

# TEZSPIRE™

## Tezepelumab, 210 mg, Solution for injection

### CONSUMER MEDICINE INFORMATION

#### What is in this leaflet

This leaflet answers some of the common questions people ask about **Tezspire**. It does not contain all the information that is known about **Tezspire**.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor will have weighed the risks of you taking **Tezspire** against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

#### What Tezspire is used for

**Tezspire** is used with other asthma medicines to treat severe asthma in adults and adolescents (12 years of age and older). **Tezspire** may reduce the number of asthma attacks you experience, improve your breathing and reduce your asthma symptoms.

**Tezspire contains the active ingredient tezepelumab.** Tezepelumab is an antibody (a type of protein) that recognises and binds to a specific target substance in the body. The target of tezepelumab is a protein called thymic stromal lymphopoietin (TSLP). TSLP plays a central role in causing the signs and symptoms of asthma. This medicine works by blocking the action of TSLP.

Your doctor may have prescribed **Tezspire** for another reason. Ask your doctor if you have any questions about why this medicine has been prescribed for you.

This medicine is only available with a doctor's prescription.

#### Before you use Tezspire

##### *When you must not use it*

Do not use **Tezspire** if:

- you are allergic to tezepelumab or any of the other ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- you have a sudden asthma attack. **Tezspire** is **not a rescue medicine**.

##### *Before you start to use it*

Check with your doctor if:

- your asthma remains uncontrolled or worsens during treatment with **Tezspire**.
- you have ever had a severe allergic reaction (hypersensitivity) (symptoms may vary, but can include breathing problems, hives, and rash).
- you have a parasitic infection or if you live in an area where parasitic infections are common or if you are travelling to such a region. **Tezspire** may weaken your ability to fight certain types of parasitic infections.
- you are taking or have recently taken any other medicines for any other condition, even those not prescribed.
- you have recently had or are due to have a vaccination.

##### *Pregnancy and breastfeeding*

Check with your doctor if you are pregnant, think you may be pregnant or intend to become pregnant. Do not use **Tezspire** unless your doctor tells you to. It is not known if **Tezspire** can harm your unborn baby.

Talk to your doctor if you are breastfeeding or intend to breastfeed. **Tezspire** may pass into breast milk. Your doctor will discuss with you whether you should stop treatment with **Tezspire** while you are breast-feeding, or if you should stop breast-feeding.

**When you must not use it**

Do not use this medicine if it has been dropped or damaged, if the security seal on the carton has been broken or after the expiry date which is stated on the label.

Do not give this medicine to anyone else even if their symptoms seem similar to yours.

**Tezspire** is not recommended for children aged under 12 years, as the safety and effectiveness are not known in this population.

**Taking other medicines**

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Tezspire.**

**Do not suddenly stop taking** your other asthma medicines once you have started **Tezspire**. These medicines (especially ones called corticosteroids) must be stopped gradually, under the direct supervision of your doctor and on your response to **Tezspire**.

**Tell your doctor if you have recently received a vaccine or are due to have a vaccination.**

**How to use Tezspire**

**Follow the instructions provided and use Tezspire exactly as your doctor has instructed you.**

**How much to take and when to take it**

The recommended dose is 210 mg every 4 weeks.

**How to take it**

**Tezspire** is given as an injection under the skin (subcutaneously).

**Always use Tezspire exactly as your doctor has instructed you. If you or your caregiver have any questions, talk to your doctor.**

Your doctor should decide if you or your caregiver should inject **Tezspire**. Before using your **Tezspire** prefilled syringe or prefilled pen, your doctor should show you or your caregiver how to use it the right way. Read the 'Instructions for use for **Tezspire** prefilled syringe' or 'Instructions for use for **Tezspire** prefilled pen' carefully before using **Tezspire** and each time you get a refill. There may be new information.

Do not share or use **Tezspire** prefilled syringe or prefilled pen more than one time.

**How long to take it**

Do not stop using **Tezspire** without speaking to your healthcare professional first. Interrupting or stopping the treatment with **Tezspire** may cause your asthma symptoms and attacks to come back.

**If you forget to take it**

If you missed a dose, inject a dose as soon as possible. Continue your next injection on your usual injection day. If you did not notice that you have missed a dose until it is time for your next scheduled dose, then inject the next scheduled dose as planned. If you are not sure when to inject **Tezspire**, call your doctor.

**Do not take a double dose to make up for the dose you missed.**

**While you are using Tezspire****Things you must do**

**Call your doctor straight away if:**

- your asthma remains uncontrolled or worsens during treatment with **Tezspire**
- you have had any symptoms of an allergic reaction (symptoms may vary, but can include breathing problems, hives, and rash).

Remind any doctor, dentist or pharmacist you visit that you are using **Tezspire**.

### **Things you must not do**

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

If you have any further questions on the use of **Tezspire**, ask your doctor.

### **Overdose**

Immediately telephone your doctor or the National Poisons Centre (Ph: 0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency at your nearest hospital if you think that you or anyone else may have taken too much **Tezspire**. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

### **Side effects**

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking **Tezspire**.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment for some side effects.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

#### **Less serious side effects**

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- Sore throat (pharyngitis)
- Injection site reaction (i.e. redness, swelling, and pain)
- Joint pain (arthralgia)
- Rash

##### **What to do**

**Speak to your doctor if you have any of these less serious side effects and they worry you.**

#### **Serious side effects**

<b>Serious side effects</b>	<b>What to do</b>
<p>Allergic reaction - some of the symptoms of an allergic reaction may include:</p> <ul style="list-style-type: none"> <li>• rash, itching or hives on the skin</li> <li>• swelling of the face, lips, tongue or other parts of the body</li> <li>• shortness of breath, wheezing or difficulty breathing</li> <li>• fainting, dizziness, feeling lightheaded (due to a drop in blood pressure)</li> </ul> <p>Allergic reactions may occur within minutes or hours after an injection or may even occur several days after an injection.</p>	<p><b>Call your doctor or nurse straight away, or go straight to the Emergency Department at your nearest hospital.</b> You may need urgent medical attention or hospitalisation.</p>

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

**Important:** This leaflet alerts you to some of the situations when you should call your doctor. Other situations, which cannot be predicted, may arise. Nothing in this leaflet should stop you from calling your doctor or pharmacist with any questions or concerns you have about using **Tezspire**.

### **After taking Tezspire**

#### **Storage**

Store **Tezspire** in the refrigerator at 2°C to 8°C. Do not freeze, shake or expose to heat. **Tezspire** should be kept in the original package to protect it from light.

**Tezspire** may be kept at room temperature up to 25°C in the original carton for a maximum of 30 days. Once **Tezspire** has reached room temperature, do not put it back in the refrigerator. Follow the instructions in the carton on how to take care of your medicine properly.

**Keep it where young children cannot reach it.** A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

### **Disposal**

Dispose of **Tezspire** that has been stored at room temperature after 30 days.

If your doctor tells you to stop taking **Tezspire** or the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

### **Product description**

#### **What Tezspire looks like**

**Tezspire** is a clear to opalescent, colourless to light yellow solution.

**Tezspire** is available in a pack containing 1 single-use prefilled syringe or 1 single-use prefilled pen.

#### **Ingredients**

**Tezspire** prefilled syringe and prefilled pen contain 210 mg of Tezepelumab.

Other ingredients include:

- glacial acetic acid
- proline
- polysorbate 80
- sodium hydroxide
- water for injections

This medicine does not contain latex, lactose, sucrose, gluten, tartrazine or any other azo dyes.

### **Marketed by:**

AstraZeneca Limited  
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### **Date of preparation**

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