Package leaflet: Information for the user

Comirnaty LP.8.1 30 micrograms/dose dispersion for injection in pre-filled syringe (glass)
Adults and adolescents from 12 years
COVID-19 mRNA Vaccine
mRNA encoding LP.8.1

▼This medicine 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. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you receive this vaccine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Comirnaty LP.8.1 is and what it is used for

Comirnaty LP.8.1 is a vaccine used for preventing COVID-19 caused by SARS-CoV-2.

Comirnaty LP.8.1 30 micrograms/dose dispersion for injection in pre-filled syringe is given to adults and adolescents from 12 years of age and older.

The vaccine causes the immune system (the body's natural defences) to produce antibodies and blood cells that work against the virus, so giving protection against COVID-19.

As Comirnaty LP.8.1 does not contain the virus to produce immunity, it cannot give you COVID-19.

The use of this vaccine should be in accordance with official recommendations.

2. What you need to know before you receive Comirnaty LP.8.1

Comirnaty LP.8.1 should not be given
- if you are allergic to the active substance or any of the other ingredients of this medicine (listed in section 6)

Warnings and precautions
Talk to your doctor, pharmacist or nurse before you are given the vaccine if:
- you have ever had a severe allergic reaction or breathing problems after any other vaccine injection or after you were given this vaccine in the past.
- you are feeling nervous about the vaccination process or have ever fainted following any needle injection.
- you have 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.

- you have a bleeding problem, you bruise easily or you use a medicine to prevent blood-clots.
- you have a weakened immune system, because of a disease such as HIV infection or a medicine such as corticosteroid that affects your immune system.

There is an increased risk of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) after vaccination with Comirnaty (see section 4). These conditions can develop within just a few days after vaccination and have primarily occurred within 14 days. They have been observed more often after the second vaccination, and more often in younger males. The risk of myocarditis and pericarditis seems lower in children ages 5 to 11 years compared with ages 12 to 17 years. 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.

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.

The efficacy of Comirnaty LP.8.1 may be lower in people who are immunocompromised. If you are immunocompromised, you may receive additional doses of Comirnaty LP.8.1. In these cases, you should continue to maintain physical precautions to help prevent COVID-19. In addition, your close contacts should be vaccinated as appropriate. Discuss appropriate individual recommendations with your doctor.

Children
Comirnaty LP.8.1 30 micrograms/dose dispersion for injection in pre-filled syringe is not recommended for children aged under 12 years.

There are paediatric formulations available for infants aged 6 months and above and children below 12 years of age. For details, please refer to the Package Leaflet for other formulations.

The vaccine is not recommended for infants aged under 6 months.

Other medicines and Comirnaty LP.8.1
Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines or have recently received any other vaccine.

Comirnaty LP.8.1 may be given at the same time as a flu vaccine.

In adults 18 years of age and older, Comirnaty LP.8.1 may be given at the same time as a pneumococcal conjugated vaccine (PCV).

In adults 18 years of age and older, Comirnaty LP.8.1 may be given at the same time as a respiratory syncytial virus (RSV) vaccine.

In older adults 65 years of age and older, Comirnaty LP.8.1 may be given at the same time as a high dose flu and an RSV vaccine.

Pregnancy and breast-feeding
If you are pregnant or think you may be pregnant, tell your doctor, nurse or pharmacist before you receive this vaccine.

No data are available yet regarding the use of Comirnaty LP.8.1 during pregnancy. However, a large amount of information from pregnant women vaccinated with the initially approved Comirnaty vaccine during the second and third trimester have not shown negative effects on the pregnancy or the newborn baby. While information on effects on pregnancy or the newborn baby after vaccination during the first trimester is limited, no change to the risk for miscarriage has been seen. Comirnaty LP.8.1 can be used during pregnancy.

No data are available yet regarding the use of Comirnaty LP.8.1 during breast-feeding. However, no effects on the breastfed newborn/infant are anticipated. Data from women who were breast-feeding after vaccination with the initially approved Comirnaty vaccine have not shown a risk for adverse effects in breastfed newborns/infants. Comirnaty LP.8.1 can be used while breast-feeding.

Driving and using machines
Some of the effects of vaccination mentioned in section 4 (Possible side effects) may temporarily affect your ability to drive or use machines. Wait until these effects have worn off before you drive or use machines.

3. How Comirnaty LP.8.1 is given

Comirnaty LP.8.1 is given as an injection of 0.3 mL into a muscle of your upper arm.

You will receive 1 injection, regardless whether you have received a COVID-19 vaccine before.

If you were previously vaccinated with a COVID-19 vaccine, you should not receive a dose of Comirnaty LP.8.1 until at least 3 months after the most recent dose.

If you are immunocompromised, you may receive additional doses of Comirnaty LP.8.1.

If you have any further questions on the use of Comirnaty LP.8.1, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all vaccines, Comirnaty LP.8.1 can cause side effects, although not everybody gets them.

Very common side effects: may affect more than 1 in 10 people
- injection site: pain, swelling
- tiredness, headache
- muscle pain, joint pain
- chills, fever
- diarrhoea

Some of these side effects were slightly more frequent in adolescents 12 to 15 years than in adults.

Common side effects: may affect up to 1 in 10 people
- nausea
- vomiting (‘very common’ in pregnant women 18 years of age and older and in immunocompromised individuals 12 to 18 years of age)
- injection site redness (‘very common’ in immunocompromised individuals 12 years of age and older)
- enlarged lymph nodes (more frequently observed after a booster dose)

Uncommon side effects: may affect up to 1 in 100 people
- feeling unwell, feeling weak or lack of energy/sleepy
- arm pain
- insomnia
- injection site itching
- allergic reactions such as rash or itching
- decreased appetite
- dizziness
- excessive sweating, night sweats

Rare side effects: may affect up to 1 in 1 000 people
- temporary one sided facial drooping
- allergic reactions such as hives or swelling of the face

Very rare side effects: may affect up to 1 in 10 000 people
- inflammation of the heart muscle (myocarditis) or inflammation of the lining outside the heart (pericarditis) which can result in breathlessness, palpitations or chest pain

Not known (cannot be estimated from the available data)
- severe allergic reaction
- extensive swelling of the vaccinated limb
- swelling of the face (swelling of the face may occur in patients who have had facial dermatological fillers)
- a skin reaction that causes red spots or patches on the skin, that may look like a target or "bulls-eye" with a dark red centre surrounded by paler red rings (erythema multiforme)
- unusual feeling in the skin, such as tingling or a crawling feeling (paraesthesia)
- decreased feeling or sensitivity, especially in the skin (hypoaesthesia)
- heavy menstrual bleeding (most cases appeared to be non-serious and temporary in nature)

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via a Yellow card. Reporting forms and information can be found at https://coronavirus-yellowcard.mhra.gov.uk/or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Comirnaty LP.8.1

Keep this medicine out of the sight and reach of children.

The following information about storage, expiry and use and handling is intended for healthcare professionals.

Do not use this medicine after the expiry date which is stated on the carton and label after EXP.

Store in a refrigerator at 2 °C to 8 °C. DO NOT FREEZE.

Store in the original package in order to protect from light.

The vaccine will be received and stored at 2 °C to 8 °C (refrigerated only). Prior to use, pre-filled syringes can be stored for up to 12 hours at temperatures between 8 °C to 30 °C and can be handled in room light conditions.

Do not use this vaccine if you notice particulates or discolouration.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Comirnaty LP.8.1 contains

The active substance of COVID-19 mRNA Vaccine (nucleoside modified) is called mRNA encoding LP.8.1. Each pre-filled syringe contains 1 dose of 0.3 mL with 30 micrograms mRNA encoding LP.8.1 each.

- The other ingredients are:
  - ((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
  - trometamol
  - trometamol hydrochloride
  - sucrose
  - water for injections

What Comirnaty LP.8.1 looks like and contents of the pack
The vaccine is a white to off-white dispersion (pH: 6.9 - 7.9) provided in a pre-filled syringe (type I glass syringe) with plunger stopper (synthetic bromobutyl rubber) and a tip cap (synthetic bromobutyl rubber) without needle.

Pack sizes:
1 pre-filled syringe
10 pre-filled syringes
Not all pack sizes may be marketed.

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For any information about this medicine, please contact: Medical Information, Pfizer Ltd, Walton Oaks, Dorking Road, Tadworth, Surrey, KT20 7NS. Telephone 01304 616161.

This leaflet was last revised in 09/2025.

Ref: bCY (LP.8.1) 30 mcg PFS Glass 2_0

The following information is intended for healthcare professionals only:

Administer Comirnaty LP.8.1 intramuscularly as a single dose of 0.3 mL regardless of prior COVID−19 vaccination status.

For individuals who have previously been vaccinated with a COVID-19 vaccine, Comirnaty LP.8.1 should be administered at least 3 months after the most recent dose of a COVID-19 vaccine.

Additional doses may be given to individuals who are severely immunocompromised.

Traceability
In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

Handling instructions prior to use
Comirnaty LP.8.1 should be prepared by a healthcare professional using aseptic technique to ensure the sterility of the prepared dispersion.

Instructions applicable to pre-filled syringes

Glass pre-filled syringes
- Prior to use, the glass pre-filled syringes can be stored for up to 12 hours at temperatures between 8 °C to 30 °C and can be handled in room light conditions.
- Remove tip cap by slowly turning the cap counterclockwise. Do not shake. Attach a needle appropriate for intramuscular injection and administer the entire volume.

Disposal
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.