

Comirnaty® Omicron XBB.1.5 COVID-19 Vaccine for Age 6 months to 4 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 infants and children from 6 months to 4 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?

Your child should not be given Comirnaty Omicron XBB.1.5 if he/she has 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 your child has 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 your child has 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 your child is taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription. Tell your doctor or pharmacist if your child has 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 child's upper arm or thigh by a doctor, nurse or pharmacist. Your child will be given one dose followed by a second dose at least 21 days later and a third dose at least 8 weeks after the second dose as the primary vaccination. It is very important that your child receives all three doses. If your child has previously been vaccinated with a COVID-19 vaccine, 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. A doctor, nurse or pharmacist will observe you for at least 15 minutes after being given Comirnaty 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">• If your child received one dose of Comirnaty Omicron XBB.1.5, he/she should continue to receive the same vaccine to complete the primary vaccination schedule.• 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.• Your child may not be protected against COVID-19 disease until at least seven days after completing primary vaccination. Your child may not be protected if you only receive one dose, so it is very important to complete all 3 doses of the primary vaccination.
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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 6 months to 4 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 infants and children from 6 months to 4 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 (Maroon cap, must dilute) is a 3 microgram/0.2 mL dose, concentrate for suspension for injection, for infants and children from 6 months to 4 years of age.

Comirnaty Omicron XBB.1.5 (Yellow cap, must dilute) is a 3 microgram/0.3 mL dose, concentrate for suspension for injection, for infants and children from 6 months to 4 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 your child is allergic to raxtozinameran or any of the ingredients listed at the end of this leaflet.

Check with your doctor if your child has:

- 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, your child 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.

Your child may develop a temporary, stress-related response associated with the process of receiving the 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.

Infants and Children

Comirnaty Omicron XBB.1.5 (Maroon and Yellow cap) can be given to infants and children from 6 months to 4 years of age.

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

3. What if I am taking other medicines?

Tell your doctor or pharmacist if your child is taking, has 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 your child has recently received any other vaccine.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements your child is 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 child's upper arm or thigh by a doctor, nurse or pharmacist.
- For primary vaccination, your child will be given three doses. One dose followed by a second dose at least 21 days later, and a third dose at least 8 weeks after the second dose. If your child misses the second or third dose, ask your doctor for advice.
- If your child has previously been vaccinated with a COVID-19 vaccine, 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.
- A doctor, nurse or pharmacist will observe your child for at least 15 minutes after being given Comirnaty Omicron XBB.1.5.

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

Things you should know

- If your child received one dose of Comirnaty Omicron XBB.1.5, he/she should continue to receive the same vaccine to complete the primary vaccination schedule.
- 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.
- Your child may not be protected against COVID-19 disease until at least seven days after completion of primary vaccination.
- Your child may not be protected if he/she only receives one dose, so it is very important to complete all 3 doses of the primary vaccination schedule.

Driving or using machines

Be careful before your child drives, cycles or use any machines or tools until you know how Comirnaty Omicron XBB.1.5 affects him/her.

Some of the side effects of Comirnaty Omicron XBB.1.5 may temporarily affect the ability to drive, cycle 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 your child before he/she is 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 your child does 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/ tenderness/redness at injection site • tiredness (uncommon in 6 months to less than 2 years of age) • diarrhoea (common in 6 months to less than 2 years of age) • irritability (in 6 months to less than 2 years of age) • 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"> • injection site swelling • vomiting • joint pain • muscle pain • chills (uncommon in 6 months to less than 2 years of age) • headache (uncommon in 6 months to less than 2 years of age) 	<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/weak • nausea • decreased appetite (very common in 6 months to less than 2 years of age) • hives • itchy skin • rash • pain in arm 	<p>Speak to your doctor if you have any of these side effects and they worry you.</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 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	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

Maroon cap vial (For Age 6 months to 4 Years):

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

Comirnaty Omicron XBB.1.5 (Maroon cap) is provided in packs of 10 clear glass vials with Maroon flip-off caps. After dilution, each dose is 0.2 mL and each vial contains 10 doses of vaccine (0.4 mL fill).

Yellow cap vial (For Age 6 months to 4 Years):

Comirnaty Omicron XBB.1.5 (Yellow cap) is a clear to slightly opalescent frozen suspension.

Comirnaty Omicron XBB.1.5 (Yellow cap) is provided in packs of 10 clear glass vials with Yellow flip-off caps. After dilution, each dose is 0.3 mL and each vial contains 3 doses of vaccine (0.48 mL fill).

Not all presentations may be available.

Who distributes Comirnaty Omicron XBB.1.5

Pfizer New Zealand Limited

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Auckland

Toll Free Number: 0800 736 363

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