

Comirnaty™

concentrate for dispersion for injection

COVID-19 mRNA Vaccine (nucleoside modified)

▼ 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 is and what it is used for
2. What you need to know before you receive Comirnaty
3. How Comirnaty is given
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1 What Comirnaty is and what it is used for

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

Comirnaty is given to adults and adolescents from 16 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 does not contain the virus to produce immunity, it cannot give you COVID-19.

2 What you need to know before you receive Comirnaty

Comirnaty 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 Comirnaty in the past.
- you 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

As with any vaccine, the 2-dose vaccination course of 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 is not recommended for children under 16 years.

Other medicines and Comirnaty

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.

Pregnancy and breast-feeding

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.

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.

Comirnaty contains potassium and sodium

This vaccine contains less than 1 mmol potassium (39 mg) per dose, that is to say essentially 'potassium-free'.

This vaccine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

3 How Comirnaty is given

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

You will receive 2 injections, given at least 21 days apart.

After the first dose of Comirnaty, you should receive a second dose of the same vaccine after 21 days to complete the vaccination course.

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

4 Possible side effects

Like all vaccines, Comirnaty can cause side effects, although not every-body gets them.

Very common: may affect more than 1 in 10 people

- injection site: pain, swelling
- tiredness
- headache
- muscle pain
- joint pain
- chills, fever

Common side effects: may affect up to 1 in 10 people

- injection site redness
- nausea

Uncommon side effects: may affect up to 1 in 100 people

- enlarged lymph nodes
- feeling unwell

- pain in limb
- insomnia
- injection site itching

Rare side effects: may affect up to 1 in 1,000 people

- temporary one sided facial drooping

Not known (cannot be estimated from the available data)

- severe allergic reaction

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 the national reporting system and include batch/Lot number if available:

- Ireland: HPRA Pharmacovigilance, Website: www.hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Comirnaty

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. The expiry date refers to the last day of that month.

Store in freezer at -90 °C to -60 °C.

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

After thawing, the vaccine should be diluted and used immediately. However, in-use stability data have demonstrated that once removed from freezer, the undiluted vaccine can be stored for up to 5 days at 2 °C to 8 °C, or up to 2 hours at temperatures up to 30 °C, prior to use.

After dilution, store the vaccine at 2 °C to 30 °C and use within 6 hours. Discard any unused vaccine.

Once removed from the freezer and diluted, the vials should be marked with the new discard date and time. Once thawed, the vaccine cannot be re-frozen.

Do not use this vaccine if you notice particulates in the dilution 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 contains

The active substance is COVID-19 mRNA Vaccine. After dilution, the vial contains 6 doses of 0.3 mL with 30 micrograms mRNA each. The other ingredients are:

((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-ethyldecanoate) (ALC-0315)

2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide (ALC-159) - 1,2-Distearoyl-sn-glycero-3-phosphocholine (DSPC)

cholesterol

potassium chloride

potassium dihydrogen phosphate

sodium chloride

disodium phosphate dihydrate

sucrose

Version: Comirnaty PIL Ireland 21_01_08

- water for injections

What Comirnaty looks like and contents of the pack

The vaccine is a white to off-white dispersion (pH: 6.9 - 7.9) provided in a multidose vial of 6 doses in a 2 mL clear vial (type I glass), with a rubber stopper and a flip-off plastic cap with aluminium seal.

Pack size: 195 vials

Marketing Authorisation Holder

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For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

- Ireland: Pfizer Healthcare Ireland, Tel: 1800 633 363 (toll free), +44 (0)1304 616161

This leaflet was last revised in 01/2021.

This medicine has been given 'conditional approval'. This means that there is more evidence to come about this medicine. The European Medicines Agency will review new information on this medicine at least every year and this leaflet will be updated as necessary.

Scan the code with a mobile device to get this information in different languages.



URL: www.comirnatyglobal.com

Detailed information on this medicine is available on the European Medicines Agency web site: <http://www.ema.europa.eu>.

This package leaflet is available in all EU/EEA languages on the European Medicines Agency website.