

COMIRNATY™ COVID-19 VACCINE

tozinameran

Consumer Medicine Information

This leaflet provides important information about using COMIRNATY. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about receiving COMIRNATY.**

Where to find information in this leaflet:

1. Why am I being given COMIRNATY?
2. What should I know before I am given COMIRNATY?
3. What if I am taking other medicines?
4. How will I be given COMIRNATY?
5. What should I know while being given COMIRNATY?
6. Are there any side effects?
17. Product details

1. Why am I being given COMIRNATY?

COMIRNATY contains the active ingredient tozinameran.

COMIRNATY is an mRNA (messenger ribonucleic acid) vaccine.

COMIRNATY is a vaccine given to prevent COVID-19 disease caused by SARS-CoV-2 virus in adults and children from 5 years of age and older.

COMIRNATY works by triggering your immune system to produce antibodies and blood cells that work against the virus, to protect against COVID-19 disease.

2. What should I know before I am given COMIRNATY?

Warnings

COMIRNATY should not be given:

1. if you are allergic to tozinameran or any of the ingredients listed at the end of this leaflet.

Check with your doctor if you have:

- had a severe allergic reaction or breathing problems after any other vaccine or after being given COMIRNATY in the past.
- fainted following any needle injection.
- a severe illness or infection with high fever. However, you can have your vaccination if you have a mild fever or upper airway infection like a cold.
- a weakened immune system, such as due to HIV infection or are on a medicine that affects your immune system.
- a bleeding disorder, bruise easily or are on a blood thinning medicine.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

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 COMIRNATY. The cases have

mostly 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.

You may develop a temporary, stress-related response associated with the process of receiving your injection. This may include dizziness, fainting, sweating, increased heart rate and/or anxiety. If you start to feel faint at any time during the process of receiving your injection, let your doctor, nurse or pharmacist know and take actions to avoid falling and injuring yourself, such as sitting or lying down.

As with any vaccine, COMIRNATY may not fully protect all those who receive it and it is not known how long you will be protected.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before you receive this vaccine.

Children and adolescents

COMIRNATY should not be given to children under 5 years.