Funded and produced by:

AstraZeneca

INFORMATION FOR THE PATIENT

TEZSPIRE®▼(tezepelumab)

210 mg solution for injection in pre-filled pen.

This information leaflet is intended only for patients in the United Kingdom who have been prescribed **Tezspire pre-filled pen** and their caregivers. This leaflet is consistent with the 'Patient Information Leaflet' and complements the 'Instructions for Use', which are found in the carton.

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet. You can report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard. Side effects can also be reported to AstraZeneca by visiting https://contactazmedical.astrazeneca.com or by calling 0800 783 0033.

By reporting side effects you can help provide more information on the safety of the medicine.

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READ ALL OF THIS LEAFLET CAREFULLY BEFORE YOU START USING THIS MEDICINE BECAUSE IT CONTAINS IMPORTANT INFORMATION FOR YOU.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

WHAT IS IN THIS LEAFLET

1. **What Tezspire is and what it is used for**
2. **What you need to know before you use Tezspire**
3. **How to use Tezspire**
4. **Possible side effects**
5. **How to store Tezspire**
6. **Contents of the pack and other information**

1. WHAT TEZSPIRE IS AND WHAT IT IS USED FOR

What Tezspire is and how it works

Tezspire 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 ***thymic stromal lymphopoietin* (TSLP).** TSLP plays a key role in causing the inflammation in your airways that leads to the signs and symptoms of asthma and chronic rhinosinusitis with nasal polyps (CRSwNP). **By blocking the action of TSLP, this medicine helps to reduce inflammation and symptoms of asthma and CRSwNP.**

What Tezspire is used for

Tezspire is used with other medicines to treat CRSwNP in adults.

How Tezspire can help

Tezspire may reduce the size of your polyps and improves symptoms including nasal congestion and loss of smell. Tezspire may also reduce the need for oral corticosteroids and surgery.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE TEZSPIRE

Do not use Tezspire

- **if you are allergic** to tezepelumab or any of the other ingredients of this medicine (listed in section 6). If this applies to you, or if you are not sure, **check with your doctor, pharmacist or nurse.**

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using 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, but 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 recognise 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:
  - 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 Tezspire.

- **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.** Tezspire may weaken your body's ability to fight certain types of parasitic infections.

Children

- Do not give this medicine to **children under 18 years** of age for the treatment of CRSwNP because the safety and benefits of this medicine are not known in this age group.

Other medicines and Tezspire

Tell your doctor or pharmacist:

- if you are taking, have recently taken or might use any other medicines.
- if you have recently had or are due to have a vaccination.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice 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, talk to your doctor.

Driving and using machines

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

Tezspire contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per 210 mg dose, that is to say **essentially 'sodium-free'.**

3. HOW TO USE TEZSPIRE

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor, pharmacist or nurse if you are not sure.

Adults aged 18 years and over:

- **The recommended dose is 210 mg (1 injection) every 4 weeks.** Tezspire is given as an injection under the skin (subcutaneously).

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 yourself, carefully read the **'Instructions for Use'** for your Tezspire pre-filled pen. Do this each time you get another injection. There may be new information.

Do not share Tezspire pre-filled device or use more than one time.

If you forget to use Tezspire

- If you have forgotten to inject a dose, inject a dose as soon as possible. Then have your next injection on your next scheduled injection day.

- 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 symptoms or attacks to come back.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets 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:
  - swelling of your face, tongue, or mouth
  - breathing problems, fast heartbeat
  - fainting, dizziness, feeling lightheaded.

Other side effects

Common (these may affect up to 1 in 10 people)

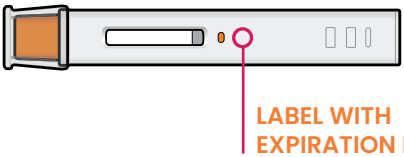
- sore throat
- rash
- joint pain
- injection site reaction (such as redness, swelling, and pain)

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse.
This includes any possible side effects not listed in this leaflet.
You can also report side effects directly via the Yellow Card Scheme at **www.mhra.gov.uk/yellowcard** or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE TEZSPIRE

- **Keep this medicine out of the sight and reach of children.**
- **Do not use after the expiry date** which is stated on the label and carton. The expiry date refers to the last day of that month.



- Store in a **refrigerator (2°C to 8°C)** in the original package.
- Tezspire may be **kept at room temperature (20°C to 25°C) in the outer carton for a maximum of 30 days. Once Tezspire has reached room temperature, do not put it back in the refrigerator.** Tezspire that has been stored at room temperature for more than 30 days should be safely disposed of.
- **Do not shake, freeze or expose to heat.**
- Do not use this medicine if it has been **dropped or damaged, or if the security seal on the carton has been broken.**

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. CONTENTS OF THE PACK AND OTHER INFORMATION

What Tezspire contains

- The active substance is **tezepelumab.**
- The other ingredients are acetic acid, L-proline, polysorbate 80, sodium hydroxide, and water for injections.

What Tezspire looks like and contents of the pack

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

Tezspire is available in a pack containing 1 single-use pre-filled pen.

Other sources of information

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000

Please be ready to give the following information:

Product name	**Reference number**
Tezspire 210 mg	17901/0372

This is a service provided by the Royal National Institute of the Blind. You will be directed to a non-AstraZeneca number and service.