Temaze

contains the active ingredient temazepam

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about Temaze.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking Temaze against the benefits expected for you.

If you have any concerns about taking this medicine, talk to your doctor or pharmacist.

Keep this leaflet with your medicine.

You may need to read it again.

What Temaze is used for

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

Temaze belongs to a group of medicines called benzodiazepines. These medicines are thought to work by their action on brain chemicals.

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.

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

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.

Temaze is available only with a doctor's prescription.

Before you take Temaze

When you must not take it

Do not take Temaze if you are allergic to:

* temazepam or any other benzodiazepine medicine
* 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.

Do not take Temaze if you have:

* severe lung disease or breathing difficulties
* sleep apnoea, a condition where you have breathing problems when you sleep.

Do not take Temaze after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

Tell your doctor if you are pregnant or plan to become pregnant.

The use of Temaze during pregnancy is not recommended and may increase the risk of complications in your baby. Your doctor will discuss the risks and benefits of taking Temaze during pregnancy.

Tell your doctor if you are breastfeeding or wish to breastfeed.

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

Tell your doctor if you have, any medical conditions, especially the following:

* severe muscle weakness known as myasthenia gravis
* glaucoma (increased pressure in the eye)
* depression, psychosis or schizophrenia
* epilepsy (fits or convulsions)
* low blood pressure
* liver, kidney or lung problems
* any blood disorder
* drug or alcohol dependence.

Your doctor may want to take special care if you have any of these conditions.

Tell your doctor if you drink alcohol regularly.

Alcohol may increase the effects of Temaze and make you more drowsy.

If you have not told your doctor about any of the above, tell them before you start taking Temaze.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines may be affected by Temaze, or may affect how well it works. These include:

* other sleeping tablets, sedatives or tranquillisers
* medicines for depression and other mental illnesses
* medicines used to treat epilepsy or fits
* medicines used to relieve stomach cramps and to prevent motion sickness
* antihistamines, medicines for allergies, hayfever or colds
* theophylline, a medicine used to treat asthma
* muscle relaxants
* some pain relievers.

Your doctor can tell you what to do if you are taking any of these medicines.

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking Temaze.

How to take Temaze

Follow all directions given to you by your doctor and pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the pack, ask your doctor or pharmacist.

How much to take

The dose varies from person to person.

The usual starting dose is one 10 mg tablet each night. Your doctor may adjust this dose depending on how you respond to this medicine. This depends on your condition and whether or not you are taking any other medicines.

Elderly people over 65 years of age may need smaller doses.

How to take it

Swallow the tablets whole with a full glass of water.

When to take it

Take Temaze tablets one hour before going to bed.

Temaze can be taken with or without food.

How long to take Temaze for

Keep taking Temaze for as long as your doctor recommends.

Usually, 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.

If you forget to take it

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.

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 not sure what to do or have any questions, ask your doctor or pharmacist.

If you take too much (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much Temaze. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you have taken too much Temaze, you may feel drowsy, tired, confused, dizzy, have difficulty breathing, feel weak or become unconscious.

While you are taking Temaze

Things you must do

Before starting any new medicine, tell your doctor or pharmacist that you are taking Temaze.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking Temaze.

If you become pregnant while taking Temaze, tell your doctor.

If you plan to have surgery (that needs a general anaesthetic), including dental surgery, tell your doctor or dentist that you are taking Temaze.

Visit your doctor regularly so they can check on your progress.

If you feel that Temaze is not helping your condition, tell your doctor.

Things you must not do

Do not drive or operate machinery until you know how Temaze affects you.

Temaze may cause drowsiness or dizziness in some people. Even though you take Temaze at night, you may still be drowsy or dizzy the next day. Make sure you know how Temaze affects you before you drive a car, operate machinery or do anything else that could be dangerous. This is very important if you are taking other drugs that also make you drowsy.

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 stop taking Temaze, or change the dose, without checking with your doctor.

Your doctor may want you to gradually reduce the amount of Temaze 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 suddenly may make your epilepsy worse.

Do not use Temaze to treat any other conditions unless your doctor tells you to.

Do not give Temaze to anyone else, even if they have the same condition as you.

Things to be careful of

Some sleep medicines may cause short-term memory loss. When this occurs, a person may not remember what has happened for several hours after taking the medicine. This is usually not a problem since most people fall asleep after taking the medicine. To reduce this risk, ensure that you are able to get a full night's sleep (7 to 8 hours) before you need to be active again.

Be careful when drinking alcohol while taking Temaze.

Combining Temaze and alcohol can make you more sleepy, dizzy or lightheaded, 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 whilst 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.

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 the risk of a fall.

Side effects

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

Temaze helps most people with sleeping problems, but it may have unwanted side effects in some people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

If you are over 65 years of age, you may have an increased chance of getting side effects.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

* daytime drowsiness, tiredness
* clumsiness, lack of coordination
* dizziness, headache
* upset stomach, nausea, vomiting, dry mouth
* loss of memory, confusion, disorientation
* depression, irritability, vivid dreams
* weakness, leg cramps
* tremor, faintness
* blurred vision
* change in libido or sex drive.

The list above includes the milder side effects of Temaze.

Tell your doctor as soon as possible if you notice any of the following:

* fast, irregular or pounding heart beats
* unusual bleeding or bruising
* frequent infections such as fever, severe chills, sore throat or mouth ulcers.

The above list includes serious side effects which may require medical attention. Serious side effects are rare.

Tell your doctor immediately or go to Accident and Emergency at the nearest hospital if you notice any of the following:

* sudden excitement or rage, aggression
* hallucinations
* difficulty breathing
* skin rash, severe itch, swelling of the face, lips or tongue.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Tell your doctor if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some patients. Some of these side effects can only be found when your doctor does tests from time to time to check your progress.

After taking Temaze

Storage

Keep Temaze where children cannot reach it.

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

Keep your tablets in the pack until it is time to take them.

If you take the tablets out of the pack they will not keep well.

Keep Temaze tablets in a cool dry place where the temperature stays below 30 degrees C.

Do not store Temaze or any other medicine in the bathroom or near a sink.

Do not leave Temaze in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking Temaze, or your medicine has passed its expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

Temaze tablets are round, white and marked "TE" over "10" on one side and a Greek alpha symbol on the other.

Each bottle contains 25 tablets.

Ingredients

The active ingredient in Temaze is temazepam.

Each Temaze tablet contains 10 mg of temazepam. The tablets also contain:

* lactose
* maize starch
* microcrystalline cellulose
* magnesium stearate.

The tablets are gluten free.

Manufacturer

Temaze is made in Australia by:

Alphapharm Pty Limited
(ABN 93 002 359 739)
Chase Building 2
Wentworth Park Road
Glebe NSW 2037
Phone: (02) 9298 3999

www.alphapharm.com.au

Medical Information
Phone: 1800 028 365

Australian registration numbers:
AUST R 63863

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