

Patient Package Leaflet in Accordance With the Pharmacists' Regulations (Preparations) – 1986
The medicine is dispensed with a doctor's prescription only

Tezpire®

Solution for injection

For subcutaneous injection

Composition:
Each pre-filled syringe (1.91 ml) contains:
Tezepelumab 210 mg

For inactive ingredients please refer to Section 6 – “Further Information”.

Read this leaflet carefully in its entirety before using the medicine.
Keep this leaflet, you may need it again.

This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed for the treatment of your ailment. Do not pass it on to others. It may harm them, even if it seems to you that their ailment is similar.

1. WHAT IS TEZSPIRE AND WHAT IS IT USED FOR?

Tezpire is indicated as an add-on-maintenance treatment in patients with severe asthma aged 12 years and older.

Therapeutic group:

Medicines to treat narrowing of the airways.

Anti-TSLP (thymic stromal lymphopoeitin) monoclonal antibody.

What Tezpire is

Tezpire is a medicine contains the active substance tezepelumab, which is a monoclonal antibody. Antibodies are proteins that recognise and bind to a specific target substance in the body, which in the case of tezepelumab is a protein called TSLP (thymic stromal lymphopoeitin). TSLP plays a key role in causing the inflammation in your airways that leads to the signs and symptoms of asthma. By blocking the action of TSLP, this medicine helps to reduce inflammation and asthma symptoms.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- you are hypersensitive (allergic) to Tezepelumab or any of the other ingredients of this medicine (detailed in section 6). **Check with a doctor, nurse or pharmacist** if you are not sure or think it may be relevant to you.

Special warnings regarding use of Tezpire:

- Tezpire is **not a rescue medicine**. Do not use it to treat a sudden asthma attack.
- **If your asthma is not getting any better, or it gets worse** during treatment with this medicine, **talk to a doctor or nurse**.
- **Look out for signs of allergic reactions.** Medicines like Tezpire can potentially cause allergic reactions in some people. The signs of allergic reactions may vary, and can include breathing problems, hives and rash. If you notice any of these signs, **speak to a doctor or nurse immediately**. Talk to your doctor about how to recognize early signs of allergy, and how to manage reactions if they occur.

- **Look out for any signs of a possible serious infection** while you are taking Tezpire such as:

- fever, flu-like symptoms, night sweats
- cough which will not go away
- warm, red and painful skin, or a painful skin rash with blisters

If you notice any of these signs, **speak to a doctor or nurse immediately**.

If you already have a serious infection, talk to your doctor before taking Tezpire

- **Look out for any symptoms of a heart problem**, such as:

- chest pain
- shortness of breath
- a general feeling of discomfort, illness, or lack of well-being
- feeling lightheaded or faint

If you notice any of these symptoms, **speak to a doctor or nurse immediately**.

- If you have a parasitic infection or if you live in (or travel to) an area where parasitic infections are common, **talk to your doctor**. Tezpire may weaken your body's ability to fight certain types of parasitic infections.

Children and adolescents

Tezpire is not intended for use in children below 12 years of age. There is no data regarding efficacy and safety of this preparation in children below 12 years of age.

Drug interactions:

If you are taking, or have recently taken, other medicines including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. Especially if you take:

- tell your doctor if you have recently had or are due to have a vaccination.

Other medicines for asthma

Do not suddenly stop taking your other asthma medicines when you start Tezpire. This is especially important if you take steroids (also called corticosteroids). These medicines must be stopped gradually, under the supervision of your doctor and based on your response to Tezpire.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to become pregnant, consult with your doctor before taking this medicine.

Do not use Tezpire during pregnancy unless your doctor advises it. It is not known if Tezpire can harm your unborn baby.

Tezpire may pass into breast milk. If you are breast-feeding or plan to breast-feed, consult with your doctor.

Driving and using machines

Tezpire is unlikely to affect your ability to drive and use machines.

Important information regarding some of the ingredients of the medicine Tezpire contains less than 1 mmol sodium (23 mg) per 210 mg dose, this means that the medicine is essentially 'sodium-free'.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use Tezpire according to the doctor's instructions.

Check with the doctor or pharmacist if you are not sure about the dosage and manner of treatment.

The dosage and course of treatment will be determined only by the doctor. The usual dosage is generally:

Adults and adolescence above 12 years:

The recommended dose is 210 mg (one injection) every 4 weeks. Tezpire is given as injection under the skin (subcutaneously).

Do not exceed the recommended dosage.

Your doctor or nurse will decide if you can inject yourself or if your caregiver can do that for you. If so, you or your caregiver will receive training on the right way to prepare and inject Tezpire.

Before injecting Tezpire, carefully read the 'Instructions for Use' for Tezpire pre-filled syringe. Do this each time you get another injection. There may be new information.

Do not share Tezpire pre-filled syringes or use a syringe more than one time.

If you missed a Tezpire dose

- If you have forgotten to inject a dose of Tezpire, inject a dose as soon as possible. Then have your next injection on your next scheduled injection time.
- If you did not notice that you missed a dose until it is time for your next dose, simply inject the next dose as scheduled. **Do not inject a double dose to make up for a forgotten dose.**
- If you are not sure when to inject Tezpire, ask your doctor, pharmacist or nurse.

If you stop using Tezpire

Do not stop using Tezpire without speaking first to your doctor, pharmacist or nurse. Interrupting or stopping the treatment with Tezpire may cause your asthma symptoms and attacks to come back.

If you accidentally take a higher dose or if a child has accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you.

Do not take medicines in the dark! Check the label and the dose each time you take your medicine. Wear glasses if you need them.
If you have any further questions regarding the use of this medicine, ask your doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Tezpire may cause side effects in some users. Do not be alarmed by reading the list of side effects. You may not suffer from any of them.

Common side effects (may affect up to 1 of 10 patients):

- sore throat
- rash
- joint pain
- injection site reaction (such as redness, swelling, and pain)

If any side effect appears, if one of the side effects worsens or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.

Reporting of side effects

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>

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid Poisoning! This medicine, and any other medicine, should be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning.
- Store at 2°C-8°C (in a refrigerator). After removal from refrigeration, Tezpire may be kept at room temperature (up to 25°C) for a maximum of 30 days. Do not put back in the refrigerator once Tezpire has stored in room temperature.
- Store Tezpire in the original carton to protect from light.
- Do not shake, freeze or expose to heat.
- Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month. In any case of doubt, consult the pharmacist who dispensed the medicine to you.
- Do not store different medicines in the same pack.
- Do not use Tezpire if the syringe has been dropped, damaged or if the security seal on the carton has been damaged.

Do not throw away any medicines via wastewater. 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, the medicine also contains:

L-proline, Acetic acid glacial, Polysorbate 80, Sodium hydroxide, Water for injection

What does the medicine look like?

Tezpire is a solution that is clear to opalescent and colorless to light yellow. Tezpire is available in a pack containing one pre-filled syringe.

Manufacturer:

AstraZeneca AB, Södertälje, Sweden.

License holder:

AstraZeneca (Israel) Ltd.,

1 Atirei Yeda St., Kfar Saba 4464301.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 171-59-37290-00

Approved in January 2023 according to MOH guidelines.

Instructions for self-administration

Tezpire®

solution for injection in pre-filled syringe

Each pre-filled syringe (1.91 ml) contains:
Tezepelumab 210 mg

For subcutaneous injection

Single use pre-filled syringe

This instructions for use contain information on how to inject Tezpire.

Before you use your Tezpire syringe, a healthcare provider should show you or your caregiver how to use the syringe in the right way.

Read this 'Instructions for self-administration' before you start using your Tezpire syringe and each time you get another injection. There may be new information. This information should not replace talking to your healthcare provider about your medical condition and your treatment.

If you or your caregiver have any questions, talk to your attending doctor.

Important information you need to know before injecting Tezpire
Store Tezpire in a refrigerator between 2°C to 8°C in its original pack until you are ready to use the medicine. Tezpire may be kept at room temperature (up to 25°C) in the outer carton for a maximum of 30 days.

Once Tezpire has been stored at room temperature, do not put it back in the refrigerator. Throw away (dispose of) Tezpire that has been stored at room temperature for more than 30 days (see Step 10).

Do not use your Tezpire pre-filled syringe if:

- The syringe has been frozen
- The syringe has been dropped or damaged
- The security seal on the carton has been damaged
- The expiry date (EXP) has passed

Do not shake the pre-filled syringe.

Do not share the pre-filled syringe or use it more than 1 time.

Do not expose the pre-filled syringe to heat.

If any of the above happens, throw away the syringe in a puncture-resistant (sharps) container and use a new pre-filled syringe.

Each Tezpire pre-filled syringe contains 1 dose of Tezpire that can only be used 1 time.

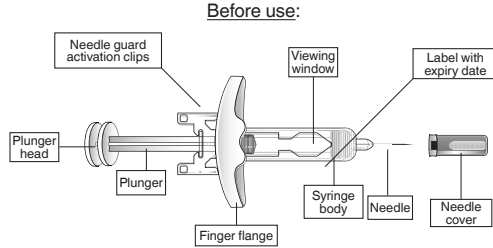
Avoid poisoning! Keep Tezpire and all medicines out of the sight and reach of children.

Tezpire is given only as an injection under the skin (subcutaneous).

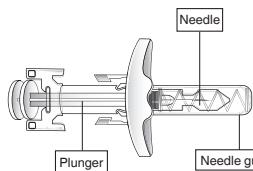
The pre-filled syringe

Do not remove the needle cover until Step 7 of these instructions when you are ready to inject Tezpire.

Do not touch the needle guard activation clips. This will keep you from activating the safety device (needle guard) too soon.



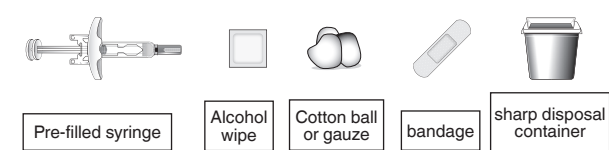
After use:



Preparing to inject Tezpire

Step 1 – Gather supplies

- 1 Tezpire pre-filled syringe from the refrigerator
- 1 alcohol wipe
- 1 cotton ball or gauze
- 1 small bandage (optional)
- 1 puncture-resistant (sharps) disposal container (See Step 10 - Dispose of the used pre-filled syringe)



Step 2 – Prepare to use your Tezpire syringe



Let Tezpire come to room temperature (between 20°C to 25°C) for about 60 minutes or longer (up to a maximum of 30 days) before giving the injection.

Keep the Tezpire syringe in the outer carton to protect from light.

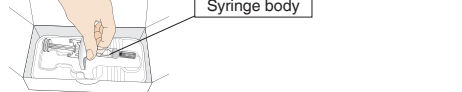
Do not warm the pre-filled syringe in any other way. For example, do not warm it in a microwave or hot water, in direct sunlight, or near other heat sources.

Do not put Tezpire back in the refrigerator after it has reached room temperature. Throw away (dispose of) Tezpire syringe that has been stored at room temperature for more than 30 days.

Do not remove the needle cover until Step 7.

Step 3 – Remove pre-filled syringe from the pack

Grab the syringe body (not the plunger) to remove the pre-filled syringe from its tray.



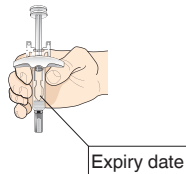
Step 4 – Check the pre-filled syringe

Check the pre-filled syringe for damage. Do not use the pre-filled syringe if the pre-filled syringe is damaged. **Check the expiry date** on the pre-filled syringe. **Do not** use the pre-filled syringe if the expiry date has passed.

Look at the liquid through the viewing window. The liquid should be clear and colourless to light yellow.

Do not inject Tezpire if the liquid is cloudy, discoloured, or contains large particles.

You may see small air bubbles in the liquid. This is normal. You do not need to do anything about it.



Injecting Tezpire

Step 5 – Choose an injection site for Tezpire

If you are giving yourself the injection, the **recommended injection site** is the front of your thigh or the lower part of your stomach (abdomen). Do not inject yourself in the arm.

A caregiver may inject you in the upper arm, thigh, or abdomen. For each injection, choose a different site that is at least 3 cm away from where you last injected.

- **Do not inject** into the 5 cm area around your belly button
- **Do not inject** where the skin is tender, bruised, scaly or hard
- **Do not inject** into scars or damaged skin
- **Do not inject** through clothing

Step 6 – Wash your hands and clean the injection site

Wash your hands well with soap and water.

Clean the injection site with an alcohol wipe in a circular motion. Let it air dry.

Do not touch the cleaned area before injecting.

Do not fan or blow on the cleaned area.

Step 7 – Pull off the needle cover

Do not remove the cap until you are ready to inject.

Hold the syringe body with 1 hand, and carefully pull the needle cover straight off with your other hand.

Do not hold the plunger or plunger head while removing the needle cover.

Put the needle cover to the side and throw it away later. You may see a drop of liquid at the end of the needle. This is normal.

Do not touch the needle or let it touch any surface.

Do not put the needle cover back on the syringe.

Step 8 – Inject Tezpire

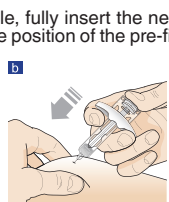
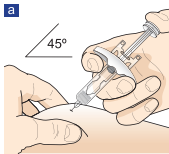
Hold the pre-filled syringe in 1 hand as shown in the picture.

Use your other hand to gently pinch and hold the area of skin where you want to inject. This will make the skin firmer and ready for the injection.

Do not press down on the plunger head until the needle is fully inserted into the skin.

Do not pull back on the plunger head at any time.

Inject Tezpire by following the steps in figures a, b and c.



1. Using a 45 degree angle, fully insert the needle into the pinched skin. **Do not** try to change the position of the pre-filled syringe after you insert it into the skin.

2. Use your thumb to push down on the plunger head. Keep pushing until it is down as far as it will go to make sure you inject all of the medicine.

3. Keep your thumb pressed down on the plunger head as you take the needle out of the skin. Slowly let go of the plunger until the needle guard covers the needle.

Step 9 – Check the injection site

There may be a small amount of blood or liquid where you injected. This is normal. Gently hold pressure over your skin with a cotton ball or gauze until the bleeding stops.

Do not rub the injection site. If needed, cover the injection site with a small bandage.

Disposing of the syringe

Step 10 – Dispose of the used pre-filled syringe safely
Each pre-filled syringe contains a single dose of Tezpire and **cannot be used again. Do not** put the needle cover back on the pre-filled syringe.

Put your used syringe and needle cover in a **sharps disposal container** right away after use. Put other used supplies in your household trash.

Do not throw away the pre-filled syringe in your household trash.

Dispose of the full container as instructed by your doctor or pharmacist.

Do not dispose of your used sharps disposal container in your household trash unless your community guidelines permit this.

Do not recycle your used sharps disposal container.

