse reactions to:**

- **The National Pharmacovigilance Center (NPC); Saudi Food and Drug Authority (SFDA) via:**

**The National Pharmacovigilance Centre (NPC) SFDA call center: 19999**

**E-mail: [npc.drug@sfda.gov.sa](mailto:npc.drug@sfda.gov.sa)**

**Website: <http://ade.sfda.gov.sa/>**

**You can also report any suspected adverse reactions to:**

- **Pharmacovigilance department in Tabuk Pharmaceuticals:**

**E-mail: [pv.info@tabukpharmaceuticals.com](mailto:pv.info@tabukpharmaceuticals.com)**

**Tel: +966 4774946; Ext 233**

## **5. How to store COVID-19 Vaccine Moderna**

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 COVID-19 Vaccine Moderna 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 COVID-19 Vaccine Moderna looks like and contents of the pack**

COVID-19 Vaccine Moderna is a white to off white dispersion supplied in a glass vial with a rubber stopper and aluminium seal.

Pack size: 10 multidose vials

### **Marketing Authorisation Holder in Saudi Arabia:**

Tabuk Pharmaceutical Manufacturing Co.

Address: 2nd Industrial City

Postal code: 31421

City: Dammam

Country: Saudi Arabia

### **Manufacturer:**

Rovi Pharma Industrial Services, S.A.

Paseo de Europa, 50

28703. San Sebastián de los Reyes  
Madrid, Spain

**This leaflet was last revised in Month 2021.**

This vaccine has been given ‘conditional approval’. This means that there is more evidence to come about this vaccine.

The European Medicines Agency will review new information on this vaccine at least every year and this leaflet will be updated as necessary.

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.

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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.

COVID-19 Vaccine Moderna should be administered by a trained healthcare professional.

The vaccine comes ready to use once thawed.

Do not shake or dilute.

COVID-19 Vaccine Moderna 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.

COVID-19 Vaccine Moderna 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 COVID-19 Vaccine Moderna. Individuals should be observed by a healthcare professional for at least 15 minutes after vaccination.

There are no data to assess the concomitant administration of COVID-19 Vaccine Moderna with other vaccines. COVID-19 Vaccine Moderna 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 of  $2^{\circ}$  to  $8^{\circ}\text{C}$ )

OR

**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.

