

Package leaflet: Information for the recipient

COVID-19 mRNA Vaccine BNT162b2 concentrate for solution for injection

This medicinal product has been given authorisation for temporary supply by the UK Department of Health and Social Care and the Medicines & 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 immunisation to prevent COVID-19 disease caused by SARS-CoV-2 virus in individuals aged 12 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. 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 mRNA Vaccine BNT162b2 is and what it is used for
2. What you need to know before you receive COVID-19 mRNA Vaccine BNT162b2
3. How COVID-19 mRNA Vaccine BNT162b2 is given
4. Possible side effects
5. How to store COVID-19 mRNA Vaccine BNT162b2
6. Contents of the pack and other information

1. What COVID-19 mRNA Vaccine BNT162b2 is and what it is used for

COVID-19 mRNA Vaccine BNT162b2 is a vaccine used for active immunisation to prevent COVID-19 disease caused by SARS-CoV-2 virus.

COVID-19 mRNA Vaccine BNT162b2 is given to adults and adolescents from 12 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 BNT162b2

COVID-19 mRNA Vaccine BNT162b2 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.

If you have any further questions on the use of COVID-19 mRNA Vaccine BNT162b2, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all vaccines, COVID-19 mRNA Vaccine BNT162b2 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

- injection site: pain, swelling
- tiredness
- headache
- muscle pain
- chills
- joint pain
- diarrhoea

- fever

Common: may affect up to 1 in 10 people

- redness at injection site
- nausea
- vomiting

Uncommon: may affect up to 1 in 100 people

- enlarged lymph nodes
- feeling unwell
- arm pain
- insomnia
- injection site itching
- allergic reactions such as rash or itching

Rare side effects: may affect up to 1 in 1,000 people

- temporary one sided facial drooping
- allergic reactions such as hives or swelling of the face

Not known (cannot be estimated from the available data)

- severe allergic reaction
- inflammation of the heart (myocarditis or pericarditis)

Some people have reported a sudden feeling of cold with shivering/shaking accompanied by a rise in temperature, possibly with sweating, headache (including migraine-like headaches), nausea, muscle aches and feeling unwell, starting within a day of having the vaccine and usually lasting for a day or two.