

## 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 being given TEPEZZA?

TEPEZZA contains the active ingredient teprotumumab. TEPEZZA is used to treat Thyroid Eye Disease.

For more information, see Section [1. Why am I being given TEPEZZA?](#) in the full CMI.

### 2. What should I know before I am given TEPEZZA?

Do not use if you have ever had an allergic reaction to TEPEZZA 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. You must not use this medicine if you are pregnant.**

For more information, see Section [2. What should I know before I am given TEPEZZA?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with TEPEZZA and affect how it works.

For more information, see Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How will I be given TEPEZZA?

- The dose of TEPEZZA depends on your body weight.
- A doctor or nurse will give you a diluted TEPEZZA solution by intravenous infusion (drip into your vein).

More instructions can be found in Section [4. How will I be given TEPEZZA?](#) in the full CMI.

### 5. What should I know while using TEPEZZA?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist, optometrist or pharmacist you visit that you are using TEPEZZA.</li><li>• Tell your doctor immediately if you become pregnant while taking TEPEZZA. If you are a woman who is able to become pregnant, use suitable methods of contraception and have pregnancy tests during treatment with TEPEZZA and for 6 months after your last dose.</li><li>• Speak to your doctor, nurse or hearing service if you notice changes in your hearing.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• You must not use TEPEZZA if you are pregnant.</li><li>• Do not stop treatment with TEPEZZA unless you have discussed this with your doctor.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Do not drive a car or operate machines if you experience symptoms that impair your ability to drive or operate machinery</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• TEPEZZA will be stored at the hospital or clinic in a refrigerator.</li></ul>

For more information, see Section [5. What should I know while using TEPEZZA?](#) in the full CMI.

### 6. Are there any side effects?

Very common side effects include high blood sugar, hearing impairment, muscle spasms, nausea, hair loss, diarrhoea, headache, fatigue, menstrual disorders. Common side effects include infusion-related reactions, change in the sense of taste, dry skin, ear discomfort, COVID-19, nail disorder.

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](http://www.tga.gov.au/reporting-problems).

# TEPEZZA®

Active ingredient(s): *teprotumumab*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using TEPEZZA. **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 TEPEZZA.**

Where to find information in this leaflet:

1. [Why am I being given TEPEZZA?](#)
2. [What should I know before I am given TEPEZZA?](#)
3. [What if I am taking other medicines?](#)
4. [How will I be given TEPEZZA?](#)
5. [What should I know while using TEPEZZA?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

### 1. Why am I being given TEPEZZA?

**TEPEZZA contains the active ingredient teprotumumab.** TEPEZZA is a humanised monoclonal antibody. Monoclonal antibodies attach to specific proteins in your body. Teprotumumab is designed to bind to a protein called type 1 insulin-like growth factor receptor (IGF-1R). When teprotumumab binds to IGF-1R it blocks its activation and signaling.

**TEPEZZA is used to treat Thyroid Eye Disease. It works by blocking the pathways that cause the inflammation associated with Thyroid Eye Disease.**

### 2. What should I know before I am given TEPEZZA?

#### Warnings

**Do not use TEPEZZA if:**

- you are allergic to teprotumumab, or any of the ingredients listed at the end of this leaflet
- you are pregnant

Always check the ingredients to make sure you can use this medicine.

**Check with your doctor if you:**

- have any other medical conditions
- take or might take any medicines (includes medicines obtained without a prescription and herbal medicine) for any other conditions
- have previously experienced problems after injections, such as breathlessness, increased heart rate, increased blood pressure, headache or muscle pain

- have previously experienced problems with your hearing
- suffer from inflammatory bowel disease (IBD)
- have pre-existing diabetes or impaired glucose tolerance

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



Check with your doctor if you are pregnant, think you may be pregnant or intend to become pregnant. Check with your doctor if you have changes in your menstrual cycle (periods) during treatment with TEPEZZA. You must not use this medicine if you are pregnant. TEPEZZA may cause harm to your unborn baby. Your doctor should advise you about using contraception during treatment with TEPEZZA and for at least 6 months after the last dose of TEPEZZA. Your doctor will recommend that you have pregnancy tests before, during and after treatment with TEPEZZA.

#### Breastfeeding

Talk to your doctor if you are breastfeeding or intend to breastfeed.

#### Children and adolescents

TEPEZZA is not recommended in children and adolescents under 18 years of age because the safety and benefit have not been established in these patient populations.

#### Hearing



TEPEZZA may cause hearing loss or impairment. This is usually temporary but in a very small number of people it can be permanent. Your doctor, nurse or hearing service will assess your hearing before, during and after treatment with TEPEZZA.

You should stop smoking and avoid high intensity noises during treatment with TEPEZZA. Speak to your doctor,

nurse or hearing service if you notice any changes in your hearing.

### 3. What if I am 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.

Taking medicines known to cause hearing damage may cause increased risk of hearing loss during treatment with TEPEZZA.

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

### 4. How will I be given TEPEZZA?

#### How much you will be given

- The dose of TEPEZZA depends on your body weight. The recommended dose is 10 mg per kilogram of your body weight for the first dose. You will be given a further 7 infusions at three weekly intervals with a recommended dose of 20 mg per kilogram of body weight.

#### When you will be given TEPEZZA

- A doctor or nurse will give you a diluted TEPEZZA solution by intravenous infusion (drip into your vein). The first two infusions will usually last about 90 minutes. If these are well-tolerated further infusions may be given to you over a period of 60 minutes. If they are not well-tolerated, the minimum time for the remaining 6 infusions should stay at 90 minutes.

#### If a dose of TEPEZZA is missed

Your doctor will decide when you should be given your next dose of TEPEZZA. You should discuss this with your doctor.

#### If too much TEPEZZA is given

As TEPEZZA is given to you under the supervision of your doctor, it is unlikely that you will receive too much. If this happens, your doctor will monitor you for any signs or symptoms of side effects, and treat these symptoms if necessary.

However, if you experience severe side effects after being given this medicine, tell your doctor or nurse immediately.

You may need urgent medical attention.

#### You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

### 5. What should I know while using TEPEZZA?

#### Things you should do

- Remind any doctor, dentist, optometrist or pharmacist you visit that you are using TEPEZZA.
- Tell your doctor immediately if you become pregnant while having TEPEZZA. If you are a woman who is able to become pregnant, use suitable methods of contraception during treatment with TEPEZZA and for 6 months after your last dose.
- Tell your doctor if you have changes in your menstrual cycle (periods) while having TEPEZZA so they can check you are not pregnant.
- Speak to your doctor, nurse or hearing service if you notice any changes in your hearing.

#### Call your doctor straight away if you:

- If you have an allergic reaction, the signs may include: difficulty in breathing or chest pain. You could also experience redness or flushing of the skin or a rash, chills and shivering, feeling or being sick, swelling, light headedness, fast heartbeat and loss of consciousness.

#### Things you should not do

- You must not use TEPEZZA if you are pregnant.
- Do not stop treatment with TEPEZZA unless you have discussed this with your doctor.

#### If you have the below pre-existing conditions:

- Hearing impairment  
Treatment with TEPEZZA may worsen your hearing if you have problems with hearing. Your doctor, nurse or hearing service will monitor your hearing while you are being treated with TEPEZZA. Speak to your doctor, nurse or hearing service if you notice changes in your hearing.
- Inflammatory bowel disease (IBD)  
It is possible that TEPEZZA may cause a worsening of your symptoms. Your doctor or nurse will monitor you for any signs of a flare of the disease and if necessary, discontinue treatment with TEPEZZA.
- Diabetes or impaired glucose tolerance  
TEPEZZA may cause hyperglycaemia or increased blood glucose. Your doctor or nurse will monitor glucose levels whilst you are being treated with TEPEZZA. If you have diabetes your doctor will ensure that your diabetes is under control before starting TEPEZZA.

#### Driving or using machines

**Be careful before you drive or use any machines or tools until you know how TEPEZZA affects you.**

Do not drive a car or operate machines if you experience symptoms that impair your ability to drive or use machinery.

## Looking after your medicine

Follow the instructions in the carton on how to take care of your medicine properly.

- TEPEZZA will be stored by the healthcare professionals at the hospital or clinic in a refrigerator.
- Store TEPEZZA in a refrigerator (2°C – 8°C). Do not freeze.
- Keep TEPEZZA in the original pack to protect from light.

Keep it where young children cannot reach it.

## Getting rid of any unwanted medicine

TEPEZZA is for single use in one patient only. Any residue will need to be discarded. Your doctor or nurse will dispose of TEPEZZA that is no longer used.

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

Do not use this medicine after the expiry date.

## 6. Are there any side effects?

All medicines can have side effects. 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
<p><b>Gut and digestion:</b></p> <ul style="list-style-type: none"> <li>• Nausea</li> <li>• Diarrhoea</li> </ul> <p><b>Muscle and skeletal:</b></p> <ul style="list-style-type: none"> <li>• Muscle spasms</li> </ul> <p><b>Skin (and nails):</b></p> <ul style="list-style-type: none"> <li>• Dry skin</li> <li>• Nail disorders (changes in nail colour or broken nails)</li> </ul> <p><b>Ears and mouth:</b></p> <ul style="list-style-type: none"> <li>• Change in the sense of taste</li> </ul> <p><b>Others:</b></p> <ul style="list-style-type: none"> <li>• High blood sugar</li> <li>• Hair loss</li> <li>• Headache</li> <li>• Fatigue</li> <li>• Changes in menstrual cycle (missing or irregular period(s), lighter periods, menstrual cramps, or heavy menstrual bleeding)</li> <li>• COVID-19</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

## Possibly serious side effects

Possibly serious side effects	What to do
<p><b>Ears and mouth</b></p> <ul style="list-style-type: none"> <li>• Hearing difficulties including hearing loss (deafness, including hearing loss due to inner ear or nerve damage; muffled hearing; hearing your own voice louder than normal; sensitivity to particular sounds; partial loss of hearing; ringing in the ears; or damage to the ear drum). Hearing difficulties may be permanent.</li> <li>• Ear discomfort (ear pressure, ear fullness, feeling of blocked ears or feeling of clogged/plugged ears)</li> </ul>	<p><b>Speak to your doctor, nurse or hearing service if you notice changes in your hearing.</b></p>

## Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> <li>• <b>Infusion-related reactions:</b></li> <li>• Fast heartbeat</li> <li>• Difficulty breathing/chest pain</li> <li>• Redness or flushing of the skin or rash</li> <li>• Chills and shivering</li> <li>• Nausea (feeling of being sick)</li> <li>• Swelling</li> <li>• Light headedness</li> <li>• Loss of consciousness</li> </ul> <p><b>Other:</b></p> <ul style="list-style-type: none"> <li>• Inflammatory bowel disease (inflammation of the digestive tract)</li> <li>• Diabetic ketoacidosis (body produces excess blood acids triggered by uncontrolled blood sugar. Symptoms can include excessive thirst, vomiting, feeling tired or confused, stomach pain, faster or deeper breathing, fruity-smelling breath)</li> <li>• Hyperosmolar hyperglycaemic state (Sugar levels are very high for a long time. This can lead to extreme thirst due to loss of water in the body and altered consciousness, varying from confusion to coma)</li> </ul>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></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.

## 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](http://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 TEPEZZA contains

<b>Active ingredient (main ingredient)</b>	teprotumumab
<b>Other ingredients (inactive ingredients)</b>	histidine histidine hydrochloride monohydrate polysorbate 20 trehalose dihydrate

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

### What TEPEZZA looks like

TEPEZZA is a white to off white powder containing 500 mg of teprotumumab supplied in a single-dose vial. Each pack contains one vial.

(AUST R 444610).

### Who distributes TEPEZZA

Amgen Australia Pty Ltd  
Level 11, 10 Carrington St  
Sydney NSW 2000  
Ph: 1800 803 638

[www.amgenmedinfo.com.au](http://www.amgenmedinfo.com.au)

To check for CMI updates and obtain the latest version scan this QR code:



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