

Comirnaty® Omicron XBB.1.5 COVID-19 Vaccine for Age 5 to 11 years

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about receiving this vaccine, speak to your doctor or pharmacist.

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 children from 5 to 11 years of age. Comirnaty Omicron XBB.1.5 contains the active ingredient raxtozinameran. For more information, see Section [1. Why am I being given Comirnaty Omicron XBB.1.5?](#) in the full CMI.

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. See list at the end of the CMI.

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; 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.

Talk to your doctor if you have any other medical conditions or take any other medicines.

For more information, see Section [2. What should I know before I am given Comirnaty Omicron XBB.1.5?](#) in the full CMI.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription. Tell your doctor or pharmacist if you have recently received any other vaccine. For more information, see Section [3. What if I am taking other medicines?](#) in the full CMI.

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 doctor, nurse or pharmacist. You will be given one dose of the vaccine, regardless of prior COVID-19 vaccination status. A doctor, nurse or pharmacist will observe you for at least 15 minutes after being given the vaccine. For more information, see Section [4. How will I be given Comirnaty Omicron XBB.1.5?](#) in the full CMI.

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

Things you should know	<ul style="list-style-type: none">• A dose of Comirnaty Omicron XBB.1.5 may be given at least 3 months after the most recent dose of a COVID-19 vaccine.• You may not be protected against COVID-19 disease until at least seven days after your second dose.
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For more information, see Section [5. What should I know while being given Comirnaty Omicron XBB.1.5?](#) in the full CMI.

6. Are there any side effects?

Very common side effects of Comirnaty include pain/swelling at injection site, tiredness, headache, muscle pain, chills, joint pain and fever. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Comirnaty® Omicron XBB.1.5 COVID-19 Vaccine for Age 5 to 11 years

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 doctor or pharmacist if you would like further information or if you have any concerns or questions about receiving 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 children from 5 to 11 years of age.

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

Comirnaty Omicron XBB.1.5 (Orange cap, must dilute) is a 10 microgram/0.2 mL dose, concentrate for suspension for injection, for children 5 to 11 years of age.

Comirnaty Omicron XBB.1.5 (Light Blue and Dark Blue cap) are 10 microgram/0.3 mL dose, suspension for injection, for children 5 to 11 years of age.

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

Warnings

Comirnaty Omicron XBB.1.5 should not be given:

- if you are allergic to raxtozinameran 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, 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.

Children and adolescents

Comirnaty Omicron XBB.1.5 can be given to individuals 6 months of age and older.

Comirnaty Omicron XBB.1.5 should not be given to infants under 6 months of age.

Refer to the Comirnaty Omicron XBB.1.5 (Maroon or Yellow cap) CMI leaflet for infants and children aged 6 months to 4 years.

3. What if I am taking other medicines?

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

Tell your doctor or pharmacist if you have recently received any other vaccine.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect, or are affected by, Comirnaty Omicron XBB.1.5.

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 doctor, nurse or pharmacist.
- You will be given one dose, regardless of prior COVID-19 vaccination status.
- A doctor, nurse or pharmacist 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 3 months after the most recent dose of a COVID-19 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 3 months after the most recent dose of a COVID-19 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 doctor, nurse or pharmacist will prepare the injection for you before you are given it.

Getting rid of any unwanted vaccine

A doctor, nurse or pharmacist 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 doctor or pharmacist 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/redness at injection site • tiredness • headache • muscle pain • chills • diarrhoea 	Speak to your doctor if you have any of these very common side effects and they worry you.

Common side effects

Common side effects	What to do
<ul style="list-style-type: none"> • vomiting • joint pain • fever 	Speak to your doctor if you have any of these common side effects and they worry you.

Uncommon side effects

Uncommon side effects	What to do
<ul style="list-style-type: none"> • enlarged lymph nodes • feeling unwell • nausea • decreased appetite • hives • itchy skin • rash • pain in arm 	Speak to your doctor if you have any of these side effects and they worry you.

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 your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice this serious side effect.
<ul style="list-style-type: none"> • extensive swelling of vaccinated arm • dizziness • heavy menstrual bleeding 	Speak to your doctor if you have any of these side effects and they worry you.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

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,N-ditetradecylacetamide (ALC-0159)• 1,2-Distearoyl-sn-glycero-3-phosphocholine (DSPC)• Cholesterol• Sucrose• Trometamol• Trometamol hydrochloride• Water for injections

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

What Comirnaty Omicron XBB.1.5 looks like

Orange cap vial (For Age 5 to 11 Years):

Comirnaty Omicron XBB.1.5 (Orange cap) is a white to off-white frozen suspension.

Comirnaty Omicron XBB.1.5 (Orange cap) is provided in packs of 10 clear glass vials with Orange flip-off caps. After dilution, each dose is 0.2 mL and each vial contains 10 doses of vaccine (1.3 mL fill).

Light and Dark Blue cap vials (For Age 5 to 11 Years):

Comirnaty Omicron XBB.1.5 (Light and Dark Blue cap) is a clear to slightly opalescent frozen suspension.

Comirnaty Omicron XBB.1.5 (Light Blue cap) is provided in packs of 10 clear glass vials with Light Blue flip-off caps. Each dose is 0.3 mL and each vial contains 1 dose of vaccine (0.48 mL fill).

Comirnaty Omicron XBB.1.5 (Dark Blue cap) is provided in packs of 10 clear glass vials with Dark Blue flip-off caps. Each dose is 0.3 mL and each vial contains 6 doses of vaccine (2.25 mL fill).

Not all presentations may be available.

Who distributes Comirnaty Omicron XBB.1.5

Pfizer New Zealand Limited

PO Box 3998

Auckland

Toll Free Number: 0800 736 363

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