

Information Sheet for Patients, Parents And Caregivers

This is a preparation that is not registered in Israel, which was approved for pre-exposure prophylaxis for prevention of coronavirus disease by the Director General of the Ministry of Health, according to Regulation 29 (a) 9 of the Pharmacists' Regulations (Preparations) - 1986, and in accordance with the Director's Notice according to Pharmacists' Regulations (Preparations) (Section 9 of Part B of the Notice Concerning the Director's Consent "A Preparation Intended for Medication for the Protection of the Residents of the State in the Event of an Epidemic or Infectious Disease").

EVUSHELD™ (tixagevimab co-packaged with cilgavimab)

The co-pack contains two single-dose vials.

One vial contains:	Second vial contains:
Tixagevimab 150 mg / 1.5 ml (100 mg/ml)	Cilgavimab 150 mg / 1.5 ml (100 mg/ml)

For intramuscular Injection

You are being given this Information Sheet because your doctor recommends to provide you EVUSHELD for pre-exposure prophylaxis for prevention of coronavirus disease (COVID-19) caused by the SARS-CoV-2 virus.

This Information Sheet contains information to help you understand the potential risks and potential benefits of taking EVUSHELD, which you have received or may receive.

1. What is EVUSHELD?

EVUSHELD is a combination of two antibodies against the spike protein found on SARS-CoV-2 virus. This combination of antibodies

binds to the spike protein and neutralizes the virus' entry into the cells thus reducing the risk of developing a symptomatic disease.

EVUSHELD is a preparation used for pre-exposure prophylaxis for prevention of COVID-19 used in adults and adolescents (12 years of age and older who weigh at least 40 kg) who are:

- not currently infected with SARS-CoV-2 and who have not had recent known close contact with someone who is infected with SARS-CoV-2 **and**:
 - o Who have moderate to severe immune compromise due to a medical condition or have received immunosuppressive medicines or treatments **and** may not mount an adequate immune response to COVID-19 vaccination

There is limited information known about the safety and effectiveness of using EVUSHELD for pre-exposure prophylaxis for prevention of COVID-19. EVUSHELD is not authorized for post-exposure prophylaxis for prevention of COVID-19.

2. What should you tell the doctor before receiving EVUSHELD?

Tell your doctor if you:

- Have any allergies.
- Have low numbers of blood platelets (which help blood clotting), a bleeding disorder, or are taking anticoagulants (to prevent blood clots).
- Have had a heart attack or stroke, have other heart problems, or are at high risk of cardiac (heart) events.
- Are pregnant or plan to become pregnant.
- Are breastfeeding.
- Have any serious illness.
- Are taking any medications (prescription, over-the-counter, vitamins, or herbal products).

3. How you will receive EVUSHELD?

- EVUSHELD consists of two medicines, tixagevimab and cilgavimab.
- You will receive 1 dose of EVUSHELD, consisting of 2 separate injections (tixagevimab and cilgavimab).
- EVUSHELD will be given as 2 intramuscular injections. They are usually, given one after the other. It can be injected into the muscle of the arm, thigh or buttocks as long as each injection will be given on a different side.

After the initial dose, if your doctor determines that you need to receive additional doses of EVUSHELD for ongoing protection, the additional doses would be administered once every 6 months.

4. Who should not take EVUSHELD?

Do not take EVUSHELD if you have had a severe allergic reaction to EVUSHELD or any ingredient in EVUSHELD.

5. What are the important possible side effects of EVUSHELD?

Possible side effects of EVUSHELD are:

Most common adverse events observed in the studies (incidence $\geq 3\%$) are headache, fatigue, cough.

Allergic reactions: Allergic reactions can happen during and after injection of EVUSHELD. Tell your doctor right away if you get any of the following signs and symptoms of allergic reactions: fever, chills, nausea, headache, shortness of breath, low or high blood pressure, rapid or slow heart rate, chest discomfort or pain, weakness, confusion, feeling tired, wheezing, swelling of your lips, face, or throat, rash including hives, itching, muscle aches, dizziness and sweating. These reactions may be severe or life threatening.

The side effects of getting medicine by intramuscular injection may include pain, bruising of the skin, soreness, swelling, and possible bleeding or infection at the injection site.

Serious and unexpected side effects may happen. EVUSHELD is still being studied so it is possible that all of the risks are not known at this time.

It is possible that EVUSHELD may reduce your body's immune response to a COVID-19 vaccine. If you have received a COVID-19 vaccine, you should wait to receive EVUSHELD until at least 2 weeks after COVID-19 vaccination.

6. What if I am pregnant or breastfeeding?

If you are pregnant or breastfeeding, discuss your options and specific situation with your doctor.

7. How to report a side effect occurred with EVUSHELD?

Contact your doctor if you have any side effects that bother you or do not go away.

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: <https://sideeffects.health.gov.il>

8. Importer:

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Approved by the Ministry of Health in X