

Package leaflet: Information for the user

Comirnaty XFG 10 micrograms/dose dispersion for injection, single dose vial Infants and children 6 months to 11 years COVID-19 mRNA Vaccine mRNA encoding XFG

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects your child may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before your child receives this vaccine because it contains important information for your child.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your child's doctor, pharmacist or nurse.
- If your child gets any side effects, talk to your child's 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 XFG is and what it is used for
2. What you need to know before your child receives Comirnaty XFG
3. How Comirnaty XFG is given
4. Possible side effects
5. How to store Comirnaty XFG
6. Contents of the pack and other information

1. What Comirnaty XFG is and what it is used for

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

Comirnaty XFG 10 micrograms/dose dispersion for injection, single dose vial is given to infants and children from 6 months to 11 years of age.

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 XFG does not contain the virus to produce immunity, it cannot give your child COVID-19.

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

2. What you need to know before your child receives Comirnaty XFG

Comirnaty XFG should not be given

- if your child is allergic to the active substance or any of the other ingredients of this medicine (listed in section 6)

Warnings and precautions

Talk to your child's doctor, pharmacist or nurse before your child is given the vaccine if your child:

- has ever had a severe allergic reaction or breathing problems after any other vaccine injection or after having been given this vaccine in the past.
- is feeling nervous about the vaccination process or has ever fainted following any needle injection.

- has a severe illness or infection with high fever. However, your child can have the vaccination if he/she has a mild fever or upper airway infection like a cold.
- has a bleeding problem, bruises easily or uses a medicine to prevent blood-clots.
- has a weakened immune system, because of a disease such as HIV infection or a medicine such as corticosteroid that affects the 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 XFG may not fully protect all those who receive it and it is not known how long your child will be protected.

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

Children

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

Other medicines and Comirnaty XFG

Tell your child's doctor or pharmacist if your child is using, has recently used or might use any other medicines or has recently received any other vaccine.

Pregnancy and breast-feeding

If your child is pregnant, tell your child's doctor, nurse or pharmacist before your child receives this vaccine.

No data are available yet regarding the use of Comirnaty XFG 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 XFG can be used during pregnancy.

No data are available yet regarding the use of Comirnaty XFG 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 XFG 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 child's ability to use machines or undertake activities such as cycling. Wait until these effects have worn off before resuming activities that require your child's full attention.

3. How Comirnaty XFG is given

If your infant is from 6 months to less than 12 months of age, he/she will be given Comirnaty XFG as an injection of 0.3 mL into a muscle of the thigh. If your infant or child is 1 year of age or older, he/she will be given Comirnaty XFG as an injection of 0.3 mL into a muscle of the thigh or into a muscle of the upper arm.

Children 5 years to 11 years of age

Your child will receive 1 injection, regardless whether he/she has received a COVID-19 vaccine before.

If your child was previously vaccinated with a COVID-19 vaccine, he/she should not receive a dose of Comirnaty XFG until at least 3 months after the most recent dose.

Infants and children 6 months to 4 years of age

If your child has not received a COVID-19 vaccine in the past, your child will receive a maximum of 2 doses (the total number of doses required as a primary course). It is recommended to receive the second dose 8 weeks after the first dose to complete the primary course.

If your child turns 5 years old between their doses in the primary course, he/she should complete the primary course at the same 10 micrograms dose level.

If your child has previously completed a COVID-19 primary vaccination course, your child will receive 1 injection. If your child was previously vaccinated with a COVID-19 vaccine, your child should not receive a dose of Comirnaty XFG until at least 3 months after the most recent dose.

If your child has previously received 1 or 2 doses of the 3 micrograms 3-dose primary course but has not completed the COVID-19 primary vaccination course, he/she may receive additional doses of Comirnaty XFG 10 micrograms. The second dose may be administered 3 weeks after the first dose followed by a third dose at least 8 weeks after the second dose.

Immunocompromised infants and children 6 months to 11 years of age

If your child is immunocompromised, he/she may receive additional doses of Comirnaty XFG.

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

4. Possible side effects

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

Very common side effects: may affect more than 1 in 10 people

- irritability (children 6 months to less than 2 years of age)
- injection site: pain/tenderness, swelling
- tiredness, headache
- drowsiness (children 6 months to less than 2 years of age)
- muscle pain, joint pain
- chills, fever
- diarrhoea

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 2 to 18 years of age)
- injection site redness ('very common' in children 6 months to 11 years of age and in immunocompromised individuals 2 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 ('common' for children 6 months to less than 2 years of age) or itching
- decreased appetite ('very common' for children 6 months to less than 2 years of age)
- 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 (hypoesthesia)
- heavy menstrual bleeding (most cases appeared to be non-serious and temporary in nature)

Reporting of side effects

If your child gets any side effects, talk to your child's 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 XFG

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.

The vaccine will be received frozen at -90 °C to -60 °C. Frozen vaccine can be stored either at -90 °C to -60 °C or 2 °C to 8 °C upon receipt.

Single dose vials: When stored frozen at -90 °C to -60 °C, 10-vial packs of single dose vials of the vaccine can be thawed at 2 °C to 8 °C for 2 hours or individual vials can be thawed at room temperature (up to 30 °C) for 30 minutes.

Thawed (previously frozen) vials: Once removed from the freezer, the unopened vial may be stored and transported refrigerated at 2 °C to 8 °C for up to 10 weeks; not exceeding the printed expiry date (EXP). The outer carton should be marked with the new expiry date at 2 °C to 8 °C. Once thawed, the vaccine cannot be re-frozen.

Prior to use, the unopened vials can be stored for up to 12 hours at temperatures between 8 °C and 30 °C.

Thawed vials 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 XFG contains

- The active substance of COVID-19 mRNA Vaccine (nucleoside modified) is called mRNA encoding XFG.
 - A single dose vial contains 1 dose of 0.3 mL with 10 micrograms of mRNA encoding XFG per dose.
- 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 XFG looks like and contents of the pack

The vaccine is a clear to slightly opalescent dispersion (pH: 6.9 - 7.9) provided a single dose vial of 1 dose in a 2 mL clear vial (type I glass), with a rubber stopper and a blue flip-off plastic cap with aluminium seal.

Pack size: 10 vials

Marketing Authorisation Holder

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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 08/2026.

Ref: bCY (XFG) 10 mcg SDV 1_0

The following information is intended for healthcare professionals only:*Children 5 years to 11 years of age*

Administer Comirnaty XFG 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 XFG should be administered at least 3 months after the most recent dose of a COVID-19 vaccine.

Infants and children 6 months to 4 years of age

If the child has not received a COVID-19 vaccine, administer Comirnaty XFG intramuscularly as a primary course of 2 doses of 0.3 mL. Administer the second dose 8 weeks after the first dose.

If the child has completed a COVID-19 vaccine primary course, administer Comirnaty XFG intramuscularly as a single dose of 0.3 mL. For individuals who have previously been vaccinated

with a COVID-19 vaccine, Comirnaty XFG should be administered at least 3 months after the most recent dose of a COVID-19 vaccine.

If the child has received 1 or 2 doses of the 3 micrograms 3-dose primary series but has not completed the primary vaccination course, additional doses of Comirnaty XFG 10 micrograms may be given. The second dose may be administered 3 weeks after the first dose followed by a third dose at least 8 weeks after the second dose.

Immunocompromised infants and children 6 months to 11 years of age

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 XFG should be prepared by a healthcare professional using aseptic technique to ensure the sterility of the prepared dispersion.

- **Verify** that the vial has a **blue plastic cap** and the product **name is Comirnaty XFG 10 micrograms/dose dispersion for injection, single dose vial** (infants and children 6 months to 11 years).
- If the vial has another product name on the label, please make reference to the Summary of Product Characteristics for that formulation.
- If the vial is stored frozen it must be thawed prior to use. Frozen vials should be transferred to an environment of 2 °C to 8 °C to thaw. Ensure vials are completely thawed prior to use.
 - Single dose vials: A 10-vial pack of single dose vials may take 2 hours to thaw.
- Upon moving vials to 2 °C to 8 °C storage, update the expiry date on the carton.
- Unopened vials can be **stored for up to 10 weeks at 2 °C to 8 °C**; not exceeding the printed expiry date (EXP).
- Alternatively, individual frozen vials may be thawed for 30 minutes at temperatures up to 30 °C.
- Prior to use, the unopened vial can be stored for up to 12 hours at temperatures up to 30 °C. Thawed vials can be handled in room light conditions.

Preparation of 0.3 mL doses

- Gently mix by inverting vials 10 times prior to use. Do not shake.
- Prior to mixing, the thawed dispersion may contain white to off-white opaque amorphous particles.
- After mixing, the vaccine should present as a clear to slightly opalescent dispersion with no particulates visible. Do not use the vaccine if particulates or discolouration are present.
- Check whether the vial is a single dose vial or a multidose vial and follow the applicable handling instructions below:
 - Single dose vials
 - Withdraw a single 0.3 mL dose of vaccine.
 - Discard vial and any excess volume.

Disposal

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