

**Patient Package Leaflet in Accordance With
the Pharmacists' Regulations (Preparations) – 1986**

The medicine is dispensed with a doctor's prescription only

Tezspire®

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.

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 the medicine intended for?

Tezspire is indicated as an add-on maintenance treatment of adult and pediatric patients aged 12 years and older with severe asthma.

Therapeutic group

Medicines to treat narrowing of the airways.

Anti-TSLP (thymic stromal lymphopoietin) monoclonal antibody.

What Tezspire is

Tezspire is a medicine that 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 lymphopoietin). 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 Tezspire:

- Tezspire 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 Tezspire can potentially cause serious allergic reactions in some people. The signs of these reactions may vary, and can include swelling of your face, tongue or mouth, breathing problems, fast heartbeat, fainting, dizziness, feeling lightheaded, 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 Tezspire such as:
 - o fever, flu-like symptoms, night sweats
 - o cough which will not go away
 - o 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 Tezspire.

- **Look out for any symptoms of a heart problem**, such as:
 - o chest pain
 - o shortness of breath
 - o a general feeling of discomfort, illness, or lack of well-being.
 - o 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**. Tezspire may weaken your body's ability to fight certain types of parasitic infections.

Children and adolescents

Tezspire 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 Tezspire. 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 Tezspire.

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

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

Driving and using machines

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

Important information regarding some of the ingredients of the medicine

Tezspire 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 Tezspire 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 adolescent above 12 years:

The recommended dose is 210 mg (one injection) every 4 weeks. Tezspire 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 Tezspire.

Before injecting Tezspire, carefully read the 'Instructions for Use' for Tezspire pre-filled syringe.

Do this each before each injection, there may be new information in the "instructions for use".

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

If you missed a Tezspire dose

- If you have forgotten to inject a dose of Tezspire, 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 Tezspire, ask your doctor, pharmacist or nurse.

If you stop using Tezspire

Do not stop using Tezspire without speaking first to your doctor, pharmacist or nurse. Interrupting or stopping the treatment with Tezspire 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 Tezspire 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.

Serious allergic reactions

Seek medical attention immediately if you think you may be having an allergic reaction. Such reactions may happen within hours or days after the injection.

Not known (the frequency cannot be estimated from the available data)

- allergic reactions, including serious allergic reaction (anaphylaxis)
 - symptoms usually include:
 - o swelling of your face, tongue, or mouth
 - o breathing problems, fast heartbeat
 - o fainting, dizziness, feeling lightheaded

Other side effects

Common (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, Tezspire may be kept at room temperature (20°C - 25°C) for a maximum of 30 days. Do not put back in the refrigerator once Tezspire has stored in room temperature.
- Store Tezspire in the original carton to protect from light until time of use.
- 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 Tezspire 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 the medicine looks like and contents of the pack

Tezspire is a solution that is clear to opalescent and colorless to light yellow.

Tezspire 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 March 2024.

Instructions for self-administration

Tezspire®

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 Tezspire.

Before you use your Tezspire 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 Tezspire 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 Tezspire

Store Tezspire in a refrigerator between 2°C to 8°C in its original pack until you are ready to use the medicine. Tezspire may be kept at room temperature (20°C - 25°C) in the outer carton for a maximum of 30 days. Once Tezspire has been stored at room temperature, do not put it back in the refrigerator. Throw away (dispose of) Tezspire that has been stored at room temperature for more than 30 days (see Step 10).

Do not use your Tezspire 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 Tezspire pre-filled syringe contains 1 dose of Tezspire that can only be used 1 time.

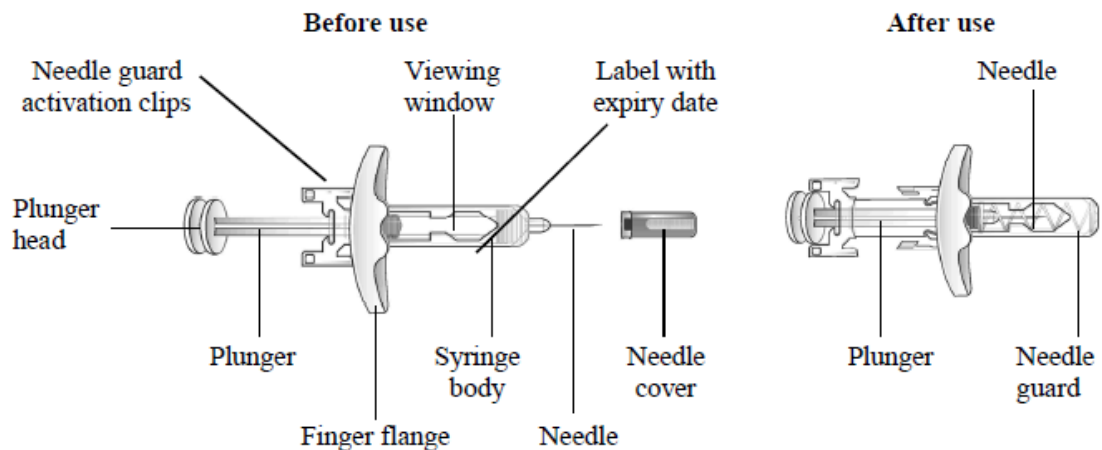
Avoid poisoning! Keep Tezspire and all medicines out of the sight and reach of children.

Tezspire 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 Tezspire.

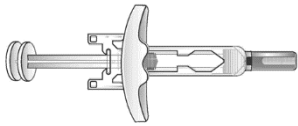
Do not touch the needle guard activation clips. This will keep you from activating the safety device (needle guard) too soon.



Preparing to inject Tezspire

Step 1 – Gather supplies

- 1 Tezspire 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)



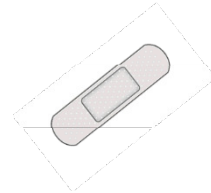
Pre-filled syringe



Alcohol wipe



Cotton ball or gauze



bandage



sharp disposal
container

Step 2 – Prepare to use your Tezspire syringe

Let Tezspire 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 Tezspire syringe in the outer carton in order 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.

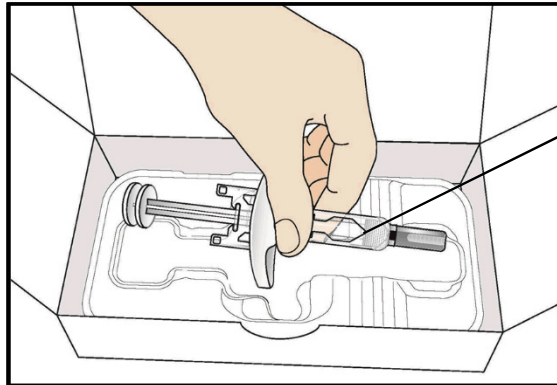
Do not put Tezspire back in the refrigerator after it has reached room temperature. Throw away (dispose of) Tezspire syringe that has been stored at room temperature for more than 30 days.

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.



Syringe body

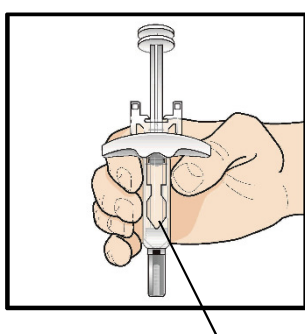
Step 4 – Check the pre-filled syringe

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 Tezspire 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.



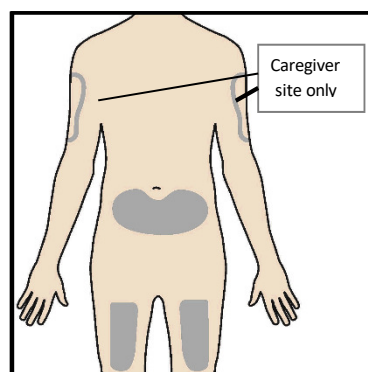
Expiry
date

Injecting Tezspire

Step 5 – Choose an injection site for Tezspire

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



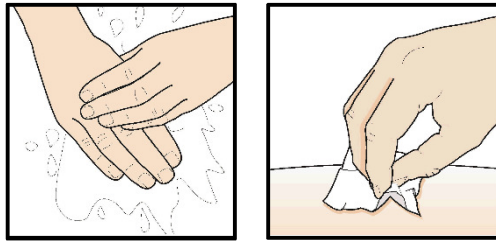
Step 6 – Wash your hands and clean the injection site

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.

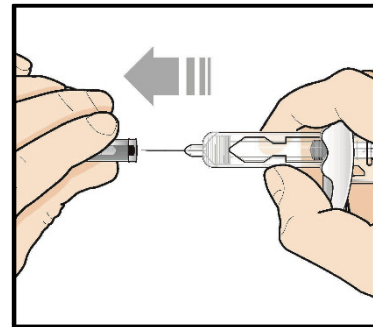
Do not hold the plunger or plunger head while removing the needle cover.

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.



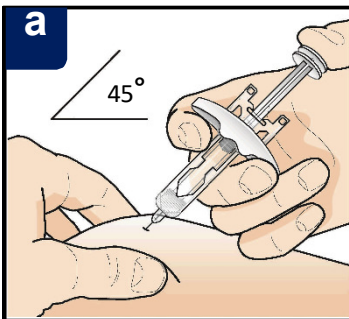
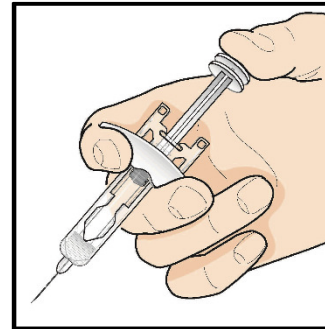
Step 8 – Inject Tezspire

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.

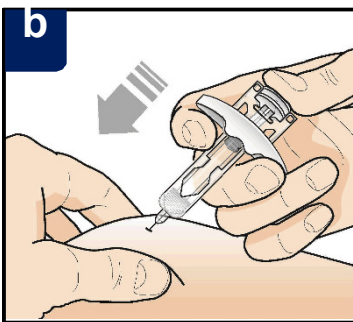
Do not press down on the plunger head until the needle is fully inserted into the skin.

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

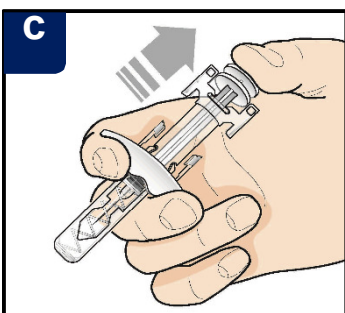
Inject Tezspire by following the steps in figures a, b and c.



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.

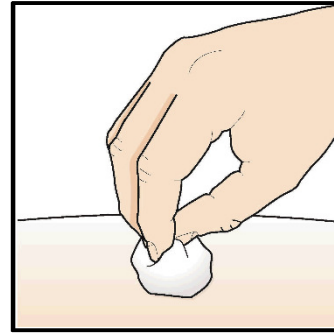


3. Keep your thumb pressed down on the plunger head as you take the needle out of the skin. Slowly let go of the plunger until the needle guard covers the needle.

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.

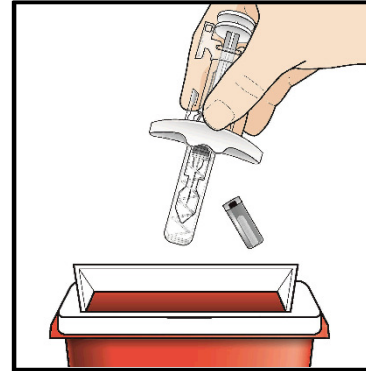
Do not rub the injection site. If needed, cover the injection site with a small bandage.



Disposing of the syringe

Step 10 – Dispose of the used pre-filled syringe safely

Each pre-filled syringe contains a single dose of Tezspire 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.