

Package leaflet: Information for the user

Comirnaty 10 micrograms/dose concentrate for dispersion for injection Children 5 to 11 years COVID-19 mRNA Vaccine (nucleoside modified) 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 your child 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 your child gets 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 your child receives 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 10 micrograms/dose concentrate for dispersion for injection is given to children from 5 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 does not contain the virus to produce immunity, it cannot give your child COVID-19.

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

Comirnaty 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 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 Comirnaty 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 have 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. 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.

Your child may receive a third dose of Comirnaty. The efficacy of Comirnaty, even after a third dose, may be lower in people who are immunocompromised. 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

There is a paediatric presentation available for infants and children 6 months to 4 years of age. For details, please refer to the Package Leaflet for Comirnaty 3 micrograms/dose concentrate for dispersion for injection.

Comirnaty is not recommended for infants aged under 6 months.

Other medicines and Comirnaty

Tell your 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 doctor, nurse or pharmacist before your child receives 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 use machines or undertake activities such as cycling. Wait until these effects have worn off before resuming activities that require your full attention.

3. How Comirnaty is given

Comirnaty is given after dilution as an injection of 0.2 mL into a muscle of the upper arm.

Your child will receive 2 injections.

It is recommended to receive the second dose of the same vaccine 3 weeks after the first dose to complete the vaccination course.

If your child is immunocompromised, he or she may receive a third dose of Comirnaty at least 28 days after the second dose.

If a child turns 12 years old between their doses in the primary vaccination course, he/she should complete the series at the same 10 micrograms dose level.

A booster dose of Comirnaty may be given at least 6 months after the primary vaccination course in children 5 to 11 years of age.

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
- chills
- joint pain
- diarrhoea
- fever

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

- nausea
- vomiting
- injection site redness ('very common' in 5 to 11 years of age)

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

- enlarged lymph nodes (more frequently observed after the booster dose)
- feeling unwell
- arm pain
- insomnia
- injection site itching
- allergic reactions such as rash or itching
- feeling weak or lack of energy/sleepy
- decreased appetite
- 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 doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRC Pharmacovigilance. Website: www.hpra.ie 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.

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 4 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 discard 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 dilution, 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 in the dilution or discolouration.

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

6. Contents of the pack and other information

What Comirnaty contains

- The active substance is COVID-19 mRNA Vaccine called tozinameran. After dilution, the vial contains 10 doses of 0.2 mL with 10 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 a multidose vial of 10 doses in a 2 mL clear vial (type I glass), with a rubber stopper and an orange flip-off plastic cap with aluminium seal.

Pack sizes: 10 vials or 195 vials

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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55131 Mainz
Germany
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Manufacturers

BioNTech Manufacturing GmbH
Kupferbergterrasse 17 - 19
55116 Mainz
Germany

Pfizer Manufacturing Belgium NV
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2870 Puurs
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For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

Ireland

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

This leaflet was last revised in 12/2022.

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>.

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

Ref: bCY/TS10 17_0

The following information is intended for healthcare professionals only:

Administer Comirnaty intramuscularly after dilution as a course of 2 doses (0.2 mL each) 3 weeks apart.

A booster dose of Comirnaty may be given at least 6 months after the primary vaccination course in children 5 to 11 years of age.

A third dose may be given at least 28 days after the second dose to individuals who are severely immunocompromised.

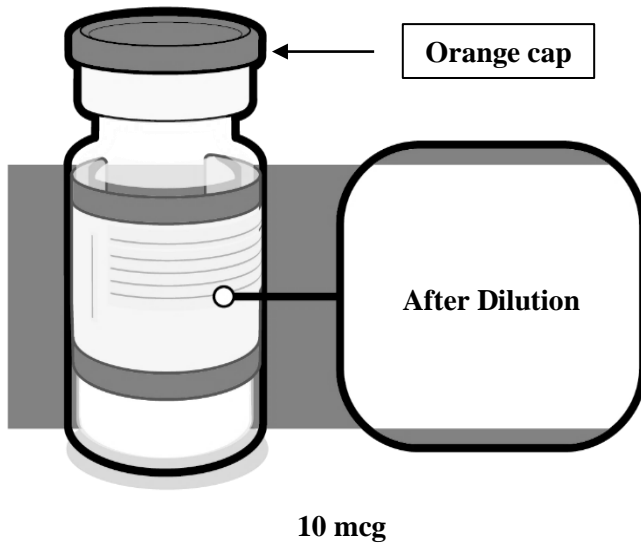
Traceability

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

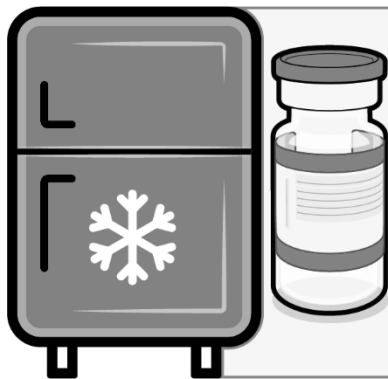
Comirnaty 10 micrograms/dose should be prepared by a healthcare professional using aseptic technique to ensure the sterility of the prepared dispersion.

VIAL VERIFICATION OF COMIRNATY 10 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION (CHILDREN 5 TO 11 YEARS)



- Verify that the vial has an orange plastic cap and an orange border around the label and the product name is Comirnaty 10 micrograms/dose concentrate for dispersion for injection.
- If the vial has an orange plastic cap and an orange border and the product name is Comirnaty Original/Omicron BA.4-5 (5/5 micrograms)/dose concentrate for dispersion for injection, please make reference to the Summary of Product Characteristics for that formulation.
- If the vial has a purple plastic cap, please make reference to the Summary of Product Characteristics for Comirnaty 30 micrograms/dose concentrate for dispersion for injection.
- If the vial has a grey plastic cap, please make reference to the Summary of Product Characteristics for Comirnaty 30 micrograms/dose dispersion for injection, Comirnaty Original/Omicron BA.1 (15/15 micrograms)/dose dispersion for injection, or Comirnaty Original/Omicron BA.4-5 (15/15 micrograms)/dose dispersion for injection.
- If the vial has a maroon plastic cap, please make reference to the Summary of Product Characteristics for Comirnaty 3 micrograms/dose concentrate for dispersion for injection.

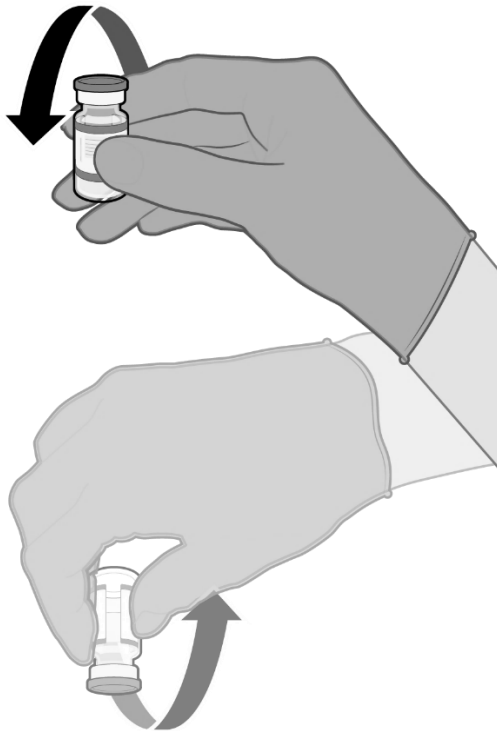
HANDLING PRIOR TO USE OF COMIRNATY 10 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION (CHILDREN 5 TO 11 YEARS)



**Store for up
to 10 weeks at
2 °C to 8 °C.**

- If the multidose 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 4 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.

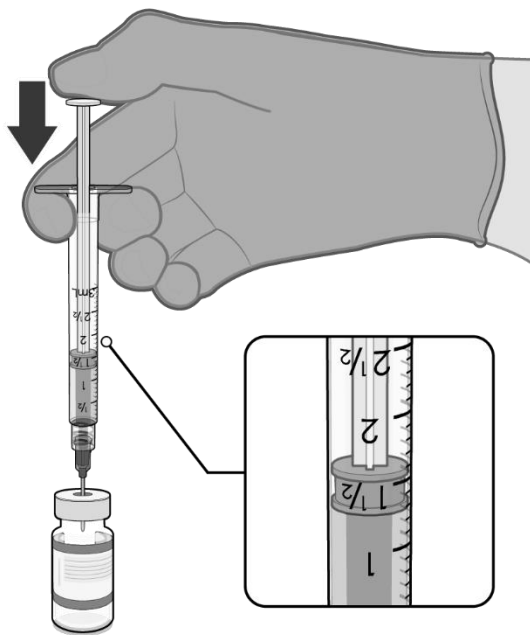
**MIXING PRIOR TO DILUTION OF COMIRNATY 10 MICROGRAMS/DOSE
CONCENTRATE FOR DISPERSION FOR INJECTION (CHILDREN 5 TO 11 YEARS)**



Gently × 10

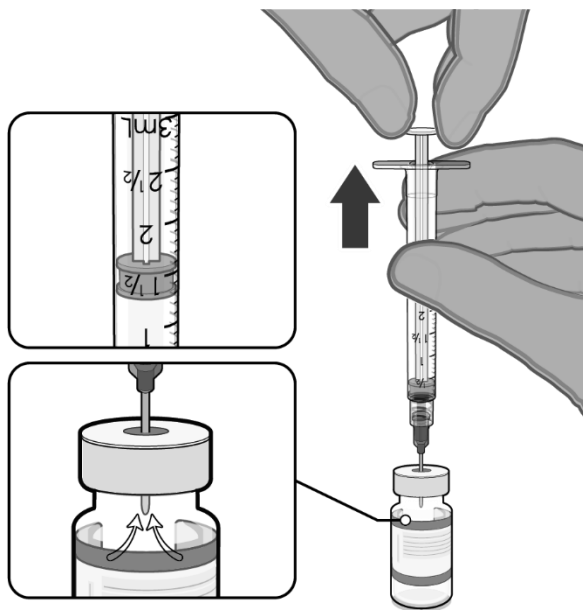
- Allow the thawed vial to come to room temperature and gently invert it 10 times prior to dilution. Do not shake.
- Prior to dilution, the thawed dispersion may contain white to off-white opaque amorphous particles.

**DILUTION OF COMIRNATY 10 MICROGRAMS/DOSE CONCENTRATE FOR
DISPERSION FOR INJECTION (CHILDREN 5 TO 11 YEARS)**



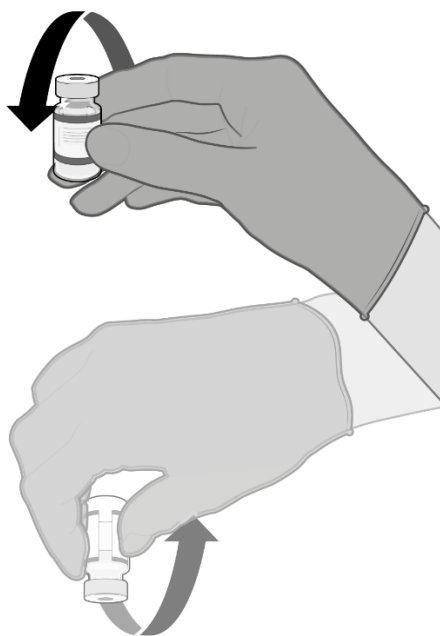
**1.3 mL of sodium chloride 9 mg/mL (0.9%)
solution for injection**

- The thawed vaccine must be diluted in its original vial with 1.3 mL sodium chloride 9 mg/mL (0.9%) solution for injection, using a 21 gauge or narrower needle and aseptic techniques.



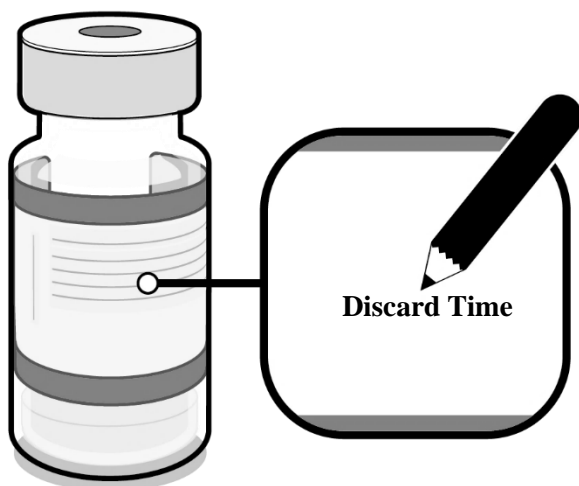
Pull back plunger to 1.3 mL to remove air from vial.

- Equalise vial pressure before removing the needle from the vial stopper by withdrawing 1.3 mL air into the empty diluent syringe.



Gently × 10

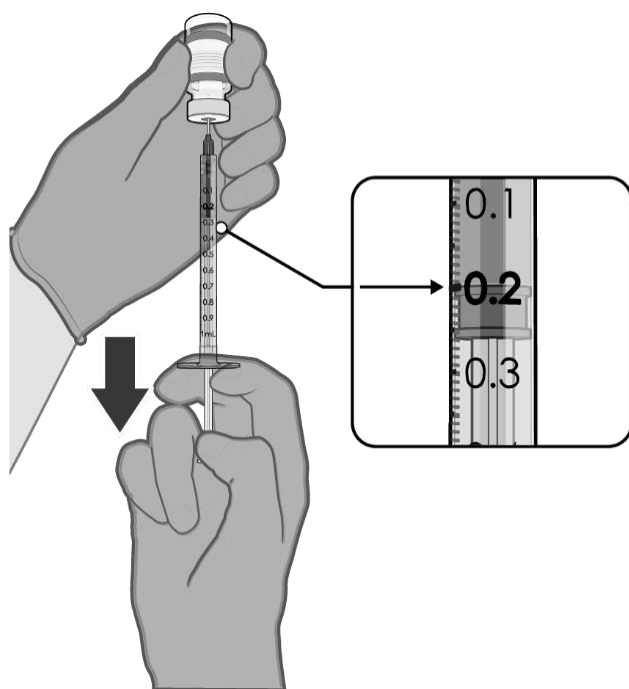
- Gently invert the diluted dispersion 10 times. Do not shake.
- The diluted vaccine should present as a white to off-white dispersion with no particulates visible. Do not use the diluted vaccine if particulates or discolouration are present.



**Record appropriate date and time.
Use within 12 hours after dilution.**

- The diluted vials should be marked with the appropriate date and time.
- After dilution, store at 2 °C to 30 °C and use within 12 hours.
- Do not freeze or shake the diluted dispersion. If refrigerated, allow the diluted dispersion to come to room temperature prior to use.

**PREPARATION OF INDIVIDUAL 0.2 mL DOSES OF COMIRNATY
10 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION
(CHILDREN 5 TO 11 YEARS)**



0.2 mL diluted vaccine

- After dilution, the vial contains 2.6 mL from which 10 doses of 0.2 mL can be extracted.
- Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab.
- Withdraw 0.2 mL of Comirnaty for children age 5 to 11 years.

Low dead-volume syringes and/or needles should be used in order to extract 10 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 ten doses from a single vial.

- Each dose must contain 0.2 mL of vaccine.
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.2 mL, discard the vial and any excess volume.
- Discard any unused vaccine within 12 hours after dilution.

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 (5/5 micrograms)/dose concentrate for dispersion for injection

Children 5 to 11 years

COVID-19 mRNA Vaccine (nucleoside modified)

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 your child 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 your child gets 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 your child receives 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 children from 5 to 11 years of age.

Comirnaty Original/Omicron BA.4-5 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.4-5 does not contain the virus to produce immunity, it cannot give your child COVID-19.

2. What you need to know before your child receives Comirnaty Original/Omicron BA.4-5

Comirnaty Original/Omicron BA.4-5 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 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 Comirnaty or Comirnaty Original/Omicron BA.4-5 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 have 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. 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. 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 (5/5 micrograms)/dose concentrate for dispersion for injection is not recommended for children aged under 5 years.

Other medicines and Comirnaty Original/Omicron BA.4-5

Tell your 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 doctor, nurse or pharmacist before your child receives 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 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 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 use machines or undertake activities such as cycling. Wait until these effects have worn off before resuming activities that require your full attention.

3. How Comirnaty Original/Omicron BA.4-5 is given

Comirnaty Original/Omicron BA.4-5 is given after dilution as an injection of 0.2 mL into a muscle of the upper arm.

Comirnaty Original/Omicron BA.4-5 may be given at least 3 months after the most recent dose of a COVID-19 vaccine.

Comirnaty Original/Omicron BA.4-5 is only indicated for individuals who have previously received at least a primary vaccination course against COVID-19.

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

For details on the primary vaccination course in children from 5 to 11 years of age, please see the Package Leaflet for Comirnaty 10 micrograms/dose concentrate for dispersion for injection.

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
- chills
- joint pain
- diarrhoea
- fever

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

- nausea
- vomiting
- injection site redness ('very common' in 5 to 11 years of age)

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

- enlarged lymph nodes (more frequently observed after the booster dose)
- feeling unwell
- arm pain
- insomnia
- injection site itching
- allergic reactions such as rash or itching
- feeling weak or lack of energy/sleepy
- decreased appetite
- 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 doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance.

Website: www.hpra.ie 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.

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 4 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 discard 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 dilution, 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 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 Original/Omicron BA.4-5 contains

- The active substances of COVID-19 mRNA Vaccine are tozinameran and famtozinameran. After dilution, the vial contains 10 doses of 0.2 mL with 5 micrograms of tozinameran (Original) and 5 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 a multidose vial of 10 doses in a 2 mL clear vial (type I glass), with a rubber stopper and an orange flip-off plastic cap with aluminium seal.

Pack sizes: 10 vials or 195 vials

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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Manufacturers

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This leaflet was last revised in 12/2022.

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>.

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

Ref: bCY/BA.4-5 (5-5) 3_0

The following information is intended for healthcare professionals only:

The dose of Comirnaty Original/Omicron BA.4-5 is 0.2 mL given intramuscularly.

There should be an interval of at least 4 months between administration of Comirnaty Original/Omicron BA.4-5 and the last prior dose of a COVID-19 vaccine.

Comirnaty Original/Omicron BA.4-5 is only indicated for individuals who have previously received at least a primary vaccination course against COVID-19.

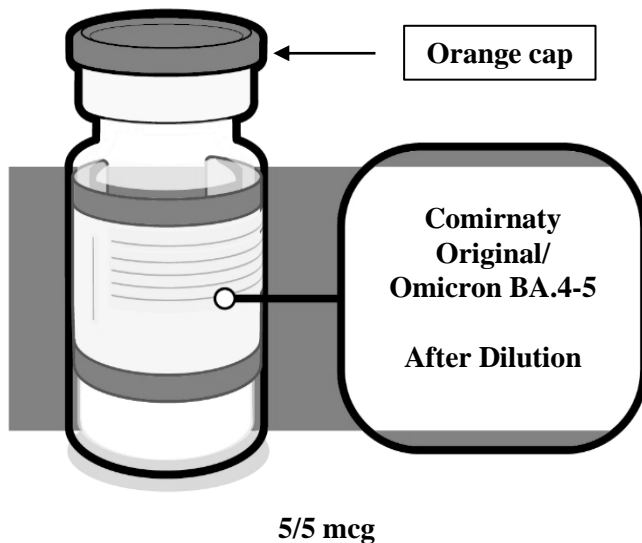
Traceability

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

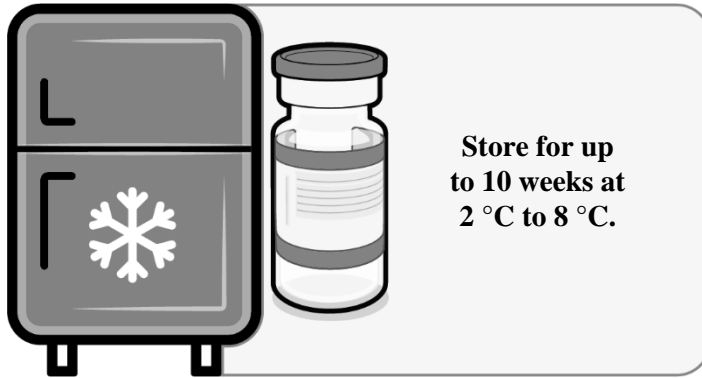
Comirnaty Original/Omicron BA.4-5 (5/5 micrograms)/dose should be prepared by a healthcare professional using aseptic technique to ensure the sterility of the prepared dispersion.

**VIAL VERIFICATION OF COMIRNATY ORIGINAL/OMICRON BA.4-5
(5/5 MICROGRAMS)/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION
(CHILDREN 5 TO 11 YEARS)**



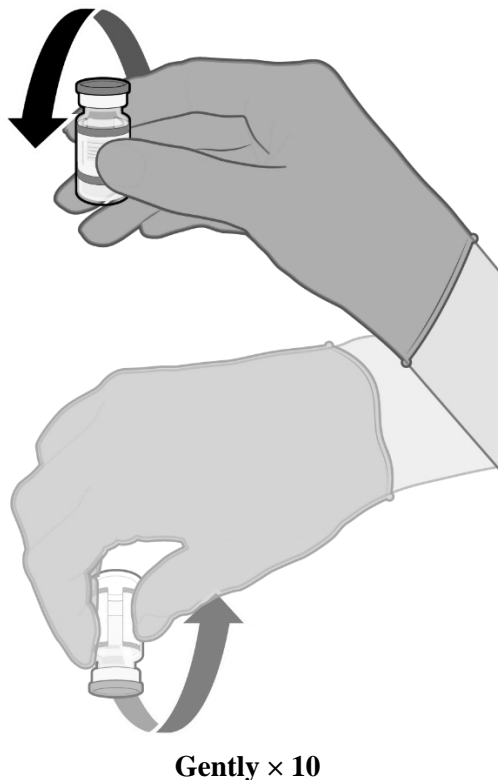
- Verify that the vial has an orange plastic cap and an orange border around the label and the product name is Comirnaty Original/Omicron BA.4-5 (5/5 micrograms)/dose concentrate for dispersion for injection.
- If the vial has an orange plastic cap and an orange border and the product name is Comirnaty 10 micrograms/dose concentrate for dispersion for injection, please make reference to the Summary of Product Characteristics for that formulation.
- If the vial has a purple plastic cap, please make reference to the Summary of Product Characteristics for Comirnaty 30 micrograms/dose concentrate for dispersion for injection.
- If the vial has a grey plastic cap, please make reference to the Summary of Product Characteristics for Comirnaty 30 micrograms/dose dispersion for injection, Comirnaty Original/Omicron BA.1 (15/15 micrograms)/dose dispersion for injection, or Comirnaty Original/Omicron BA.4-5 (15/15 micrograms)/dose dispersion for injection.
- If the vial has a maroon plastic cap, please make reference to the Summary of Product Characteristics for Comirnaty 3 micrograms/dose concentrate for dispersion for injection.

**HANDLING PRIOR TO USE OF COMIRNATY ORIGINAL/OMICRON BA.4-5
(5/5 MICROGRAMS)/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION
(CHILDREN 5 TO 11 YEARS)**



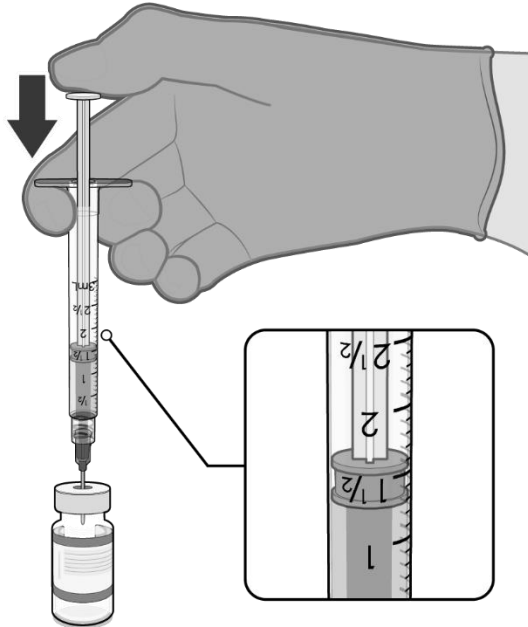
- If the multidose vial is stored frozen it must be thawed prior to use. Frozen vials should be transferred to an environment of 2 °C to 8 °C to thaw; a 10 vial pack may take 4 hours to thaw. Ensure vials are completely thawed prior to use.
- Upon moving vials to 2 °C to 8 °C storage, update the expiry 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.

**MIXING PRIOR TO DILUTION OF COMIRNATY ORIGINAL/OMICRON BA.4-5
(5/5 MICROGRAMS)/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION
(CHILDREN 5 TO 11 YEARS)**



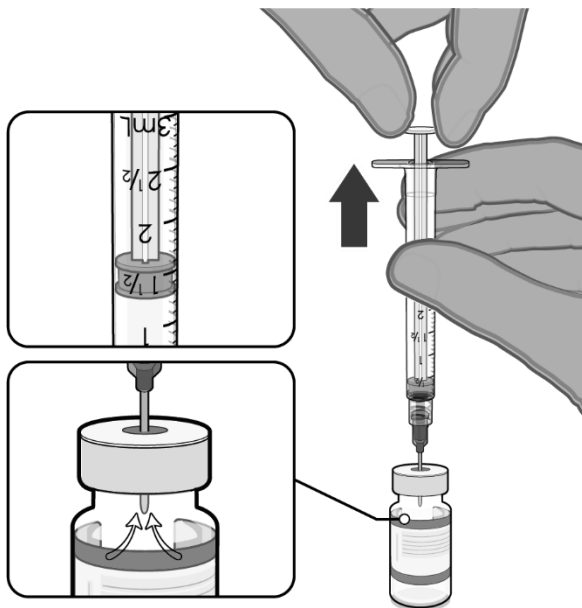
- Allow the thawed vial to come to room temperature and gently invert it 10 times prior to dilution. Do not shake.
- Prior to dilution, the thawed dispersion may contain white to off-white opaque amorphous particles.

DILUTION OF COMIRNATY ORIGINAL/OMICRON BA.4-5 (5/5 MICROGRAMS)/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION (CHILDREN 5 TO 11 YEARS)



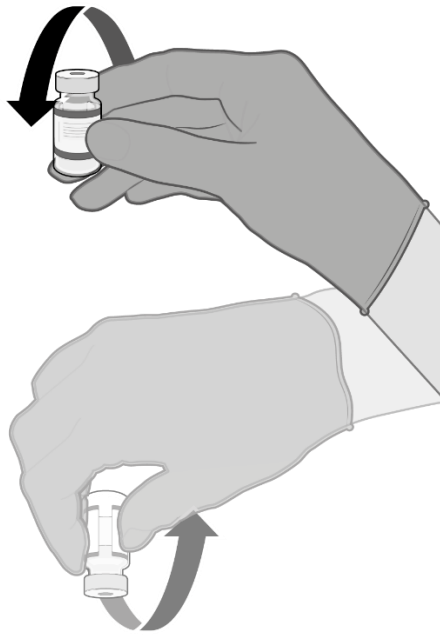
**1.3 mL of sodium chloride 9 mg/mL (0.9%)
solution for injection**

- The thawed vaccine must be diluted in its original vial with 1.3 mL sodium chloride 9 mg/mL (0.9%) solution for injection, using a 21 gauge or narrower needle and aseptic techniques.



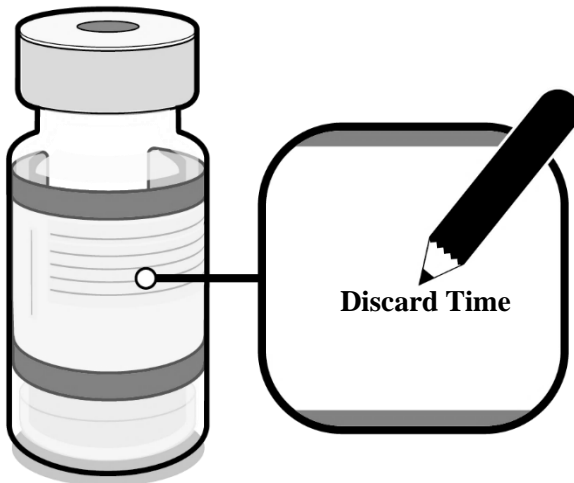
Pull back plunger to 1.3 mL to remove air from vial.

- Equalise vial pressure before removing the needle from the vial stopper by withdrawing 1.3 mL air into the empty diluent syringe.



Gently × 10

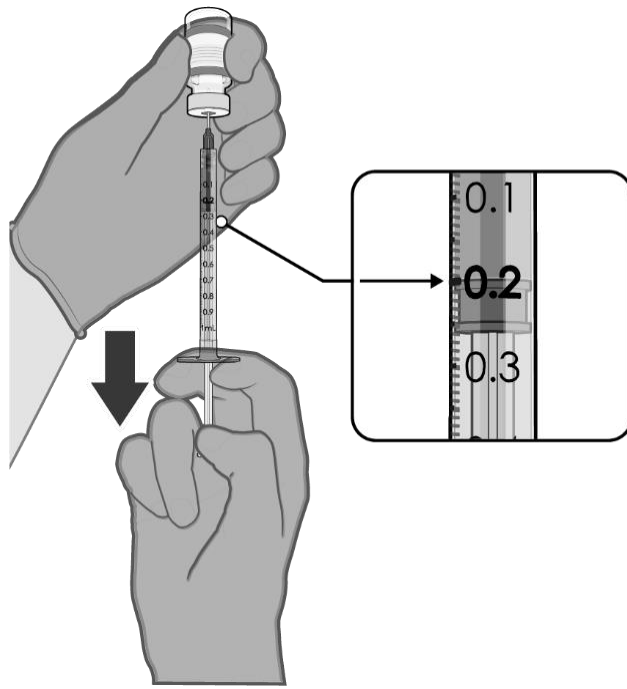
- Gently invert the diluted dispersion 10 times. Do not shake.
- The diluted vaccine should present as a white to off-white dispersion with no particulates visible. Do not use the diluted vaccine if particulates or discoloration are present.



**Record appropriate date and time.
Use within 12 hours after dilution.**

- The diluted vials should be marked with the appropriate date and time.
- After dilution, store at 2 °C to 30 °C and use within 12 hours.
- Do not freeze or shake the diluted dispersion. If refrigerated, allow the diluted dispersion to come to room temperature prior to use.

PREPARATION OF INDIVIDUAL 0.2 mL DOSES OF COMIRNATY ORIGINAL/OMICRON BA.4-5 (5/5 MICROGRAMS)/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION (CHILDREN 5 TO 11 YEARS)



0.2 mL diluted vaccine

- After dilution, the vial contains 2.6 mL from which 10 doses of 0.2 mL can be extracted.
- Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab.
- Withdraw 0.2 mL of Comirnaty for children age 5 to 11 years.

Low dead-volume syringes and/or needles should be used in order to extract 10 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 ten doses from a single vial.

- Each dose must contain 0.2 mL of vaccine.
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.2 mL, discard the vial and any excess volume.
- Discard any unused vaccine within 12 hours after dilution.

Disposal

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