Package leaflet: Information for the patient **EN**

TEPEZZA 500 mg powder for concentrate for solution for infusion
teprotumumab

▼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. See the end of section 4 for how to report side effects.

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 or nurse.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

MCK07001

AMGEN TEPEZZA® EN

MCK07001

1. What TEPEZZA is and what it is used for

TEPEZZA is a medicine that contains the active substance teprotumumab, which 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.

What is TEPEZZA used for

TEPEZZA is used to treat adults with moderate to severe Thyroid Eye Disease (TED).

What is Thyroid Eye Disease

Thyroid Eye Disease (TED) is anautoimmune condition where your immune system attacks the muscles and fat around the eyes. A protein called IGF-1R is found in the muscles and fat around the eyes. These muscles and fat help cushion the eyes and support their movement. In Thyroid Eye Disease, the immune system activates IGF-1R, causing inflammation and swelling in these tissues. This swelling pushes the eyes forward, causing them to bulge. It can also result in double vision, and in severe cases, may cause permanent vision damage.

2. What you need to know before you are given TEPEZZA

Do not use TEPEZZA

- if you are allergic to teprotumumab or any of the other ingredients of this medicine (listed in section 6).
- if you are pregnant.

If you are not sure, talk to your doctor or nurse before being given TEPEZZA.

Warnings and precautions

Talk to your doctor or nurse before you are given TEPEZZA.

- It is possible that TEPEZZA can cause an infusion reaction (reactions related to your injection of medicine). These reactions are usually mild but please let your doctor or nurse know if you have previously experienced problems after injections, such as breathlessness, increased heart rate, increased blood pressure, headache or muscle pain.
- It is possible that TEPEZZA may cause a worsening of your symptoms if you suffer from inflammatory bowel disease (IBD). Your doctor or nurse will monitor you for any signs of a flare of the disease and if necessary, discontinue treatment with TEPEZZA.
- TEPEZZA may cause hyperglycaemia or increased blood glucose, especially if you have pre-existing diabetes or impaired glucose tolerance. Your doctor or nurse will monitor glucose levels whilst you are being treated with TEPEZZA. If you have pre-existing diabetes your doctor will ensure that your diabetes is under control before starting TEPEZZA.
- It is possible that TEPEZZA may cause severe hearing loss or impairment. Before starting treatment, please tell your doctor if you have ever had any of the following:
  - Hearing problems or if you use hearing aids
  - Sensitivity to loud noises
  - A history of smoking

Your doctor will check your hearing before you start treatment and explain any potential side effects related to hearing and to stop smoking if you haven't already.

Your doctor will continue to monitor your hearing during and after treatment with TEPEZZA. If you notice any changes in your hearing, please contact your doctor immediately.

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.

Other medicines and TEPEZZA

Tell your doctor or nurse if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription and herbal medicines.

Pregnancy and breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or nurse for advice before using this medicine.

You must not use this medicine if you are pregnant. TEPEZZA may cause damage 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.

Women of childbearing potential
The use of highly effective contraception during treatment and up to at least 6 months after treatment should be considered in women who are able to get pregnant.

Driving and using machines

While you are being treated with TEPEZZA you may experience fatigue or headaches. This may impair your ability to drive or use machines. Do not drive a car or operate machines if you have these symptoms.

3. How TEPEZZA is given

This medicine is given in a heathcare facility under the supervison of a healthcare profesional.

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 receive additional 7 infusions at three weekly intervals with a recommended dose of 20 mg per kilogram of body weight.

For the first 2 infusions, the diluted solution is administered as an intravenous infusion (drip into your vein) over at least 90 minutes. If well-tolerated, infusions 3 to 8 can be administered over 60 minutes every three weeks.

If too much TEPEZZA is given

If this happens, your doctor will monitor you for any signs or symptoms of side effects, and treat these symptoms if necessary.

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 you stop treatment with TEPEZZA

Do not stop treatment with TEPEZZA unless you have discussed this with your doctor.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Serious side effects:

Infusion related reactions (may affect up to 1 in 10 people)
If you have an infusion related reaction, tell your doctor or nurse straight away. Your doctor will decide if you need to interrupt or stop treatment and when it's safe to start it again (see section 2 Warnings and precautions).

Deafness (may affect up to 1 in 10 people)
Tell your doctor immediately, if you experience deafness in one or both ears.

Exacerbation of inflammatory bowel disease (may affect up to 1 in 100 people)
TEPEZZA may cause worsening of inflammation of the digestive tract. Symptoms may include an increased number of loose stools with stomach pain or cramps, or blood in your stools.
Tell your doctor immediately. Your doctor will decide if you need to stop treatment.

Diabetic ketoacidosis (may affect up to 1 in 100 people)

These are the signs of diabetic ketoacidosis (see also section 2 Warnings and precautions):

- increased levels of "ketone bodies" in your blood
- excessive thirst
- queasiness or vomiting
- feeling tired or confused
- stomach pain
- faster or deeper breathing
- fruity-smelling breath.

Contact your doctor immediately, if you develop any of these symptoms while being treated with TEPEZZA.

Other side effects:

Most of the following side effects are mild to moderate. If any of these side effects become severe, tell your doctor or nurse.

Very common (may affect more than 1 in 10 people)
- High blood sugar (hyperglycaemia)
- Muscle spasms
- Feeling queasy, like you need to vomit (nausea)
- Hair loss (alopecia)
- Diarrhoea
- Headache
- Feeling extremely tired or lacking energy (fatigue)

Common (may affect up to 1 in 10 people)
- Change in the sense of taste (dysgeusia)
- Dry skin
- Feeling of blocked ears, or pressure in the ear (ear discomfort)
- COVID-19
- Problems with the tissue underneath the nail (nail bed disorder)
- Discolouring of the nails
- Nail splitting or breaking (onychoclasis)
- Loss of body weight.
- Partial loss of hearing (hypoacusis)
- Ringing in the ears (tinnitus)
- Hearing your own voice louder than normal (autophony, eustachian tube patulous), muffled hearing (eustachian tube dysfunction), hearing loss due to inner ear or nerve damage (neurosensory hypoacusis)
- Missing one or more periods (amenorrhea)
- Irregular periods
- Heavy periods
- Lighter periods (hypomenorrhea)
- Pain or cramping during your period (dysmenorrhea)

Uncommon (may affect up to 1 in 100 people)
- Ingrowing nail
- Damage to the ear drum (Tympanic membrane disorder)
- Sensitivity to particular sounds (Hyperacusis)

Not known (frequency cannot be estimated from the available data)
- Very high blood sugar levels for a long time – symptoms can include excessive thirst and altered levels of consciousness (hyperosmolar hyperglycaemic state).

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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

5. How to store TEPEZZA

TEPEZZA will be stored by the healthcare professionals at the hospital or clinic.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the outer carton and on the vial label after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C – 8°C).
Do not freeze.
Keep the vial in the outer carton in order to protect from light.

Infusion solutions should be used immediately after dilution. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and should not be longer than 4 hours at 20°C to 25°C or up to 48 hours at 2°C to 8°C.

Do not use this medicine if you notice any particulate matter of discolouration prior to administration.

Do not throw away any medicines via wastewater or household waste. 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 TEPEZZA contains

- The active substance is teprotumumab.
- Each vial contains 500 mg powder for concentrate for solution for infusion
- The other ingredients are Histidine, histidine hydrochloride monohydrate, polysorbate 20 (E432) and trehalose dihydrate.

What TEPEZZA looks like and contents of the pack

TEPEZZA is a powder for concentrate for solution, which is supplied in a glass vial with a rubber stopper containing 500 mg of teprotumumab. The powder is a white to off white powder for concentration for solution for infusion supplied in a single-dose vial. Each pack contains one vial.

Marketing Authorisation Holder
Amgen Limited,
216 Cambridge Science Park,
Milton Road,
Cambridge,
CB4 0WA,
United Kingdom

Manufacturer
Horizon Therapeutics Ireland DAC
Pottery Road
Dun Laoghaire
Co. Dublin
A96 F2A8
Ireland

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

Amgen Limited
Tel: +44 (0)1223 420305

This leaflet was last revised in March 2025.

The following information is intended for healthcare professionals only:

Posology and method of administration

Preparation of the medicinal product before administration

Step 1: Calculate the dose (mg) and determine the number of vials needed for the 10 or 20 mg/kg dosage based on patient weight. Each TEPEZZA vial contains 500 mg of the teprotumumab antibody.

Step 2: Using appropriate aseptic technique, reconstitute each TEPEZZA vial with 10 mL of sterile water for injection. Ensure that the stream of diluent is not directed onto the lyophilised powder, which has a cake-like appearance. Do not shake, but gently swirl the solution by rotating the vial until the lyophilised powder is dissolved. The reconstituted solution has a total volume of 10.5 mL. Withdraw 10.5 mL of reconstituted solution to obtain 500 mg. After reconstitution, the final concentration is 47.6 mg/mL.

Step 3: The reconstituted TEPEZZA solution must be further diluted in sodium chloride 9 mg/mL (0.9%) solution for infusion, prior to infusion. To prepare the diluted solution, use 100 mL infusion bags for a dose less than 1800 mg, and 250 mL infusion bags for a dose equal of greater than 1800 mg. To maintain a constant volume in the infusion bag, a sterile syringe and needle should be used to remove the volume equivalent to the amount of the reconstituted TEPEZZA solution to be placed into the infusion bag. Discard the volume of sodium chloride 9 mg/mL (0.9%) solution for infusion withdrawn.

Step 4: Withdraw the required volume from the reconstituted TEPEZZA vial(s) based on the patient's weight (in kg) and transfer into an intravenous bag containing sodium chloride 9 mg/mL (0.9%) solution for infusion. Mix diluted solution by gentle inversion. Do not shake. If refrigerated prior to administration, allow the diluted solution to reach room temperature prior to infusion.

Care should be taken to ensure the sterility of the prepared solution.

Appearance on reconstitution
After reconstitution, TEPEZZA is a colourless or slightly brown, clear to opalescent solution which is free of foreign particulate matter. The reconstituted solution should be inspected for particular matter and discolouration prior to administration. Discard the solution if particulate matter is present or discolouration is observed.

Stability of reconstituted solution
The product does not contain any preservative. The combined storage time of reconstituted TEPEZZA solution in the vial and the diluted solution in the infusion bag containing sodium chloride 9 mg/mL (0.9%) is a total of 4 hours at 20°C to 25°C or up to 48 hours at 2°C to 8°C protected from light. If refrigerated prior to administration, allow the diluted solution to reach room temperature prior to infusion.

Administration
Administer the diluted solution intravenously over a period of 90 minutes for the first two infusions. If well tolerated, the minimum time for subsequent infusions can be reduced to 60 minutes. If not well tolerated, the minimum time for subsequent infusions should remain at 90 minutes.

Do not administer as an intravenous push or bolus. TEPEZZA should not be infused concomitantly with other agents.

Special precautions for disposal and other handling

Care should be taken to ensure the sterility of the prepared solution.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Amgen Information Panel (Legend)		**Colors** (Printing)	**Technical Colors** (Non-Printing)
Product name:	Tepezza	PROCESS BLACK ■	DIE CUT ■
Specification:	PCS-006033		TECHNICAL INFO ■
Component type:	Leaflet		NO VARNISH ■
Scale:	1 to 1		
Dimensions:	512 mm x 360 mm		