

PFIZER VACCINATION – COVID-19 mRNA

This medicine does not have a UK marketing authorisation but has been given authorisation for temporary supply by the UK Department of Health and Social Care and the Medicines & Healthcare products Regulatory Agency for active immunization to prevent COVID-19 disease caused by SARS-CoV-2 virus in individuals aged 16 years of age and over.

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.

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.

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

COVID-19 mRNA Vaccine is given to adults and adolescents from 16 years. The vaccine triggers the body's natural production of antibodies and stimulates immune cells to protect against COVID-19 disease.

2. What you need to know before you receive COVID-19 mRNA Vaccine

COVID-19 mRNA Vaccine should not be given if you are allergic to the active substance or any of the other ingredients of this medicine (listed in section 6). 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 room right away if you have an allergic reaction. It can be life-threatening.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before you are given the vaccine if you have:
had

- any problems following previous administration of COVID-19 mRNA Vaccine such as allergic reaction or breathing problems
- a severe illness with high fever. However, a mild fever or upper airway infection, like a cold, are not reasons to delay vaccination.
- a weakened immune system, such as due to HIV infection, or are on a medicine that affects your immune system
- a bleeding problem, bruise easily or use a medicine to inhibit blood clotting
- As with any vaccine, COVID-19 mRNA Vaccine BNT162b2 may not fully protect all those who receive it. No data are currently available in individuals with a weakened immune system or who are taking chronic treatment that suppresses or prevents immune responses.

Children and adolescents

COVID-19 mRNA Vaccine is not recommended for children under 16 years.

Other medicines and COVID-19 mRNA Vaccine

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines or have recently received any other vaccine.

Pregnancy and breast-feeding

There is currently limited data available on the use of this vaccine in pregnant women. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before you receive this vaccine. As a precaution, you should avoid becoming pregnant until at least 2 months after the vaccine.

Driving and using machines

COVID-19 mRNA Vaccine has no or negligible influence on the ability to drive and use machines. However, some of the effects mentioned under section 4 'Possible side effects' may temporarily affect the ability to drive or use machines. Do not drive or operate machinery until you are sure that you are not affected.

COVID-19 mRNA Vaccine contains sodium and potassium

This vaccine contains potassium, less than 1 mmol (39 mg) per dose, i.e. essentially 'potassium-free'. This vaccine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially sodiumfree'.

3. How COVID-19 mRNA Vaccine is given

COVID-19 mRNA Vaccine is given after dilution as an injection of 0.3 mL into a muscle of your upper arm. You will receive 2 injections, given 21 days apart. If you receive one dose of the vaccine, you should receive a second dose of the same vaccine 21 days later to complete the vaccination series. Protection against COVID-19 disease may not be effective until at least 7 days after the second dose. If you have any further questions on the use of COVID-19 mRNA Vaccine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all vaccines, COVID-19 mRNA Vaccine can cause side effects, although not everybody gets them. Most side effects are mild or moderate and 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. Side effects may occur with following frequencies:

Very common: may affect more than 1 in 10 people

- pain at injection site
- tiredness
- headache
- muscle pain
- chills
- joint pain
- fever

Common: may affect up to 1 in 10 people

- injection site swelling
- redness at injection site
- nausea

Uncommon: may affect up to 1 in 100 people

- enlarged lymph nodes
- feeling unwell

Reporting of side effects

If you get any side effects, call 111 for advice. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Coronavirus Yellow Card reporting site <https://coronavirus-yellowcard.mhra.gov.uk/>

By reporting side effects, you can help provide more information on the safety of this vaccine.