

Package leaflet: Information for the user

Comirnaty Omicron XBB.1.5 30 micrograms/dose dispersion for injection Adults and adolescents from 12 years COVID-19 mRNA Vaccine raxtozinameran

▼ 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 Omicron XBB.1.5 is and what it is used for
2. What you need to know before you receive Comirnaty Omicron XBB.1.5
3. How Comirnaty Omicron XBB.1.5 is given
4. Possible side effects
5. How to store Comirnaty Omicron XBB.1.5
6. Contents of the pack and other information

1. What Comirnaty Omicron XBB.1.5 is and what it is used for

Comirnaty Omicron XBB.1.5 is a vaccine used for preventing COVID-19 caused by SARS-CoV-2.

Comirnaty Omicron XBB.1.5 30 micrograms/dose dispersion for injection 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 Omicron XBB.1.5 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 Omicron XBB.1.5

Comirnaty Omicron XBB.1.5 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 Omicron XBB.1.5 may not fully protect all those who receive it and it is not known how long you will be protected.

The efficacy of Comirnaty Omicron XBB.1.5 may be lower in people who are immunocompromised. If you are immunocompromised, you may receive additional doses of Comirnaty Omicron XBB.1.5. 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 Omicron XBB.1.5 30 micrograms/dose dispersion for injection 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 Omicron XBB.1.5

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 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 Omicron XBB.1.5 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 Omicron XBB.1.5 can be used during pregnancy.

No data are available yet regarding the use of Comirnaty Omicron XBB.1.5 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 Omicron XBB.1.5 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 Omicron XBB.1.5 is given

Comirnaty Omicron XBB.1.5 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 Omicron XBB.1.5 until at least 3 months after the most recent dose.

If you are immunocompromised, you may receive additional doses of Comirnaty Omicron XBB.1.5.

If you have any further questions on the use of Comirnaty Omicron XBB.1.5, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all vaccines, Comirnaty Omicron XBB.1.5 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

- injection site redness
- nausea
- vomiting
- 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.

Ireland

You can also report side effects directly via HPRa Pharmacovigilance.

Website: www.hpra.ie and include batch/Lot number if available. **United Kingdom (Northern Ireland)**

If you are concerned about a side-effect it can be reported directly via the Coronavirus Yellow Card reporting site <https://coronavirus-yellowcard.mhra.gov.uk/> or search for MHRA Yellow Card in the Google Play or Apple App Store and include batch/Lot number if available.

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

5. How to store Comirnaty Omicron XBB.1.5

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.

Multidose vials: When stored frozen at -90 °C to -60 °C, 10-vial packs of the vaccine can be thawed at 2 °C to 8 °C for 6 hours or individual vials can be thawed at room temperature (up to 30 °C) for 30 minutes.

Thawed 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.

Opened vials: After first puncture, store the vaccine at 2 °C to 30 °C and use within 12 hours, which includes up to 6 hours transportation time. Discard any unused vaccine.

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 Omicron XBB.1.5 contains

- The active substance of COVID-19 mRNA Vaccine (nucleoside modified) is called raxtozinameran.
 - A single dose vial contains 1 dose of 0.3 mL with 30 micrograms raxtozinameran each.
 - A multidose vial contains 6 doses of 0.3 mL with 30 micrograms raxtozinameran 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 Omicron XBB.1.5 looks like and contents of the pack

The vaccine is a white to off-white dispersion (pH: 6.9 - 7.9) provided in either:

- A single dose vial of 1 dose in a 2 mL clear vial (type I glass), with a rubber stopper and a grey flip-off plastic cap with aluminium seal; or
- A multidose vial of 6 doses in a 2 mL clear vial (type I glass), with a rubber stopper and a grey flip-off plastic cap with aluminium seal.

Single dose vial pack size: 10 vials

Multidose vial pack sizes: 10 vials or 195 vials

Not all pack sizes may be marketed.

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

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This leaflet was last revised in 5/2024.

Scan the code with a mobile device to get the package leaflet in different languages.



URL: www.comirnatyglobal.com

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

Ref: bCY (XBB.1.5) 30 mcg 4_0

The following information is intended for healthcare professionals only:

Administer Comirnaty Omicron XBB.1.5 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 Omicron XBB.1.5 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 Omicron XBB.1.5 should be prepared by a healthcare professional using aseptic technique to ensure the sterility of the prepared dispersion.

- **Verify that the vial has a grey plastic cap and the product name is Comirnaty Omicron XBB.1.5 (30 micrograms)/dose dispersion for injection** (12 years and older).
- 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.
 - Multidose vials: A 10-vial pack of multidose vials may take 6 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 white to off-white 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.
 - Multidose vials
 - Multidose vials contain 6 doses of 0.3 mL each.
 - Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab.
 - Withdraw 0.3 mL of Comirnaty Omicron XBB.1.5.

Low dead-volume syringes and/or needles should be used in order to extract 6 doses from a single vial. The low dead-volume syringe and needle combination should have a dead volume of no more than 35 microlitres. If standard syringes and needles are used, there may not be sufficient volume to extract a sixth dose from a single vial.

- Each dose must contain 0.3 mL of vaccine.
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume.
- Record the appropriate date/time on the vial. Discard any unused vaccine 12 hours after first puncture.

Disposal

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

Package leaflet: Information for the user

Comirnaty Original/Omicron BA.4-5 (15/15 micrograms)/dose dispersion for injection Adults and adolescents from 12 years COVID-19 mRNA Vaccine tozinameran/famtozinameran

▼ 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 Original/Omicron BA.4-5 is and what it is used for
2. What you need to know before you receive Comirnaty Original/Omicron BA.4-5
3. How Comirnaty Original/Omicron BA.4-5 is given
4. Possible side effects
5. How to store Comirnaty Original/Omicron BA.4-5
6. Contents of the pack and other information

1. What Comirnaty Original/Omicron BA.4-5 is and what it is used for

Comirnaty Original/Omicron BA.4-5 is a vaccine used for preventing COVID-19 caused by SARS-CoV-2. It 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 Original/Omicron BA.4-5 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 Original/Omicron BA.4-5

Comirnaty Original/Omicron BA.4-5 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 Original/Omicron BA.4-5 may not fully protect all those who receive it and it is not known how long you will be protected.

The efficacy of Comirnaty Original/Omicron BA.4-5 may be lower in people who are immunocompromised. If you are immunocompromised, you may receive additional doses of Comirnaty Original/Omicron BA.4-5. 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 Original/Omicron BA.4-5 (15/15 micrograms)/dose dispersion for injection 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 Original/Omicron BA.4-5

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 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 Original/Omicron BA.4-5 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 Original/Omicron BA.4-5 can be used during pregnancy.

No data are available yet regarding the use of Comirnaty Original/Omicron BA.4-5 during breast-feeding. However, no effects on the breast-fed 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 Original/Omicron BA.4-5 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 Original/Omicron BA.4-5 is given

Comirnaty Original/Omicron BA.4-5 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 Original/Omicron BA.4-5 until at least 3 months after the most recent dose.

If you are immunocompromised, you may receive additional doses of Comirnaty Original/Omicron BA.4-5.

If you have any further questions on the use of Comirnaty Original/Omicron BA.4-5, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all vaccines, Comirnaty Original/Omicron BA.4-5 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

- injection site redness
- nausea
- vomiting
- 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 (hypoesthesia)
- 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.

Ireland

You can also report side effects directly via HPRA Pharmacovigilance.

Website: www.hpra.ie and include batch/Lot number if available.

United Kingdom (Northern Ireland)

If you are concerned about a side-effect it can be reported directly via the Coronavirus Yellow Card reporting site <https://coronavirus-yellowcard.mhra.gov.uk/> or search for MHRA Yellow Card in the Google Play or Apple App Store and include batch/Lot number if available.

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

5. How to store Comirnaty Original/Omicron BA.4-5

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.

Multidose vials: When stored frozen at -90 °C to -60 °C, 10-vial packs of the vaccine can be thawed at 2 °C to 8 °C for 6 hours or individual vials can be thawed at room temperature (up to 30 °C) for 30 minutes.

Thawed 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.

Opened vials: After first puncture, store the vaccine at 2 °C to 30 °C and use within 12 hours, which includes up to 6 hours transportation time. Discard any unused vaccine.

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 Original/Omicron BA.4-5 contains

- The active substances of COVID-19 mRNA Vaccine (nucleoside modified) are called tozinameran and famtozinameran.
 - A single dose vial contains 1 dose of 0.3 mL with 15 micrograms of tozinameran (Original) and 15 micrograms of famtozinameran (Omicron BA.4-5) per dose.
 - A multidose vial contains 6 doses of 0.3 mL with 15 micrograms of tozinameran (Original) and 15 micrograms of famtozinameran (Omicron BA.4-5) 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 Original/Omicron BA.4-5 looks like and contents of the pack

The vaccine is a white to off-white dispersion (pH: 6.9 - 7.9) provided in either:

- A single dose vial of 1 dose in a 2 mL clear vial (type I glass), with a rubber stopper and a grey flip-off plastic cap with aluminium seal; or
- A multidose vial of 6 doses in a 2 mL clear vial (type I glass), with a rubber stopper and a

grey flip-off plastic cap with aluminium seal.

Single dose vial pack size: 10 vials

Multidose vial pack sizes: 10 vials or 195 vials

Not all pack sizes may be marketed.

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

Ireland

Pfizer Healthcare Ireland

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This leaflet was last revised in 5/2024.

Scan the code with a mobile device to get the package leaflet in different languages.



URL: www.comirnatyglobal.com

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

Ref: bCY/BA.4-5 (15-15) 16_0

The following information is intended for healthcare professionals only:

Administer Comirnaty Original/Omicron BA.4-5 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 Original/Omicron BA.4-5 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 Original/Omicron BA.4-5 should be prepared by a healthcare professional using aseptic technique to ensure the sterility of the prepared dispersion.

- **Verify** that the vial has a **grey plastic cap** and the product **name is Comirnaty Original/Omicron BA.4-5 (15/15 micrograms)/dose dispersion for injection** (12 years and older).
- 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.
 - Multidose vials: A 10-vial pack of multidose vials may take 6 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 white to off-white 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.
 - Multidose vials

- Multidose vials contain 6 doses of 0.3 mL each.
- Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab.
- Withdraw 0.3 mL of Comirnaty Original/Omicron BA.4-5.

Low dead-volume syringes and/or needles should be used in order to extract 6 doses from a single vial. The low dead-volume syringe and needle combination should have a dead volume of no more than 35 microlitres. If standard syringes and needles are used, there may not be sufficient volume to extract a sixth dose from a single vial.

- Each dose must contain 0.3 mL of vaccine.
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume.
- Record the appropriate date/time on the vial. Discard any unused vaccine 12 hours after first puncture.

Disposal

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

Package leaflet: Information for the user

Comirnaty Original/Omicron BA.1 (15/15 micrograms)/dose dispersion for injection Adults and adolescents from 12 years COVID-19 mRNA Vaccine tozinameran/riltozinameran

▼ 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 Original/Omicron BA.1 is and what it is used for
2. What you need to know before you receive Comirnaty Original/Omicron BA.1
3. How Comirnaty Original/Omicron BA.1 is given
4. Possible side effects
5. How to store Comirnaty Original/Omicron BA.1
6. Contents of the pack and other information

1. What Comirnaty Original/Omicron BA.1 is and what it is used for

Comirnaty Original/Omicron BA.1 is a vaccine used for preventing COVID-19 caused by SARS-CoV-2.

It is given to adults and adolescents from 12 years of age and older.

Comirnaty Original/Omicron BA.1 is only for individuals who have previously received at least a primary vaccination course against COVID-19.

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 Original/Omicron BA.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 Original/Omicron BA.1

Comirnaty Original/Omicron BA.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 Original/Omicron BA.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 Original/Omicron BA.1 may be lower in people who are immunocompromised. If you are immunocompromised, you may receive additional doses of Comirnaty Original/Omicron BA.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 Original/Omicron BA.1 (15/15 micrograms)/dose dispersion for injection 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 Original/Omicron BA.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.

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 Original/Omicron BA.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 Original/Omicron BA.1 can be used during pregnancy.

No data are available yet regarding the use of Comirnaty Original/Omicron BA.1 during breast-feeding. However, no effects on the breast-fed 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 breast-fed newborns/infants. Comirnaty Original/Omicron BA.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 Original/Omicron BA.1 is given

Comirnaty Original/Omicron BA.1 is given as an injection of 0.3 mL into a muscle of your upper arm.

Comirnaty Original/Omicron BA.1 is only for individuals who have previously received at least a primary vaccination course against COVID-19.

Comirnaty Original/Omicron BA.1 may be given at least 3 months after the most recent dose of a COVID-19 vaccine.

Please check with your healthcare provider regarding eligibility for and timing of the booster dose.

If you are immunocompromised, you may receive additional doses of Comirnaty Original/Omicron BA.1.

For details on the primary vaccination course in individuals 12 years of age and older, please refer to the Package Leaflet for those formulations.

If you have any further questions on the use of Comirnaty Original/Omicron BA.1, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all vaccines, Comirnaty Original/Omicron BA.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

- injection site redness
- nausea
- vomiting
- 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 (hypoesthesia)
- 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.

Ireland

You can also report side effects directly via HPRC Pharmacovigilance.

Website: www.hpra.ie and include batch/Lot number if available.

United Kingdom (Northern Ireland)

If you are concerned about a side-effect it can be reported directly via the Coronavirus Yellow Card reporting site <https://coronavirus-yellowcard.mhra.gov.uk/> or search for MHRA Yellow Card in the Google Play or Apple App Store and include batch/Lot number if available.

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

5. How to store Comirnaty Original/Omicron BA.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. 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.

When stored frozen at -90 °C to -60 °C, 10-vial packs of the vaccine can be thawed at 2 °C to 8 °C for 6 hours or individual vials can be thawed at room temperature (up to 30 °C) for 30 minutes.

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.

After first puncture, store the vaccine at 2 °C to 30 °C and use within 12 hours, which includes up to 6 hours transportation time. Discard any unused vaccine.

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 Original/Omicron BA.1 contains

- The active substances of COVID-19 mRNA Vaccine (nucleoside modified) are called tozinameran and riltozinameran. The vial contains 6 doses of 0.3 mL with 15 micrograms of tozinameran (Original) and 15 micrograms of riltozinameran (Omicron BA.1) 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 Original/Omicron BA.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 multidose vial of 6 doses in a 2 mL clear vial (type I glass), with a rubber stopper and a grey flip-off plastic cap with aluminium seal.

Pack sizes: 10 vials or 195 vials

Not all pack sizes may be marketed.

Marketing Authorisation Holder

BioNTech Manufacturing GmbH

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Germany

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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)
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United Kingdom (Northern Ireland)

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This leaflet was last revised in 5/2024.

Scan the code with a mobile device to get the package leaflet in different languages.



URL: www.comirnatyglobal.com

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

Ref: bCY/BA.1(15-15) 15_0

The following information is intended for healthcare professionals only:

The dose of Comirnaty Original/Omicron BA.1 is 0.3 mL given intramuscularly.

Comirnaty Original/Omicron BA.1 is only indicated for individuals who have previously received at least a primary vaccination course against COVID-19.

There should be an interval of at least 3 months between administration of Comirnaty Original/Omicron BA.1 and the last prior 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 Original/Omicron BA.1 should be prepared by a healthcare professional using aseptic technique to ensure the sterility of the prepared dispersion.

- **Verify** that the vial has a **grey plastic cap** and the product **name is Comirnaty Original/Omicron BA.1 (15/15 micrograms)/dose dispersion for injection** (12 years and older).
- 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; a 10-vial pack may take 6 hours to thaw. Ensure vials are completely thawed prior to use.
- 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 white to off-white dispersion with no particulates visible. Do not use the vaccine if particulates or discolouration are present.
- Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab.
- Withdraw 0.3 mL of Comirnaty Original/Omicron BA.1.
Low dead-volume syringes and/or needles should be used in order to extract 6 doses from a single vial. The low dead-volume syringe and needle combination should have a dead volume of no more than 35 microlitres. If standard syringes and needles are used, there may not be sufficient volume to extract a sixth dose from a single vial.
- Each dose must contain 0.3 mL of vaccine.
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume.
- Record the appropriate date/time on the vial. Discard any unused vaccine 12 hours after first puncture.

Disposal

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

Package leaflet: Information for the user

Comirnaty 30 micrograms/dose dispersion for injection Adults and adolescents from 12 years COVID-19 mRNA Vaccine tozinameran

▼ 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
4. Possible side effects
5. How to store Comirnaty
6. Contents of the pack and other information

1. What Comirnaty is and what it is used for

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

Comirnaty 30 micrograms/dose dispersion for injection 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 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

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 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 may not fully protect all those who receive it and it is not known how long you will be protected.

The efficacy of Comirnaty may be lower in people who are immunocompromised. If you are immunocompromised, you may receive additional doses of Comirnaty. 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 30 micrograms/dose dispersion for injection 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

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 think you may be pregnant, tell your doctor, nurse or pharmacist before you receive this vaccine.

Comirnaty can be used during pregnancy. A large amount of information from pregnant women vaccinated with Comirnaty 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 can be given during 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 is given

Comirnaty 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 until at least 3 months after the most recent dose.

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

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 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, fevers
- 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

- injection site redness
- nausea
- vomiting
- 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.

Ireland

You can also report side effects directly via HPRA Pharmacovigilance.

Website: www.hpra.ie and include batch/Lot number if available. **United Kingdom (Northern Ireland)**

If you are concerned about a side-effect it can be reported directly via the Coronavirus Yellow Card reporting site <https://coronavirus-yellowcard.mhra.gov.uk/> or search for MHRA Yellow Card in the Google Play or Apple App Store and include batch/Lot number if available.

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.

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.

Multidose vials: When stored frozen at -90 °C to -60 °C, 10-vial packs of the vaccine can be thawed at 2 °C to 8 °C for 6 hours or individual vials can be thawed at room temperature (up to 30 °C) for 30 minutes.

Thawed 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.

Opened vials: After first puncture, store the vaccine at 2 °C to 30 °C and use within 12 hours, which includes up to 6 hours transportation time. Discard any unused vaccine.

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 contains

- The active substance of COVID-19 mRNA Vaccine (nucleoside modified) is called tozinameran.
 - A single dose vial contains 1 dose of 0.3 mL with 30 micrograms tozinameran each.
 - A multidose vial contains 6 doses of 0.3 mL with 30 micrograms tozinameran 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 looks like and contents of the pack

The vaccine is a white to off-white dispersion (pH: 6.9 - 7.9) provided in either:

- A single dose vial of 1 dose in a 2 mL clear vial (type I glass), with a rubber stopper and a grey flip-off plastic cap with aluminium seal; or
- A multidose vial of 6 doses in a 2 mL clear vial (type I glass), with a rubber stopper and a grey flip-off plastic cap with aluminium seal.

Single dose vial pack size: 10 vials

Multidose vial pack sizes: 10 vials or 195 vials

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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This leaflet was last revised in 5/2024.

Scan the code with a mobile device to get the package leaflet in different languages.



URL: www.comirnatyglobal.com

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

Ref: bCY/TS30 28_0

The following information is intended for healthcare professionals only:

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

- **Verify that the vial has a grey plastic cap and the product name is Comirnaty 30 micrograms/dose dispersion for injection (12 years and older).**
- 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.
 - Multidose vials: A 10-vial pack of multidose vials may take 6 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 white to off-white 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.
 - Multidose vials
 - Multidose vials contain 6 doses of 0.3 mL each.
 - Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab.
 - Withdraw 0.3 mL of Comirnaty.

Low dead-volume syringes and/or needles should be used in order to extract 6 doses from a single vial. The low dead-volume syringe and needle combination should have a dead volume of no more than 35 microlitres. If standard syringes and needles are used, there may not be sufficient volume to extract a sixth dose from a single vial.

- Each dose must contain 0.3 mL of vaccine.

- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume.
- Record the appropriate date/time on the vial. Discard any unused vaccine 12 hours after first puncture.

Disposal

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

Package leaflet: Information for the user

Comirnaty 30 micrograms/dose concentrate for dispersion for injection Adults and adolescents from 12 years COVID-19 mRNA Vaccine tozinameran

▼ 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
4. Possible side effects
5. How to store Comirnaty
6. Contents of the pack and other information

1. What Comirnaty is and what it is used for

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

Comirnaty 30 micrograms/dose concentrate for dispersion for injection 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 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

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 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 may not fully protect all those who receive it and it is not known how long you will be protected.

The efficacy of Comirnaty may be lower in people who are immunocompromised. If you are immunocompromised, you may receive additional doses of Comirnaty. 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 30 micrograms/dose concentrate for dispersion for injection 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

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 think you may be pregnant, tell your doctor, nurse or pharmacist before you receive this vaccine.

Comirnaty can be used during pregnancy. A large amount of information from pregnant women vaccinated with Comirnaty 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 can be given during 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.

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 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 until at least 3 months after the most recent dose.

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

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 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

- injection site redness
- nausea
- vomiting
- 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 (hypoesthesia)
- 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.

Ireland

You can also report side effects directly via HPRA Pharmacovigilance.

Website: www.hpra.ie and include batch/Lot number if available.

United Kingdom (Northern Ireland)

If you are concerned about a side-effect it can be reported directly via the Coronavirus Yellow Card reporting site <https://coronavirus-yellowcard.mhra.gov.uk/> or search for MHRA Yellow Card in the Google Play or Apple App Store and include batch/Lot number if available.

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. Unopened vials may be stored and transported at -25 °C to -15 °C for a single period of up to 2 weeks and can be returned to -90 °C to -60 °C; not exceeding the printed expiry date (EXP).

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

When stored frozen at -90 °C to -60 °C, 195-vial packs of the vaccine can be thawed at 2 °C to 8 °C for 3 hours or individual vials can be thawed at room temperature (up to 30 °C) for 30 minutes.

Transfers of frozen vials stored at ultra-low temperature (< -60 °C)

- Closed-lid vial trays containing 195 vials removed from ultra-low temperature frozen storage (< -60 °C) may be at temperatures up to 25 °C for up to 5 minutes.
- Open-lid vial trays, or vial trays containing less than 195 vials, removed from ultra-low temperature frozen storage (< -60 °C) may be at temperatures up to 25 °C for up to 3 minutes.
- After vial trays are returned to frozen storage following temperature exposure up to 25 °C, they must remain in frozen storage for at least 2 hours before they can be removed again.

Transfers of frozen vials stored at -25 °C to -15 °C

- Closed-lid vial trays containing 195 vials removed from frozen storage (-25 °C to -15 °C) may be at temperatures up to 25 °C for up to 3 minutes.
- Open-lid vial trays, or vial trays containing less than 195 vials, removed from frozen storage (-25 °C to -15 °C) may be at temperatures up to 25 °C for up to 1 minute.

Once a vial is removed from the vial tray, it should be thawed for use.

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 1 month at 2 °C to 8 °C; not exceeding the printed expiry date (EXP). Within the 1-month shelf life at 2 °C to 8 °C, up to 48 hours may be used for transportation. Prior to use, the unopened vaccine can be stored for up to 2 hours at temperatures up to 30 °C.

Thawed vials can be handled in room light conditions.

After dilution, store and transport 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 expiry 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 of COVID-19 mRNA Vaccine (nucleoside modified) is called tozinameran. After dilution, the vial contains 6 doses of 0.3 mL with 30 micrograms tozinameran 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
 - potassium chloride
 - potassium dihydrogen phosphate
 - sodium chloride
 - disodium phosphate dihydrate

- sucrose
- water for injections
- sodium hydroxide (for pH adjustment)
- hydrochloric acid (for pH adjustment)

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 purple flip-off plastic cap with aluminium seal.

Pack size: 195 vials

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Ref: bCY/PBS 41_0

The following information is intended for healthcare professionals only:

Administer Comirnaty intramuscularly after dilution 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 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 should be prepared by a healthcare professional using aseptic technique to ensure the sterility of the prepared dispersion.

- **Verify that the vial has a purple plastic cap and the product name is Comirnaty 30 micrograms/dose concentrate for dispersion for injection (12 years and older).**

- If the vial has another product name on the label, please make reference to the Summary of Product Characteristics for that formulation.
- The vial is stored frozen and must be thawed prior to dilution. Frozen vials should be transferred to an environment of 2 °C to 8 °C to thaw; a 195-vial pack may take 3 hours to thaw. Alternatively, frozen vials may also be thawed for 30 minutes at temperatures up to 30 °C for immediate use.
- The unopened vial can be **stored for up to 1 month at 2 °C to 8 °C**; not exceeding the printed expiry date (EXP). Within the 1-month shelf life at 2 °C to 8 °C, up to 48 hours may be used for transportation.
- Allow the thawed vial to come to room temperature. Prior to use, the unopened vial can be stored for up to 2 hours at temperatures up to 30 °C. Thawed vials can be handled in room light conditions.

Dilution

- Gently invert the vial 10 times prior to dilution. Do not shake.
- Prior to dilution, the thawed dispersion may contain white to off-white opaque amorphous particles.
- The thawed vaccine must be diluted in its original vial with **1.8 mL of sodium chloride 9 mg/mL (0.9%) solution for injection**, using a 21 gauge or narrower needle and aseptic techniques.
- Equalise vial pressure before removing the needle from the vial stopper by withdrawing 1.8 mL air into the empty diluent syringe.
- Gently invert the diluted dispersion 10 times. Do not shake.
- The diluted vaccine should present as an off-white dispersion with no particulates visible. Do not use the diluted vaccine if particulates or discolouration are present.
- The diluted vials should be marked with the appropriate **discard date and time**.
- **After dilution**, store at 2 °C to 30 °C and use within **6 hours**, including any transportation time.
- Do not freeze or shake the diluted dispersion. If refrigerated, allow the diluted dispersion to come to room temperature prior to use.

Preparation of 0.3 mL doses

- After dilution, the vial contains 2.25 mL from which 6 doses of 0.3 mL can be extracted.
- Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab.
- Withdraw 0.3 mL of Comirnaty.
Low dead-volume syringes and/or needles should be used in order to extract 6 doses from a single vial. The low dead-volume syringe and needle combination should have a dead volume of no more than 35 microlitres. If standard syringes and needles are used, there may not be sufficient volume to extract a sixth dose from a single vial.
- Each dose must contain 0.3 mL of vaccine.
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume.
- Discard any unused vaccine within 6 hours after dilution.

Disposal

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