

Comirnaty® XFG 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 is my child being given Comirnaty XFG?

Comirnaty XFG 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 XFG contains the active ingredient SARS-CoV-2 spike protein (mRNA) XFG. For more information, see Section [1. Why is my child being given Comirnaty XFG?](#) in the full CMI.

2. What should I know before my child is given Comirnaty XFG?

Your child should not be given Comirnaty XFG 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 XFG may not fully protect all those who receive it and it is not known how long your child 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 my child is given Comirnaty XFG?](#) in the full CMI.

3. What if my child is 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 my child is taking other medicines?](#) in the full CMI.

4. How will my child be given Comirnaty XFG?

Comirnaty XFG will be given as an injection into the muscle of your child's upper arm by a doctor, nurse or pharmacist. Your child will be given one dose of the vaccine, regardless of prior COVID-19 vaccination status. A doctor, nurse or pharmacist will observe your child for at least 15 minutes after being given the vaccine. For more information, see Section [4. How will my child be given Comirnaty XFG?](#) in the full CMI.

5. What should I know while being given Comirnaty XFG?

Things you should know	• A dose of Comirnaty XFG 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 his/her second dose.
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For more information, see Section [5. What should I know while being given Comirnaty XFG?](#) 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 your child has any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Comirnaty® XFG COVID-19 vaccine for age 5 to 11 years

Active ingredient: SARS-CoV-2 spike protein (mRNA) XFG

Consumer Medicine Information (CMI)

This leaflet provides important information about using Comirnaty XFG. **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 XFG.**

Where to find information in this leaflet:

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

1. Why is my child being given Comirnaty XFG?

Comirnaty XFG contains the active ingredient (SARS-CoV-2 spike protein (mRNA) XFG.

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 XFG (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 my child is given Comirnaty XFG?

Warnings

Comirnaty XFG should not be given:

1. if your child is allergic to the active ingredient SARS-CoV-2 spike protein (mRNA) XFG 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, your child can have his/her vaccination if he/she has 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 his/her 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, 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 in your child. Sometimes the symptoms of myocarditis and pericarditis may not be specific and could include tiredness, dizziness, nausea and vomiting, abdominal pain, swelling, and cough.

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.

Children and adolescents

Comirnaty XFG can be given to individuals 6 months of age and older.

Comirnaty XFG should not be given to infants under 6 months of age.

Refer to the Comirnaty XFG (Yellow cap) CMI leaflet for infants and children aged 6 months to 4 years.

3. What if my child is 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 XFG.

4. How will my child be given Comirnaty XFG?

- Comirnaty XFG will be given as an injection into the muscle of your child's upper arm by a doctor, nurse or pharmacist.
- Your child will be given one dose, regardless of prior COVID-19 vaccination status.
- A doctor, nurse or pharmacist will observe your child for at least 15 minutes after being given Comirnaty XFG.
- A dose of Comirnaty XFG 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 XFG?

Things you should know

- A dose of Comirnaty XFG 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 the vaccination.

Driving or using machines

Be careful before your child drives, cycles or uses any machines or tools until you know how Comirnaty XFG affects him/her.

Some of the side effects of Comirnaty XFG may temporarily affect the ability to drive, cycle or use machines.

Storage of the vaccine

Comirnaty XFG 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
• pain/swelling/redness at injection site • tiredness • headache • muscle pain • chills • diarrhoea	Speak to your doctor if your child has any of these very common side effects and they worry you.

Common side effects

Common side effects	What to do
• vomiting • joint pain • fever	Speak to your doctor if your child has any of these common side effects and they worry you.

Uncommon side effects

Uncommon side effects	What to do
• enlarged lymph nodes • feeling unwell • nausea • decreased appetite • hives • itchy skin • rash • pain in arm	Speak to your doctor if your child has any of these side effects and they worry you.

Other side effects (frequency unknown)

Other side effects (frequency unknown)	What to do
• 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.
• extensive swelling of vaccinated arm • dizziness • heavy menstrual bleeding	Speak to your doctor if your child has any of these side effects and they worry you.

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

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

7. Product details

What Comirnaty XFG contains

Active ingredient (main ingredient)	• SARS-CoV-2 spike protein (mRNA) XFG
Other ingredients (inactive ingredients)	• ((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 your child is allergic to any of these ingredients.

What Comirnaty XFG looks like

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

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

Comirnaty XFG (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 XFG (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 XFG

Pfizer New Zealand Limited

Auckland

Toll Free Number: 0800 736 363

www.pfizermedicalinformation.co.nz

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