

Comirnaty® LP.8.1 COVID-19 Vaccine for Age 12 years and older

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 LP.8.1?

Comirnaty LP.8.1 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 12 years of age and older. Comirnaty LP.8.1 contains SARS-CoV-2 spike protein (mRNA) LP.8.1. For more information, see Section [1. Why am I being given Comirnaty LP.8.1?](#) in the full CMI.

2. What should I know before I am given Comirnaty LP.8.1?

You should not be given Comirnaty LP.8.1 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 LP.8.1 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, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding. For more information, see Section [2. What should I know before I am given Comirnaty LP.8.1?](#) 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 LP.8.1?

Comirnaty LP.8.1 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 LP.8.1?](#) in the full CMI.

5. What should I know while being given Comirnaty LP.8.1?

| | |
|----------------------------------|--|
| Things you should know | <ul style="list-style-type: none">• A dose of Comirnaty LP.8.1 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 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 LP.8.1 affects you. Some of the side effects of Comirnaty LP.8.1 may temporarily affect your ability to drive or use machines. |

For more information, see Section [5. What should I know while being given Comirnaty LP.8.1?](#) 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® LP.8.1 COVID-19 Vaccine for Age 12 years and older

Active ingredient: SARS-CoV-2 spike protein (mRNA) LP.8.1

Consumer Medicine Information (CMI)

This leaflet provides important information about using Comirnaty LP.8.1. **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 LP.8.1.**

Where to find information in this leaflet:

- [1. Why am I being given Comirnaty LP.8.1?](#)
- [2. What should I know before I am given Comirnaty LP.8.1?](#)
- [3. What if I am taking other medicines?](#)
- [4. How will I be given Comirnaty LP.8.1?](#)
- [5. What should I know while being given Comirnaty LP.8.1?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I being given Comirnaty LP.8.1?

Comirnaty LP.8.1 contains the active ingredient SARS-CoV-2 spike protein (mRNA) LP.8.1.

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 12 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.

Comirnaty LP.8.1 (Grey cap) is a 30 microgram/0.3 mL dose, suspension for injection, for adults 12 years of age and older.

2. What should I know before I am given Comirnaty LP.8.1?

Warnings

Comirnaty LP.8.1 should not be given:

- if you are allergic to the active ingredient SARS-CoV-2 spike protein (mRNA) LP.8.1 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.

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 LP.8.1 can be given to individuals 6 months of age and older.

Comirnaty LP.8.1 should not be given to infants under 6 months of age.

Refer to the Comirnaty LP.8.1 (Orange or Blue cap) CMI leaflet for children aged 5 to 11 years.

Refer to the Comirnaty LP.8.1 (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.

Comirnaty LP.8.1 (30 micrograms/dose only) may be given at the same time as the seasonal flu (influenza) vaccine for individuals 12 years and older.

For individuals 18 years of age and older, Comirnaty LP.8.1 may be given at the same time as the pneumococcal conjugate vaccine (PCV).

For individuals 60 years of age and older, Comirnaty LP.8.1 may be given at the same time as the unadjuvanted respiratory syncytial virus (RSV) vaccine

For individuals 65 years of age and older, Comirnaty LP.8.1 may be given at the same time as the RSV and seasonal flu vaccine.

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 LP.8.1.

4. How will I be given Comirnaty LP.8.1?

- Comirnaty LP.8.1 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 LP.8.1.
- A dose of Comirnaty LP.8.1 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 LP.8.1?

Things you should know

- A dose of Comirnaty LP.8.1 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 LP.8.1 affects you.

Some of the side effects of Comirnaty LP.8.1 may temporarily affect your ability to drive or use machines.

Storage of the vaccine

Comirnaty LP.8.1 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 at injection site• tiredness• headache• muscle pain• chills• joint pain• fever | 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">• 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 |
|---|---|
| <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 | 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 |
|---|---|
| <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 | <p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice this serious side effect.</p> |
| <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 | <p>Speak to your doctor if you have any of these side effects and they worry you.</p> |

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 LP.8.1 contains

| | |
|---|--|
| Active ingredient (main ingredient) | <ul style="list-style-type: none"> SARS-CoV-2 spike protein (mRNA) LP.8.1 |
| 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) Distearoylphosphatidylcholine (DSPC) Cholesterol Sucrose |

| |
|--|
| <ul style="list-style-type: none"> Trometamol Trometamol hydrochloride Water for injections |
|--|

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

What Comirnaty LP.8.1 looks like

Dark Grey cap vials (For Ages 12 Years and older):

Comirnaty LP.8.1 (Dark Grey cap) is a white to off-white suspension.

Comirnaty LP.8.1 (Dark Grey cap) is provided in packs of 10 in clear glass vials with grey flip-off caps. Each dose is 0.3 mL and each vial contains 6 doses of vaccine (2.25 mL fill).

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

Comirnaty LP.8.1 – Single dose Glass Prefilled Syringes is a white to off-white suspension.

Comirnaty LP.8.1 – 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).

Not all presentations may be available.

Who distributes Comirnaty LP.8.1

Pfizer New Zealand Limited

PO Box 3998

Auckland

Toll Free Number: 0800 736 363

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