

TEZSPIRE[®] 210mg Solution for Injection in Pre-filled Syringe

Tezepelumab

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What TEZSPIRE is used for

Asthma

TEZSPIRE is used with other asthma medicines to treat severe asthma in adults and adolescents (12 years of age and older) when the disease is not controlled with their current asthma medicines.

TEZSPIRE may reduce the number of asthma attacks you experience, improve your breathing and reduce your asthma symptoms.

CRSwNP (Chronic rhinosinusitis with nasal polyps)

TEZSPIRE is also used with other medicines to treat CRSwNP in adults.

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.

How TEZSPIRE 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 CRSwNP. By blocking the action

of TSLP, this medicine helps to reduce inflammation and symptoms of asthma and CRSwNP.

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 of this medicine (see “*Ingredient*” section). Check with your doctor, pharmacist or nurse if you think this applies to you.
- To treat a sudden asthma attack. TEZSPIRE is not a rescue medicine.

- Before you start to use it

Before you use TEZSPIRE, tell your doctor, pharmacist or nurse:

- If you have signs of serious infection 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 have a parasitic infection or if you live in (or travel to) an area where parasitic infections are common. TEZSPIRE may weaken your body’s ability to fight certain types of parasitic infections.

Talk to your doctor about how to recognise early signs of allergy, and how to manage reactions if they occur.

Each time you get a new pack of TEZSPIRE, write down the name and the Lot number shown on the outer carton and the label of the pre filled syringe, and keep this information in a safe place. You may be asked for this information in the future.

- Taking other medicines

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.

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.

How to use TEZSPIRE

- How much to use & when to use it

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.

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

Asthma

Adults and adolescents aged 12 years and over:

The recommended dose is 210 mg (1 injection) every 4 weeks.

CRSwNP

Adults aged 18 years and over:

The recommended dose is 210 mg (1 injection) every 4 weeks.

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 TEZSPIRE pre-filled syringe. Do this each time you get another injection. There may be new information.

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

- How long to use it

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.

- If you forget to use it

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 use too much (overdose)

It is important that you take your dose as stated on the pharmacist's label or as advised by your doctor. You should not exceed your prescribed dose without seeking medical advice.

While you are using it

- Things you must do

Tell your doctor, pharmacist or nurse:

- If your asthma is not getting any better, or it gets worse during treatment with TEZSPIRE.
- If you notice 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 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 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.

- Things you must not do

Do not stop using TEZSPIRE unless advised by your doctor.

- Things you must be careful of

Children

Asthma

Do not give this medicine to children under 12 years of age for the treatment of asthma because the safety and benefits of this medicine are not known in children in this age group.

CRSwNP

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 children in this age group.

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'.

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 effect

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

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

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of TEZSPIRE

- Storage

- 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).
- Keep the pre-filled syringe in the outer carton in order to protect from light.
- TEZSPIRE may be stored at 20°C to 25°C in the outer carton for a maximum of 30 days. Once TEZSPIRE has reached the temperature of 20°C to 25°C, do not put it back in the refrigerator. TEZSPIRE that has been stored at 20°C to 25°C 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.

- Disposal

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.

Product Description

- What it looks like

TEZSPIRE is a clear to opalescent, colourless to light yellow solution.

TEZSPIRE is available in a pack containing 1 single-use pre-filled syringe or in a multipack containing 3 (3 packs of 1) pre-filled syringes.

- Ingredients

- Active ingredient
Tezepelumab

- Inactive ingredients
Acetic acid
L-proline
Polysorbate 80
Sodium hydroxide
Water for injections

- MAL number:

MAL24116036ACRZ

Manufacturer

Amgen Manufacturing Ltd LLC,
Carr 31 KM24.6 Juncos,
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Product Registration Holder

AstraZeneca Sdn. Bhd.
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