TEZSPIRE®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the full CMI for further details.

1. Why am I using TEZSPIRE?

TEZSPIRE contains the active ingredient tezepelumab. It is used with other asthma medicines to treat severe asthma in adults and adolescents (12 years of age and older). TEZSPIRE is also used with other medicines to treat chronic rhinosinusitis with nasal polyps (CRSwNP) in adults (18 years of age and older).

For more information, see Section 1. Why am I using TEZSPIRE? in the full CMI.

2. What should I know before I use TEZSPIRE?

Do not use if you have ever had an allergic reaction to TEZSPIRE or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use TEZSPIRE? in the full CMI.

3. What if I am taking other medicines?

It is possible that some medicines and TEZSPIRE may interfere with each other.

Your doctor and pharmacist can advise you. TEZSPIRE has been used together with other commonly used asthma medicines.

4. How do I use TEZSPIRE?

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

More instructions can be found in Section 4. How do I use TEZSPIRE? in the full CMI.

5. What should I know while using TEZSPIRE?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using TEZSPIRE. • Keep all of your doctor's and/or hospital's appointments so that your progress can be checked. • Ask your doctor, nurse or pharmacist if you have any questions about your personal Asthma Action Plan.
Things you should not do	• Do not use in patients under 12 years old for asthma and under 18 years old for CRSwNP. • Do not stop using this medicine suddenly once you have started TEZSPIRE without checking with your doctor. • Do not suddenly stop taking your asthma medicines

	(especially ones called corticosteroids) once you have started TEZSPIRE, unless instructed by your doctor. • Do not use TEZSPIRE if you think it has been frozen, dropped or damaged.
Looking after your medicine	• 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. • 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. Dispose of TEZSPIRE that has been stored at room temperature after 30 days.

For more information, see Section 5. What should I know while using TEZSPIRE? in the full CMI.

6. Are there any side effects?

Serious side effects may include an allergic reaction. Common side effects may include sore throat (pharyngitis), injection site reaction (i.e. redness, swelling, and pain at the injection site), joint pain (arthralgia), rash.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

▼ 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. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

TEZSPIRE®

Active ingredient(s): *tezepelumab*

Consumer Medicine Information (CMI)

This leaflet provides important information about using TEZSPIRE. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using TEZSPIRE.**

Where to find information in this leaflet:

1. Why am I using TEZSPIRE?
2. What should I know before I use TEZSPIRE?
3. What if I am taking other medicines?
4. How do I use TEZSPIRE?
5. What should I know while using TEZSPIRE?
6. Are there any side effects?
7. Product details

1. Why am I using TEZSPIRE?

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 and chronic rhinosinusitis with nasal polyps (CRSwNP). This medicine works by blocking the action of TSLP.**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 the current Asthma medicines.** TEZSPIRE may reduce the number of asthma attacks you experience, improve your breathing and reduce your asthma symptoms.

TEZSPIRE is also used with other medicines to treat CRSwNP in adults (18 years of age and older). 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 should I know before I use TEZSPIRE?

Warnings

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**.

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 swelling of your face, tongue or mouth, breathing problems, fainting, dizziness, feeling lightheaded, hives, and rash). If you notice any of these signs, speak to your healthcare provider immediately.
- 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.

If you already have a serious infection during treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

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.

Children

Do not use TEZSPIRE in patients under 12 years old for asthma and under 18 years old for CRSwNP.
The safety and benefits of this medicine are not known in children below the specified ages.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking or have recently taken 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.

4. How do I use TEZSPIRE?

How much and when to use

- The recommended dose is 210 mg every 4 weeks.
- Follow the instructions provided and use TEZSPIRE exactly as your doctor has instructed you.

How to use TEZSPIRE

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.

If you forget to use TEZSPIRE

TEZSPIRE should be used regularly at the same time on the day of administration.

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.

If you use too much TEZSPIRE

If you are concerned that you have used too much TEZSPIRE, you should contact your doctor, nurse or pharmacist immediately.

Telephone the Poisons Information Centre (by calling 13 11 26) for advice if you think that you have taken too much TEZSPIRE.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using TEZSPIRE?

Things you should 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.

- 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.

- 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; or feeling lightheaded or faint. If you notice any of these symptoms, speak to a doctor or nurse immediately.

Things you should 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.

Driving or using machines

It is unlikely that TEZSPIRE will affect your ability to drive and use machines.

Looking after your medicine

- 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. This is important whether travelling by car, bus, train,

plane or any other form of transport. 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.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

When to discard your medicine

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

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.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

6. Are there any side effects?

All medicines can have side effects, although not everybody gets them. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

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

Less serious side effects	What to do
• Sore throat (pharyngitis) • Injection site reaction (i.e. redness, swelling, and pain) • Joint pain (arthralgia) • Rash	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Serious side effects

Serious side effects	What to do
Allergic reaction - some of the symptoms of an allergic reaction may include: • rash, itching or hives on the skin • swelling of the face, lips, tongue or other parts of the body	**Call your doctor or nurse straight away, or go straight to the Emergency Department at your nearest hospital.** You may need urgent medical attention or hospitalisation.

Serious side effects	What to do
• shortness of breath, wheezing or difficulty breathing • fainting, dizziness, feeling lightheaded (due to a drop in blood pressure) Allergic reactions may occur within minutes or hours after an injection or may even occur several days after an injection.	

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.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What TEZSPIRE contains

Active ingredient (main ingredient)	tezepelumab
Other ingredients (inactive ingredients)	glacial acetic acid, proline, polysorbate 80, sodium hydroxide, water for injections.

Do not take this medicine if you are allergic to any of these ingredients.

What TEZSPIRE looks like

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

TEZSPIRE 210 mg/1.91 mL (100 mg/mL) solution for injection prefilled syringe (AUST R 427956).

TEZSPIRE 210 mg/1.91 mL (100 mg/mL) solution for injection prefilled pen (AUST R 432812).

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

Who distributes TEZSPIRE

AstraZeneca Pty Ltd
ABN 54 009 682 311
66 Talavera Road
MACQUARIE PARK NSW 2113

Telephone: 1800 805 342

This leaflet was prepared in July 2026.

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