

Comirnaty[®] Omicron XBB.1.5 COVID-19 Vaccine Information Sheet

1. Why am I being given Comirnaty Omicron XBB.1.5?

Comirnaty Omicron XBB.1.5 is a vaccine given to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in adults and adolescents from 16 years of age and older. Comirnaty Omicron XBB.1.5 contains the active ingredient raxtozinameran.

2. What should I know before I am given Comirnaty Omicron XBB.1.5?

You should not be given Comirnaty Omicron XBB.1.5 if you have had an allergic reaction to any of the ingredients in the vaccine.

Check with your healthcare provider 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; a weakened immune system or are on a medicine that affects your immune system; a bleeding disorder, bruise easily or are on a blood thinning medicine. As with any vaccine, Comirnaty Omicron XBB.1.5 may not fully protect all those who receive it and it is not known how long you will be protected.

3. What if I am taking other medicines?

Tell your healthcare provider if you are taking any other medicines, including any medicines, family planning, vitamins or supplements that you can buy with or without a prescription. Tell your doctor or pharmacist if you have recently received any other vaccine.

4. How will I be given Comirnaty Omicron XBB.1.5?

Comirnaty Omicron XBB.1.5 will be given as an injection into the muscle of your upper arm by a healthcare provider. You will be given one dose of the vaccine, regardless of prior COVID-19 vaccination status. A healthcare provider will observe you for at least 15 minutes after being given the vaccine.

Things you should know	<ul style="list-style-type: none"> A dose of Comirnaty Omicron XBB.1.5 may be given at least 6 months after the most recent dose of a COVID-19 vaccine. You may not be protected against COVID-19 disease until at least 7 days after the vaccination.
Driving or using machines	<ul style="list-style-type: none"> Be careful before you drive or use any machines or tools until you know how Comirnaty Omicron XBB.1.5 affects you. Some of the side effects of Comirnaty Omicron XBB.1.5 may temporarily affect your ability to drive or use machines.

5. Are there any side effects?

Common side effects of Comirnaty include pain/swelling at injection site, tiredness, headache, muscle pain, chills, joint pain and fever.

Comirnaty® Omicron XBB.1.5 COVID-19 Vaccine for Age 16 years and older

Active ingredient: *raxtozinameran*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Comirnaty Omicron XBB.1.5. **You should also speak to your healthcare provider if you would like further information or if you have any concerns or questions about receiving the vaccine (Comirnaty Omicron XBB.1.5).**

Where to find information in this leaflet:

1. [Why am I being given Comirnaty Omicron XBB.1.5?](#)
2. [What should I know before I am given Comirnaty Omicron XBB.1.5?](#)
3. [What if I am taking other medicines?](#)
4. [How will I be given Comirnaty Omicron XBB.1.5?](#)
5. [What should I know while being given Comirnaty Omicron XBB.1.5?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I being given Comirnaty Omicron XBB.1.5?

Comirnaty Omicron XBB.1.5 contains the active ingredient *raxtozinameran*.

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 adolescents from 16 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 Omicron XBB.1.5?

Warnings

Comirnaty Omicron XBB.1.5 should not be given:

1. If you are allergic to *raxtozinameran* or any of the ingredients listed at the end of this leaflet.

3. What if I am taking other medicines?

Check with your healthcare provider 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.

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, but not always, in younger men. There have been cases in women.

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.

Sometimes the symptoms of myocarditis and pericarditis may not be specific and could include

- tiredness, dizziness, nausea and vomiting, abdominal pain, swelling, and cough.

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.

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 breast-feeding, think you may be pregnant or are planning to have a baby, ask your healthcare provider for advice before you receive this vaccine.

Tell your healthcare provider if you are taking, have recently taken or might take any other medicines, including any medicines, family planning, vitamins or supplements that you buy with or without a prescription from your pharmacy, supermarket or health food shop.

Tell your healthcare provider if you have recently received any other vaccine.

4. How will I be given Comirnaty Omicron XBB.1.5?

- Comirnaty Omicron XBB.1.5 will be given as an injection into the muscle of your upper arm by a healthcare provider.
- You will be given one dose, regardless of prior COVID19 vaccination status.
- A healthcare provider will observe you for at least 15 minutes after being given Comirnaty Omicron XBB.1.5.
- A dose of Comirnaty Omicron XBB.1.5 may be given at least 6 months after the most recent dose of a COVID19 vaccine.

5. What should I know while being given Comirnaty Omicron XBB.1.5?

Things you should know

- A dose of Comirnaty Omicron XBB.1.5 may be given at least 6 months after the most recent dose of a COVID19 vaccine.
- You may not be protected against COVID-19 disease until at least seven days after the vaccination.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Comirnaty Omicron XBB.1.5 affects you.

Some of the side effects of Comirnaty Omicron XBB.1.5 may temporarily affect your ability to drive or use machines. **Storage of the vaccine**

Comirnaty Omicron XBB.1.5 is stored at -90 °C to -60 °C. It must be kept in the original package in order to protect from light.

A healthcare provider will prepare the injection for you before you are given it.

Getting rid of any unwanted vaccine

A healthcare provider will dispose of any unused vaccine.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your healthcare provider if you have any further questions about side effects. **Very common side effects**

Very common side effects	What to do
<ul style="list-style-type: none"> • pain/swelling at injection site • tiredness • headache • muscle pain • chills • joint pain • fever 	<p>Speak to your doctor if you have any of these very common side effects and they worry you.</p>

Common side effects

Common side effects	What to do
<ul style="list-style-type: none"> • redness at injection site • nausea 	<p>Speak to your doctor if you have any of these common side effects and they worry you.</p>

Uncommon side effects

Uncommon side effects	What to do
<ul style="list-style-type: none"> • enlarged lymph nodes • feeling unwell • insomnia • decreased appetite • excessive sweating • night sweats • physical weakness and/or lack of energy 	<p>Speak to your doctor if you have any of these side effects and they worry you.</p>

Rare side effects

Rare side effects	What to do
<ul style="list-style-type: none"> • temporary one-sided facial drooping 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice this side effect.</p>

Other side effects (frequency unknown)

Other side effects (frequency unknown)	What to do
<ul style="list-style-type: none">• severe allergic reaction• allergic reactions such as rash, itching, hives or swelling of the face• inflammation of the heart muscle (myocarditis) or inflammation of the lining outside the heart (pericarditis) which can result in chest pain, breathlessness and/or palpitations	Call the Emergency Department 999/22664 if you notice this serious side effect.
<ul style="list-style-type: none">• diarrhoea• vomiting• pain in arm• extensive swelling of vaccinated arm• swelling of face (people who have had facial dermal fillers)• dizziness• heavy menstrual bleeding	Speak to your healthcare provider if you have any of these side effects and they worry you.

Other side effects not listed here may occur in some people.

7. Product details

What Comirnaty Omicron XBB.1.5 contains

Active ingredient (main ingredient)	<ul style="list-style-type: none">• raxtozinameran
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate) (ALC-0315)• 2-[(polyethylene glycol)-2000]-N,Nditetradecylacetamide (ALC-0159)• Distearoylphosphatidylcholine (DSPC)• Cholesterol• Sucrose• Trometamol• Trometamol hydrochloride• Water for injections

Do not receive this vaccine if you are allergic to any of the above ingredients.