COMIRNATY® XFG COVID-19 vaccine

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.

▼ This vaccine is new or being used differently. Please report side effects. See the full CMI for further details.

1. Why am I 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 adults, infants and children from 6 months of age and older. COMIRNATY XFG contains the active ingredient SARS-CoV-2 spike protein (mRNA) XFG. For more information, see Section 1. Why am I being given COMIRNATY XFG? in the full CMI.

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

You should not be given COMIRNATY XFG 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 any other COMIRNATY COVID-19 vaccine 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. Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding. COMIRNATY XFG should not be given to infants under 6 months of age. For more information, see Section 2. What should I know before I am given COMIRNATY XFG? 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 XFG?

COMIRNATY XFG will be given as an injection into the muscle of your upper arm or thigh by a doctor, nurse or pharmacist. For adults and children 5 years of age and older, you will be given one dose, regardless of prior COVID-19 vaccination status. For infants and children 6 months to less than 5 years of age, one dose followed by a second dose at least 21 days later and a third dose will be given at least 8 weeks after the second dose as a part of the primary vaccination. A doctor, nurse or pharmacist will observe you for at least 15 minutes after being given the vaccine. You may receive additional dose(s) at least 3 months after the previous dose. For more information, see Section 4. How will I be given COMIRNATY XFG? in the full CMI.

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

Things you should know	• Additional dose(s) of COMIRNATY XFG may be given at least 3 months after the previous dose for adults and children 5 years of age and older. • For infants and children 6 months to less than 5 years of age, if your child received one dose of COMIRNATY XFG, they should continue to receive the same vaccine to complete the primary vaccination schedule. • You may not be protected against COVID-19 disease until at least seven days after the last dose of your primary vaccination schedule. It is very important you complete your primary vaccination.
Driving or using machines	• Be careful before you drive or use any machines or tools until you know how COMIRNATY XFG affects you. Some of the side effects of COMIRNATY XFG may temporarily affect your ability to drive, cycle or use machines.

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 you have any side effects, see Section 6. Are there any side effects? in the full CMI.

▼ This vaccine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

COMIRNATY® XFG COVID-19 vaccine

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 am I being given COMIRNATY XFG?
2. What should I know before I am given COMIRNATY XFG?
3. What if I am taking other medicines?
4. How will I 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 am I being given COMIRNATY XFG?

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

COMIRNATY XFG is an mRNA (messenger ribonucleic acid) vaccine.

COMIRNATY XFG is a vaccine given to prevent COVID-19 disease caused by SARS-CoV-2 virus in adults, infants and children from 6 months of age and older.

COMIRNATY XFG 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 XFG?

Warnings

COMIRNATY XFG should not be given:

- if you are 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 you have:

- had a severe allergic reaction or breathing problems after any other vaccine or after being given any other COMIRNATY COVID-19 vaccine 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 (adolescents and young adults). There have been cases in women. Most cases of myocarditis and pericarditis recover. Some cases required intensive care support and fatal cases have been seen. 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. 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 XFG 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 doctor or pharmacist for advice before you receive this vaccine.

Children and adolescents

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

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.

COMIRNATY XFG (30 micrograms/dose only) may be given at the same time as the seasonal flu (influenza) vaccine for individuals 12 years and older.

COMIRNATY XFG (30 micrograms/dose only) may be given at the same time as the pneumococcal conjugated vaccine for individuals 18 years and older.

COMIRNATY XFG (30 micrograms/dose only) may be given at the same time as the respiratory syncytial virus (RSV) vaccine for individuals 60 years and older.

COMIRNATY XFG (30 micrograms/dose only) may be given at the same time as the respiratory syncytial virus (RSV) vaccine and a high dose influenza vaccine for individuals 65 years and older.

There is no available information on whether COMIRNATY XFG can be given at the same time as the respiratory syncytial virus (RSV) vaccine in pregnant women.

Different injectable vaccines should be given at different injection sites (e.g. one vaccine in each arm).

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 XFG.

4. How will I be given COMIRNATY XFG?

- COMIRNATY XFG will be given as an injection into the muscle of your upper arm or thigh by a doctor, nurse or pharmacist.
- For adults and children 5 years of age and older, you will be given one dose, regardless of prior vaccination status.
- If you are immunocompromised, you may receive an additional dose of the vaccine
- For infants and children 6 months to less than 5 years of age, 3 doses will be given. One dose followed by a second dose at least 21 days later and a third dose will be given at least 8 weeks after the second dose to complete the primary vaccination.
- A doctor, nurse or pharmacist will observe you for at least 15 minutes after being given the vaccine.
- Additional dose(s) of COMIRNATY XFG may be given at least 3 months after the previous dose for adults and children 5 years of age and older.

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

Things you should know

- For infants and children 6 months to less than 5 years of age, if your child received one dose of COMIRNATY XFG, they should continue to receive the same vaccine to complete the primary vaccination schedule.
- If you are immunocompromised, you may receive an additional dose of the vaccine.
- Additional dose(s) of COMIRNATY XFG may be given at least 3 months after the previous dose for adults and children 5 years of age and older.
- You may not be protected against COVID-19 disease until at least seven days after the vaccination.
- For infants and children 6 months to less than 5 years of age, your child may not be protected if they only receive one dose, so it is very important that they complete their primary vaccination.

Driving or using machines

Be careful before you drive, cycle or use any machines or tools until you know how COMIRNATY XFG affects you.

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

Storage of the vaccine

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
• pain/swelling/tenderness at injection site • tiredness • headache • muscle pain • chills • joint pain • fever • irritability (in 6 months to less than 2 years of age)	**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
• redness at injection site • nausea	**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
• enlarged lymph nodes • feeling unwell • arm pain • insomnia • decreased appetite (very common in 6 months to less than 2 years of age) • excessive sweating • night sweats • physical weakness and/or lack of energy	**Speak to your doctor if you have any of these side effects and they worry you.**

Rare side effects

Rare side effects	What to do
• temporary one-sided facial drooping	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice this side effect.**

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 any of these serious side effects.**
• diarrhoea • vomiting • pain in arm • extensive swelling of vaccinated arm • swelling of face (people who have had facial dermal fillers) • unusual sensation (e.g. tingling or pricking, “pins-and-needles”) • numbness • skin lesions (bull's-eye-shaped) • dizziness • genital ulcers • heavy menstrual (period) bleeding	**Speak to your doctor if you have any of these side effects and they worry you.**
• breast swelling, redness and/or pain	

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.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this vaccine.

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) • Distearoylphosphatidylcholine (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 XFG looks like

COMIRNATY XFG (Dark Grey cap) is a white to off-white frozen suspension.

COMIRNATY XFG (Blue and Yellow cap) is a clear to slightly opalescent solution.

COMIRNATY XFG (Single dose Glass Prefilled Syringe) is a white to off-white suspension.

Yellow cap vial (For Age 6 months to less than 5 Years):

COMIRNATY XFG (Yellow cap) is provided in packs of 10 in 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). AUST R 528197

Blue cap vial (For Age 5 to less than 12 Years):

COMIRNATY XFG (Light or Dark Blue cap) is provided in packs of 10 in clear glass vials with blue flip-off caps. No dilution required. Each dose is 0.3 mL.

Each single dose vial (Light Blue) contains 1 dose of vaccine (0.48 mL fill). AUST R 528196

Each multidose vial (Dark Blue) contains 6 doses of vaccine (2.25 mL fill). AUST R 528195

Grey cap vial (For Ages 12 Years and older):

COMIRNATY XFG (Dark Grey cap) is provided in packs of 10 in clear glass vials with grey flip-off caps. No dilution required. Each dose is 0.3 mL.

Each multidose vial (Dark Grey) contains 6 doses of vaccine (2.25 mL fill). AUST R 528198

Single dose Glass Prefilled Syringes (For Ages 12 Years and older):

COMIRNATY XFG – Single dose Glass Prefilled Syringes is provided in packs of 1 and 10 in clear glass syringes with a rigid cap. No dilution is required. Each dose is 0.3 mL.

Each single dose glass syringe contains 1 dose of vaccine (0.418 mL fill). AUST R 528199

Not all presentations may be available.

Who distributes COMIRNATY XFG

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

www.pfizermedical.com.au

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This leaflet was prepared in October 2026.

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