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Decision

Information for UK recipients on COVID-19 Vaccine Moderna

Updated 28 January 2021

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Package leaflet: Information for the recipient

COVID-19 Vaccine Moderna 0.20 mg/mL dispersion for injection COVID-19 mRNA Vaccine (nucleoside modified)

This medicinal product has been given authorisation for temporary supply by the UK Department of Health and Social Care and the Medicines and Healthcare products Regulatory Agency. It does not have a marketing authorisation, but this temporary authorisation grants permission for the medicine to be used for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by the SARS-CoV-2 virus in individuals 18 years of age and older.

Reporting of side effects

As with any new medicine in the UK this product will be closely monitored to 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 the vaccine is given 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

What is COVID-19 Vaccine Moderna

COVID-19 Vaccine Moderna is a vaccine used to prevent COVID-19 caused by SARS-CoV-2 virus. 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 embedded in lipid nanoparticles.

As COVID-19 Vaccine Moderna does not contain the virus to produce immunity, 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 its own protection (antibodies) against the virus that causes the COVID-19 infection. COVID-19 Vaccine Moderna uses a molecule called messenger ribonucleic

acid (mRNA) to deliver the set of instructions that cells in the body can use to make antibodies to help fight the virus that causes COVID-19. This will help to protect against COVID-19.

As with any vaccine, COVID-19 Vaccine Moderna may not fully protect all those who receive it. You may not be fully protected until 2 weeks after the second dose of the vaccine. It is not yet known how long protection lasts.

2. What you need to know before you are given COVID-19 Vaccine Moderna

Do not have the vaccine 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 any allergies. If you have experienced a severe allergic reaction after the first dose of COVID-19 Vaccine Moderna, you should not receive a second dose.
- have a very weak or compromised immune system, such as due to HIV infection, or are on a medicine that affects your immune system
- have a bleeding problem, bruise easily or use a medicine to inhibit blood clotting
- have a high fever or severe infection. However, a mild fever or upper airway infection, like a cold, are not reasons to delay vaccination.
- have any serious illness

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.

Children and adolescents

This vaccine should not be given to children and adolescents under 18 years of age as it has not been studied in this population.

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 or have recently received any other vaccines. COVID-19 Vaccine Moderna may affect the way other medicines or vaccines work, and other medicines or vaccines 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

It is not known if COVID-19 Vaccine Moderna affects your ability to drive or use machines. Do not drive or use machines if you are feeling unwell.

COVID-19 Vaccine Moderna contains sodium

Moderna COVID-19 Vaccine contains less than 23 mg sodium per dose of 0.5 mL and is 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 28 days after the first.

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 15 minutes to monitor for signs of an allergic reaction.

When COVID-19 Vaccine Moderna is given for the first injection, COVID-19 Vaccine Moderna (and not another vaccine against COVID-19) should be given for the second injection to complete the vaccination course.

If you miss an appointment for your 2nd dose of COVID-19 Vaccine Moderna:

- If you miss an appointment, tell your doctor or nurse and arrange another visit
- If you miss a scheduled injection, you may not be fully protected from COVID-19 virus

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.

You may very rarely experience a severe allergic reaction after receiving COVID-19 Vaccine Moderna. Signs of an allergic reaction may include itchy skin rash, shortness of breath and swelling of the face or tongue. Contact your doctor or healthcare professional immediately or go to the nearest hospital emergency department right away if you have an allergic reaction. It can be life-threatening.

Other side effects can include:

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

- Tenderness and swelling of the underarm glands on the same side as the injection site
- 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

Reporting of side effects

If you are concerned about a side-effect it can be reported directly via the Coronavirus Yellow Card reporting site (<https://coronavirus-yellowcard.mhra.gov.uk/>) 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.

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.

Information about storage, expiry, and use and handling are described in the Information for healthcare professionals.

Your doctor or pharmacist is responsible for storing this vaccine and disposing of any unused product correctly.

6. Contents of the pack and other information**What COVID-19 Vaccine Moderna contains**

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

This is a multidose vial which contains 10 doses of 0.5 mL.

The active substance in each dose is 0.10 mg mRNA encoding the pre-fusion stabilized Spike glycoprotein of SARS-CoV-2 embedded in lipid nanoparticles.

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 (tris)
- trometamol hydrochloride (tris HCl)
- 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.

Vials are packaged in a carton containing a total of ten vials per carton.

Manufacturer

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

This leaflet was last revised on 26 January 2021.

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