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

Comirnaty® TRIS 30
Dispersion for intramuscular injection

Active ingredient: COVID-19 mRNA vaccine 0.1 mg/ml

For a list of inactive ingredients and allergens, see 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 TRIS 30 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 TRIS 30 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 TRIS 30
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 a 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. 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 TRIS 30 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 about this vaccine, 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 TRIS 30 can be used during pregnancy. A large amount of information from pregnant women vaccinated with the vaccine during the second and third trimester has 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 TRIS 30 can be given during breast-feeding.

Driving and using machines
Comirnaty TRIS 30 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.

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 by 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 <u>each time</u> 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 TRIS 30 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 aged 12 to 15 years than in adults.

Common side effects (may affect up to 1 in 10 people):
- injection site redness
- nausea
- vomiting

Uncommon side effects (may affect up to 1 in 100 people):
- enlarged lymph nodes
- 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 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

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.
- 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 refrigerated at 2°C to 8°C for up to 10 weeks; not exceeding the printed expiry date (exp. date).
- Once thawed, the vaccine cannot be re-frozen
- Prior to use, the unopened vaccine can be stored for up to 12 hours at temperatures of 8°C and up to 30°C.
- Thawed vials can be handled in room light conditions.
- After first puncture of the vial, store the vaccine at 2°C–30°C and use within 12 hours. Discard any remaining unused vaccine.
- Do not use this vaccine if you notice particulates in the 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:

- ((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
- sucrose
- tromethamine (tris base)
- tris (hydroxymethyl) aminomethane hydrochloride (tris HCl)
- water for injections

What the medicine looks like and contents of the pack:
The active ingredient is COVID-19 mRNA vaccine. 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 grey flip-off plastic cap with aluminium seal.

Pack size: Each tray contains 10 or 195 vials.

Not all pack size may be marketed.

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: 170-97-37343

Revised in 03/2023 according to MOH guidelines.

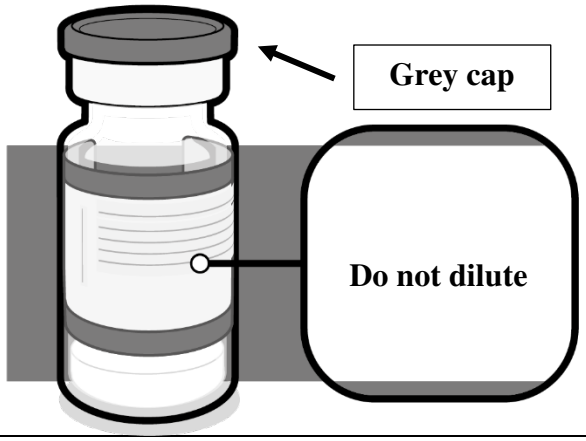
The following information is intended for healthcare professionals only:

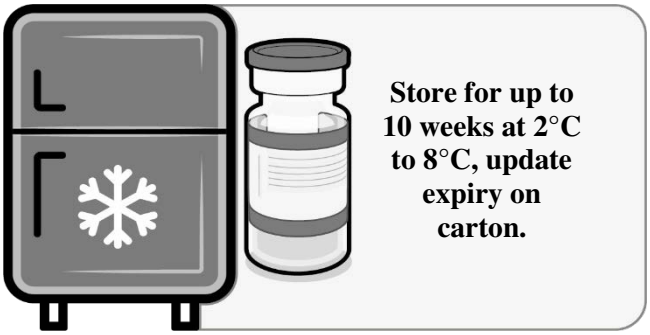
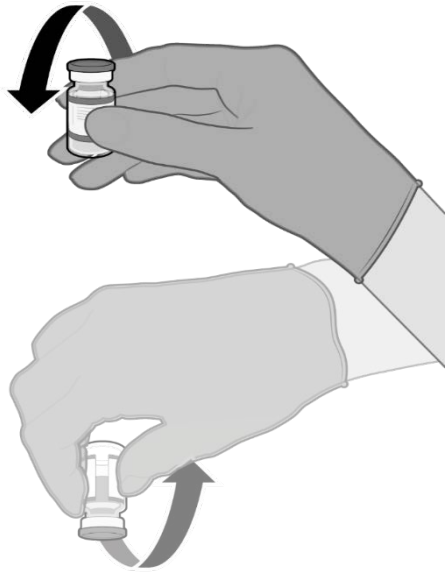
Administer Comirnaty intramuscularly as a course of 2 doses (0.3 mL each) 3 weeks apart.

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 TRIS 30 (12 YEARS AND OLDER)	
	• Verify that the vial has a grey plastic cap and a grey border around the label and the product name is Comirnaty TRIS 30. • If the vial has a purple plastic cap, please make reference to Comirnaty label. • If the vial has an orange plastic cap, please make reference to Comirnaty TRIS 10 label.

<table>
<tr><th colspan="2">HANDLING PRIOR TO USE OF COMIRNATY TRIS 30 (12 YEARS AND OLDER)</th></tr>
<tr><td> 
</td><td>• 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 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.</td></tr>
<tr><td> 
</td><td>• 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.</td></tr>
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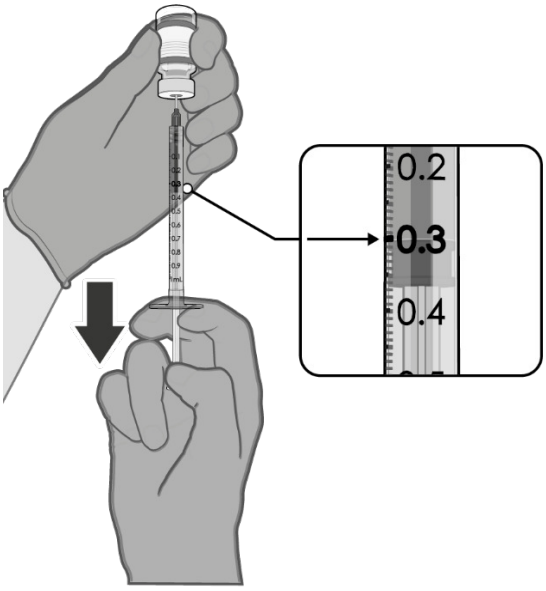
PREPARATION OF INDIVIDUAL 0.3 mL DOSES OF COMIRNATY TRIS 30 (12 YEARS AND OLDER)



0.3 mL vaccine

- 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.