TEMAZE®

Consumer Medicine Information (CMI) summary

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

1. Why am I taking TEMAZE?

TEMAZE contains the active ingredient temazepam. TEMAZE is used to treat sleeping problems, also called insomnia.

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

2. What should I know before I take TEMAZE?

Do not take if you have ever had an allergic reaction to TEMAZE 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 take TEMAZE? in the full CMI.

3. What if I am taking other medicines?

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

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I take TEMAZE?

- The dose of TEMAZE varies from patient to patient.
- Your doctor will tell you how many tablets, you need to take each day and when to take them.
- Swallow TEMAZE with a glass of water. It can be taken with or without food.

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

5. What should I know while taking TEMAZE?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are taking TEMAZE.

	• Tell your doctor if you feel this medicine is not helping your condition. • If you plan to have surgery (that needs a general anaesthetic), including dental surgery, tell your doctor or dentist that you are taking TEMAZE.
Things you should not do	• Do not stop taking this medicine or change the dose, without first checking with your doctor. • Do not take TEMAZE for a longer time than your doctor has prescribed.
Driving or using machines	• Do not drive or operate machinery until you know how TEMAZE affects you. • TEMAZE may cause drowsiness or dizziness in some people.
Drinking alcohol	• Be careful when drinking alcohol while taking TEMAZE. • Combining TEMAZE and alcohol can make

	you more sleepy, dizzy or light-headed.
Looking after your medicine	• Keep your medicine in a cool dry place where the temperature stays below 25°C. • Keep your tablets in the blister pack until it is time to take them. • Keep it where children cannot reach it.

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

6. Are there any side effects?

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking TEMAZE.

Some mild side effects include dizziness, drowsiness, light-headedness, headache, nausea, stomach pain and dry mouth.

Some serious side effects which may require medical attention include confusion, loss of memory, disorientation, behavioural or mood changes, signs of frequent infections such as fever, and yellowing of the eyes and skin (jaundice).

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.

TEMAZE®

Active ingredient: temazepam

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I taking TEMAZE?

TEMAZE contains the active ingredient temazepam. TEMAZE is a benzodiazepine which is thought to work by acting on the brain chemicals.

TEMAZE is used to treat sleeping problems, also called insomnia.

Ask your doctor if you have any questions about why TEMAZE has been prescribed for you.

Your doctor may have prescribed TEMAZE for another reason.

2. What should I know before I take TEMAZE?

In general, benzodiazepines such as TEMAZE should be taken for short periods only (for example 2 to 4 weeks). Continuous long-term use is not recommended unless advised by your doctor.

The use of benzodiazepines may lead to dependence on the medicine.

Warnings

Do not take TEMAZE if:

- you are allergic to temazepam, or any other benzodiazepine medicines or any of the ingredients listed at the end of this leaflet. Some of the symptoms of an allergic reaction may include:
  - skin rash, itching or hives
  - swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing
  - wheezing or shortness of breath

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

- you have severe and chronic lung disease or breathing difficulties
- you have sleep apnoea, a condition where you have breathing problems when you sleep
- you suffer from depression with or without anxiety problems. Temazepam can increase the thoughts of death or suicide
- the packaging shows signs of tampering or the tablets do not look quite right
- the expiry date (EXP) printed on the pack has passed.

Check with your doctor if you:

- have any medical conditions, especially the following:
  - liver, kidney or lung problems
  - epilepsy, fits or convulsions
  - severe muscle weakness known as myasthenia gravis
  - low blood pressure as it may lead to heart or brain complications
  - any blood disorder
  - glaucoma (increased pressure in the eye)
  - depression, psychosis or schizophrenia
  - drug or alcohol dependence or a past history of these problems
  - lactose intolerance

  Your doctor may want to take special care if you have any of these conditions.
- take any medicines for any other condition

- are allergic to any other medicines, foods, dyes or preservatives
- plan to have surgery.

TEMAZE is not recommended for use in children under 16 years of age, as its safety and effectiveness have not been established in this age group.

Suddenly stopping TEMAZE in patients with epilepsy can cause a temporary increase in the number and severity of seizures.

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 or intend to become pregnant.

TEMAZE should not be taken during pregnancy.

It should be avoided during the first trimester of pregnancy as it may increase the risk of defects present at birth.

It may cause unwanted effects in the newborn baby if taken during the late phase of pregnancy or during childbirth, such as low muscle strength, shallow breathing and feeding problems.

Your doctor will discuss the risks and benefits of taking TEMAZE during pregnancy.

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

TEMAZE may pass into breast milk and cause drowsiness and feeding difficulties in the baby. Your doctor will discuss the risks and benefits of taking TEMAZE when breastfeeding.

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.

Some medicines may interfere with TEMAZE and affect how it works. These include:

- other sleeping tablets, sedatives or tranquilisers
- medicines for depression, schizophrenia and other mental illnesses
- medicines to treat epilepsy and fits
- medicines for allergies, for example antihistamines or cold tablets
- medicines used to treat Parkinson's disease
- theophylline, a medicine used to treat asthma
- muscle relaxants
- some pain relievers, such as opioid medicines
- medicines taken to relieve stomach cramps and to prevent motion sickness.

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

4. How do I take TEMAZE?

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet.

How much to take

- The dose of TEMAZE varies from patient to patient.
- Your doctor will tell you how many tablets you need to take each day. This depends on your condition and whether or not you are taking any other medicines.
- The usual starting dose is one 10 mg tablet each night.
- Elderly people over 65 years of age may need smaller doses.

When to take TEMAZE

- Take TEMAZE tablets one hour before going to bed.
- Your doctor will tell you when to take TEMAZE.
- This depends on your condition and whether or not you are taking any other medicines.

How long to take TEMAZE for

- Keep taking TEMAZE for as long as your doctor recommends.

- TEMAZE is usually used for short periods only (such as 2 to 4 weeks).
- Continuous long-term use is not recommended unless advised by your doctor. The use of benzodiazepines may lead to dependence on this medicine.

How to take TEMAZE

- Swallow TEMAZE with a glass of water.
- TEMAZE can be taken with or without food.

If you forget to take TEMAZE

TEMAZE should be taken regularly at the same time each day. If you forget to take TEMAZE before you go to bed and you wake up late in the night or early in the morning, do not take TEMAZE as you may have trouble waking in the morning.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

This may increase the chance of you getting an unwanted side effect.

If you are unsure about whether to take your next dose, speak to your doctor or pharmacist.

If you take too much TEMAZE

If you think that you or anyone else has taken too much TEMAZE, urgent medical attention may be needed.

If you take too much TEMAZE you may feel drowsy, confused, tired, dizzy, have difficulty breathing, feel weak, have low blood pressure, lack mobility and coordination, be unconscious, or rarely it may be fatal.

You should immediately:

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

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

5. What should I know while taking TEMAZE?

Things you should do

- Take TEMAZE exactly as your doctor has prescribed.
- If you have any blood tests, tell your doctor that you are taking TEMAZE. It may affect the result of some tests.
- Visit your doctor regularly so they can check on your progress. Your doctor will check your condition to see whether you should continue to take TEMAZE.

- Tell your doctor if you feel this medicine is not helping your condition.
- Keep enough TEMAZE to last weekends and holidays.
- Before starting any new medicine, tell your doctor or pharmacist that you are taking TEMAZE.
- If you plan to have surgery (that needs a general anaesthetic), including dental surgery, tell your doctor or dentist that you are taking TEMAZE.

Be careful if you are elderly, unwell or taking other medicines.

Some people may experience side effects such as drowsiness, confusion, dizziness and unsteadiness, which may increase your risk of a fall.

Remind any doctor, dentist or pharmacist you visit that you are taking TEMAZE.

Call your doctor straight away if you:

- feel this medicine is not helping your condition.
- become pregnant while you are taking TEMAZE.

All thoughts of suicide must be taken seriously. Tell your doctor or a mental health professional immediately if you have any suicidal thoughts or other mental/mood changes.

Things you should not do

- Do not take TEMAZE for a longer time than your doctor has prescribed.

TEMAZE should be taken for short periods only (for example 2 to 4 weeks) unless advised otherwise by your doctor.

- Do not use this medicine to treat any other complaints unless your doctor tells you to.
- Do not give it to anyone else, even if they have the same condition as you.
- Do not stop taking your medicine or change the dose, without first checking with your doctor.

  Stopping TEMAZE suddenly may cause some unwanted withdrawal effects. It is more common in patients that have received high doses over long periods of time.

  Withdrawal symptoms include insomnia, anxiety, unusual mood, panic attacks, dizziness, light sensitivity, confusion, (seeing or hearing things that are not real (hallucinations), vomiting, sweating, fits (convulsions), a feeling of loss of identity/feeling detached from yourself (depersonalisation or derealisation) and loss of short-term memory.

  Your doctor may want you to gradually reduce the amount you are taking before stopping completely. This may help reduce the possibility of unwanted side effects.

If you suffer from epilepsy, do not suddenly stop taking TEMAZE. Stopping this medicine may make your epilepsy worse.

Driving or using machines

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

TEMAZE may cause drowsiness or dizziness in some people. Even though you may take TEMAZE at night, you may still be drowsy or dizzy the next day.

Make sure you know how you react to TEMAZE before you drive a car, operate machinery, or do anything else that could be dangerous if you are drowsy, dizzy or not alert. This is very important if you are taking other drugs that also make you drowsy.

Drinking alcohol

Tell your doctor if you drink alcohol.

Combining TEMAZE and alcohol can make you more sleepy, dizzy or light-headed or increase the risk of sleep walking and some other related sleep behaviours which may include sleep-driving, making phone calls, or preparing and eating food while asleep.

This risk is also increased if you take more than the recommended dose.

Your doctor may suggest that you avoid alcohol or reduce the amount of alcohol you drink while you are taking TEMAZE.

Looking after your medicine

- Keep your tablets in the blister pack until it is time to take them, otherwise they may not keep well.
- Store below 25°C.

Follow the instructions on 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.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Getting rid of any unwanted medicine

If your doctor tells you to stop taking TEMAZE or the tablets have passed their expiry date, ask your pharmacist what to do with any tablets left over.

Do not take this medicine after the expiry date.

6. Are there any side effects?

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking TEMAZE even if you do not think that it is connected with the medicine.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

If you are over 65 years of age, you may have an increased chance of getting 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
• dizziness, daytime drowsiness, feeling tired • light-headedness or feeling faint • headache • nausea, vomiting, stomach pain, dry mouth • depression, irritability, vivid dreams • unpleasant dreams • slurred speech • blurred vision • leg cramps, weakness	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Less serious side effects	What to do
• tingling or numbness of the hands or feet • tremor • change in libido or sex drive • clumsiness, lack of coordination	

Serious side effects

Serious side effects	What to do
• confusion, loss of memory, disorientation • behavioural or mood changes such as sudden outbursts of anger and increased excitement • signs of frequent infections such as fever, chills, sore throat or mouth ulcers • yellowing of the eyes and skin (jaundice) • dark coloured urine • fast, irregular or pounding heart beats	**Call your doctor straight away if you notice any of these serious side effects.**

Serious side effects	What to do
• unusual bleeding or bruising	

Very serious side effects

Very serious side effects	What to do
• fainting • hallucinations • any type of skin rashes, itching or hives • swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing • wheezing or shortness of breath	**Tell your doctor immediately or go straight to the Emergency Department at your hospital if you notice any of these very serious side effects.**

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.

Some of these side effects can only be found when your doctor does tests from time to time to check your progress.

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 TEMAZE contains

Active ingredient **(main ingredient)**	temazepam 10 mg
Other ingredients **(inactive ingredients)**	lactose monohydrate microcrystalline cellulose maize starch magnesium stearate Sunset Yellow FCF Aluminium Lake

Potential allergens	sugars as lactose and traces of sulfites

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

What TEMAZE looks like

TEMAZE 10 mg: 5.5 mm flat bevel edged light orange tablet, debossed TE over 10 on one side, alpha symbol on the other. (AUST R 408408).

Each blister pack contains 25 tablets.

Who distributes TEMAZE

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

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