Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986
This medicine is dispensed with a doctor's prescription only

Comirnaty®
Concentrate for dispersion for intramuscular injection

Active ingredient: COVID-19 mRNA Vaccine 0.5 mg/ml

Inactive ingredients and allergens: See section 2 under "Important information about some of this medicine's ingredients" and section 6 "Further information".

Read the entire leaflet carefully before using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

1. WHAT IS THIS MEDICINE INTENDED FOR?

Comirnaty is an active vaccine intended to prevent COVID-19 caused by SARS-CoV-2 coronavirus, in adults and adolescents from 12 years of age and older.

Therapeutic group: vaccines, other viral vaccines.

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.

The vaccine does not contain the virus so it cannot give you COVID-19 (corona).

2. BEFORE USING THIS MEDICINE

Do not use Comirnaty if:

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

Special warnings regarding use of Comirnaty
Before receiving the vaccine, tell your doctor or nurse if:

- you have ever had a severe allergic reaction or breathing problems after receiving any other vaccine or after receiving Comirnaty 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 mild upper airway infection like a cold.
- you have bleeding problems, 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 because you are taking steroid medicines which affect your immune system.

There is an increased risk of inflammation of the heart muscle (myocarditis) and inflammation of the lining outside the heart (pericarditis) 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. These conditions have been observed more often after the second vaccination, and more often in younger men and teen boys. The risk of inflammation of the heart muscle (myocarditis) and inflammation of the lining outside the heart (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.

Children
This product is not recommended for children aged under 12 years.
There is a vaccine available to prevent COVID-19 for children 5 to 11 years of age (i.e. 5 to less than 12 years of age). For further information, please refer to the Comirnaty TRIS 10 package leaflet.

Drug interactions:
If you are taking or have recently taken other medicines, including non-prescription medicines and dietary supplements, or have recently received another vaccine, tell your doctor, pharmacist, or nurse.

Pregnancy and breast-feeding
If you are pregnant or think you may be pregnant, ask your doctor for advice before you receive this vaccine.

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

Driving and using machines
Comirnaty has no or a negligible effect on your ability to drive and use machines. But, some of the side effects mentioned in section 4 (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.

Important information about some of this medicine’s ingredients
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 TO USE THIS MEDICINE?

Always use this vaccine according to your doctor's instructions.
Check with the doctor or pharmacist if you are uncertain about the dosage and about how the vaccine is given.
Only your doctor will determine your dose and how you should be given this vaccine.

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

You 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.

Do not exceed the recommended dose.

Adhere to the treatment as recommended by your doctor.

If you are given an overdose, immediately see a doctor or go to a hospital emergency room.

Do not take medicines in the dark! Check the label and dose each time you take medicine. Wear glasses if you need them.

If you have any further questions about use, consult your doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Comirnaty may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of 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

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

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

Rare side effects (may affect up to 1 in 1000 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

Side effects of unknown frequency (the frequency of these effects has not been established yet):
- severe allergic reaction
- extensive swelling of the vaccinated arm

- 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)

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the link ‘Reporting Side Effects of Drug Treatment’ on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects or by using the link: https://sideeffects.health.gov.il .

5. HOW TO STORE THE MEDICINE?

- Prevent poisoning! This and any other medicine should be kept in a closed place, out of the reach and sight of children and/or infants to avoid poisoning.
- **The following information about storage, expiry, and instructions for preparation and use is intended for healthcare professionals.**
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.
- Unopened vial: Store in freezer at -90°C to -60°C.
- Store in the original package to protect from light.
- After thawing, the vaccine should be diluted and used immediately. However, in-use stability data have demonstrated that once removed from the freezer, the undiluted vaccine can be stored for up to 1 month at 2°C-8°C; not exceeding the printed expiry date (exp. date).
- 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 the vaccine at 2°C-30°C and use within 6 hours. Discard any remaining unused vaccine.
- Once removed from the freezer and diluted, the vials should be marked with the new discard date and time. Once thawed, the vaccine cannot be re-frozen.
- Do not use this vaccine if you notice particulates in the diluted solution or discolouration.
- Do not throw away the medicine 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. FURTHER INFORMATION

In addition to the active ingredient, this medicine also contains:

- sucrose
- ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate) (ALC-0315)
- sodium chloride
- cholesterol
- 1,2-distearoyl-sn-glycero-3-phosphocholine (DSPC)
- disodium phosphate dihydrate
- 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide (ALC-0159)
- potassium chloride
- potassium dihydrogen phosphate
- water for injections
- sodium hydroxide (for pH adjustment)
- hydrochloric acid (for pH adjustment)

What the medicine looks like and contents of the pack:

The active substance is COVID-19 mRNA vaccine. After dilution, the vial contains 6 doses of 0.3 mL with 30 micrograms of active ingredient in each dose.

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, with a rubber stopper and a purple flip-off plastic cap with aluminium seal.

Pack size: Each tray contains 195 vials.

Registration holder's name and address: Pfizer Pharmaceuticals Israel Ltd., 9 Shenkar St., Herzliya Pituach 46725

Registration number of the medicine in the Ministry of Health's National Drug Registry: 168-25-36766

Revised in 11/2023 according to MOH guidelines.

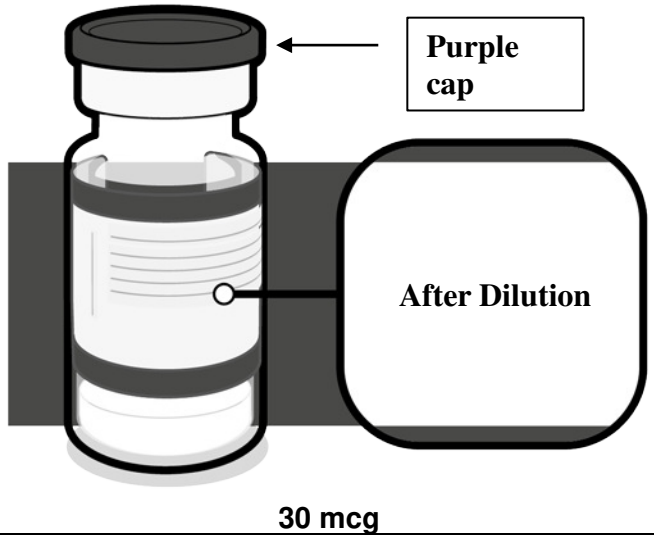
The following information is intended for healthcare professionals only:

Administer Comirnaty intramuscularly after dilution as a course of 2 doses (0.3 mL each) 3 weeks apart.

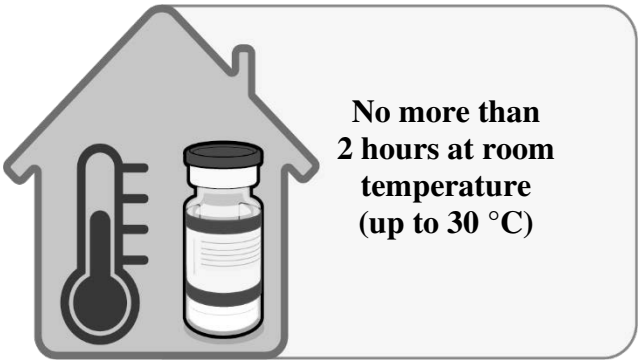
Traceability

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

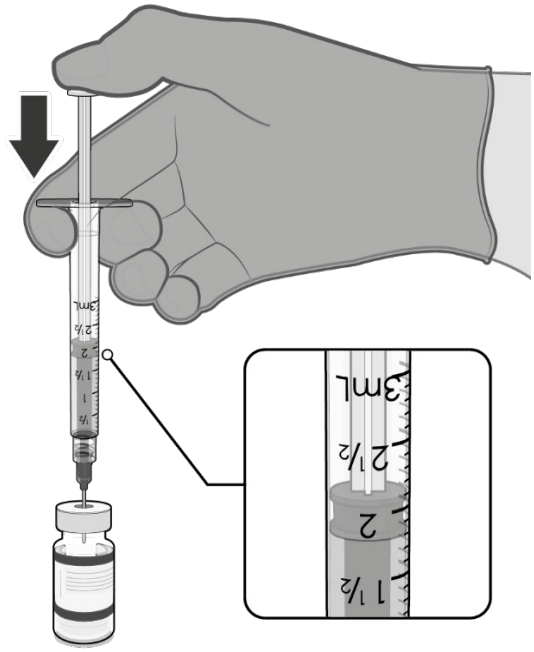
VIAL VERIFICATION OF COMIRNATY (12 YEARS AND OLDER)	
 **30 mcg**	• Verify that the vial has a purple plastic cap. • If the vial has a grey plastic cap, please make reference Comirnaty TRIS 30 label. • If the vial has an orange plastic cap, please make reference to Comirnaty TRIS 10 label.

THAWING PRIOR TO DILUTION OF COMIRNATY



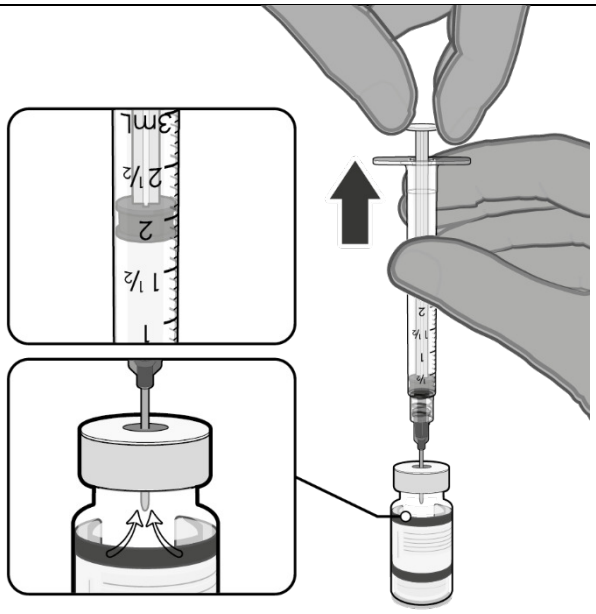
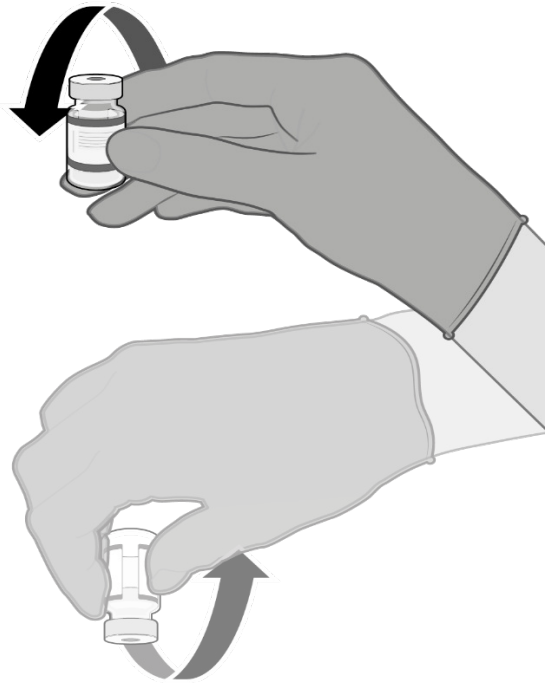
- The multidose vial is stored frozen and must be thawed prior to dilution. Frozen vials should be transferred to an environment of 2 °C to 8 °C to thaw; a 195 vial pack may take 3 hours to thaw. Alternatively, frozen vials may also be thawed for 30 minutes at temperatures up to 30 °C for immediate use.
- 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.
- 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.

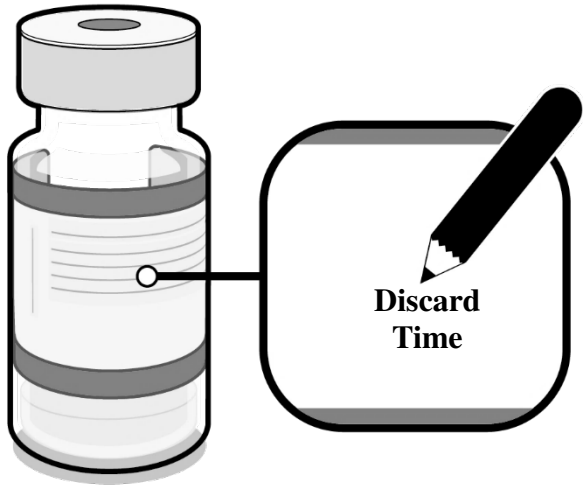
DILUTION OF COMIRNATY



1.8 mL of sodium chloride 9 mg/mL (0.9%) solution for injection.

- The thawed vaccine must be diluted in its original vial with 1.8 mL sodium chloride 9 mg/mL (0.9%) solution for injection, using a 21 gauge or narrower needle and aseptic techniques.

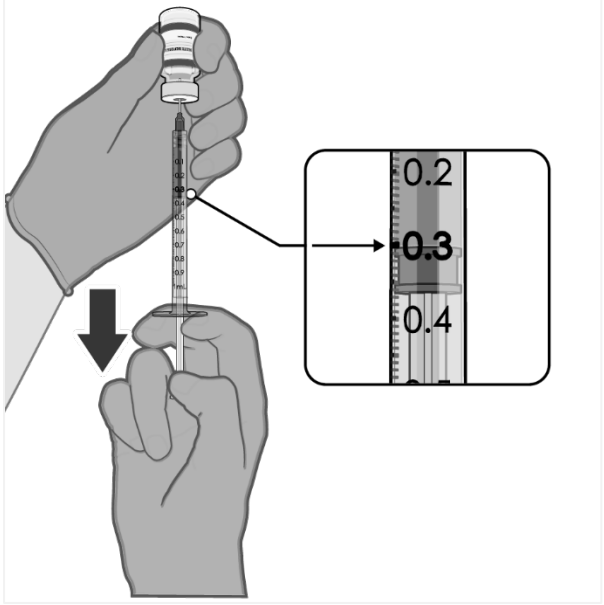
 **Pull back plunger to 1.8 mL to remove air from vial.**	• Equalise vial pressure before removing the needle from the vial stopper by withdrawing 1.8 mL air into the empty diluent syringe.
 **Gently × 10**	• Gently invert the diluted dispersion 10 times. Do not shake. • The diluted vaccine should present as an 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 6 hours after dilution.

- The diluted vials should be marked with the appropriate date and time.
- After dilution, store at 2 ºC to 30 ºC 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 INDIVIDUAL 0.3 mL DOSES OF COMIRNATY



0.3 mL diluted vaccine

- 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.