

APO-TEMAZEPAM

Contains the active ingredient, temazepam

For a copy of a large print leaflet, Ph: 1800 195 055

Consumer Medicine Information

What is in this leaflet

Read this leaflet carefully before taking your medicine. Ask your doctor or pharmacist if you do not understand anything or are worried about taking your medicine.

This leaflet answers some common questions about temazepam.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the last page. Some more recent information on your medicine may be available. Speak to your pharmacist or doctor to obtain the most up-to-date information.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

Keep this leaflet with your medicine.

You may want to read it again.

What temazepam is used for

The name of your medicine is Apo-Temazepam. It contains the active ingredient, temazepam.

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

In general, temazepam should be taken for short periods only (for example 2 - 4 weeks). Continuous long-term use is not recommended unless advised by your doctor. The use of benzodiazepines such as temazepam may lead to dependence on the medicine.

How it works

Temazepam belongs to a group of medicines called benzodiazepines. They are thought to work by acting on brain chemicals.

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

Your doctor may have prescribed temazepam for another reason.

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

Use in children

There is not enough information to recommend the use of this medicine in children.

Use when Driving or Operating Machinery

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

Temazepam may cause drowsiness or dizziness in some people.

Before you take temazepam

When you must not take it

Do not take this medicine if you have had an allergic reaction to temazepam, other benzodiazepines, or any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include: shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; muscle pain or tenderness or joint pain or rash, itching or hives on the skin.

Do not take this medicine if you have severe lung disease or breathing difficulties.

Do not take this medicine if you have sleep apnoea, a condition where you have breathing problems when you sleep.

Do not take this medicine if you are intolerant or allergic to lactose.

These tablets contain lactose.

Do not take this medicine after the expiry date (EXP) printed on the pack.

If you take this medicine after the expiry date has passed, it may not work as well.

Do not take this medicine if the packaging is torn, shows signs of tampering or if it does not look quite right.

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

Do not give this medicine to children unless advised by the child's doctor.

The safety and effectiveness of temazepam in children under 16 years have not been established.

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

Before you start to take it

Tell your doctor if:

1. You have allergies to:

- * any other medicines
- * any other substances, such as foods, preservatives or dyes.

2. You have or have had any medical conditions, especially the following:

- * liver, kidney or lung disease
- * blood disorders
- * encephalopathy, a type of brain disease
- * fits or convulsions (epilepsy)
- * severe muscle weakness, seen in a condition known as myasthenia gravis
- * low blood pressure
- * narrow angle glaucoma (high pressure in the eye)
- * depression, psychosis or schizophrenia
- * addiction to any drugs

3. You plan to become pregnant or breast-feed.

Do not take this medicine if you are or planning to become pregnant unless you and your doctor have discussed the risks and benefits involved.

Do not take this medicine if you are breastfeeding or planning to breastfeed unless you and your doctor have discussed the risks and benefits involved.

Temazepam may pass into breast milk and cause drowsiness and/or feeding difficulties in the baby.

4. You drink alcohol regularly.

Alcohol may increase the effects of temazepam.

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

Taking other medicines

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

Some medicines and temazepam may interfere with each other. These include:

- * other sleeping tablets, sedatives or tranquillisers
- * medicines for schizophrenia and similar disorders
- * medicines for depression
- * antihistamines, found in medicines for allergies or for colds
- * strong pain relievers
- * muscle relaxants
- * medicines to control fits
- * anaesthetics
- * medicines to help breathing (theophylline, aminophylline).

These medicines may be affected by temazepam or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist can tell you if you are taking any of these medicines. They may also have more information on medicines to be careful with or avoid while taking temazepam.

Other interactions not listed above may also occur.

How to take this medicine

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

They may be different to the information in this leaflet.

If you do not understand any written instructions, ask your doctor or pharmacist for help.

How much to take

Your doctor or pharmacist will tell you how many tablets you will need to take. This depends on your condition and whether or not you are taking any other medicines.

The recommended dose is 10 to 30 mg, taken half an hour before going to bed.

If you are elderly or unwell 10 mg is the usual starting dose.

How to take it

Swallow the tablets whole with a glass of water. Do not chew them.

When to take it

Take temazepam half an hour before going to bed in the evening.

It does not matter if you take it before, with or after food.

How long to take it for

Do not take temazepam for longer than your doctor says.

Temazepam is usually used for short periods only (for example 2 - 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.

Only take your medicine for as long as your doctor tells you.

If you forget to take it

If you forget to take temazepam before you go to bed and you wake

up late in the night or early morning, do not take any temazepam as you may have trouble waking in the morning. If you have any questions about this, ask your doctor or pharmacist.

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

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

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 for Australia) for advice, or go to the Accident and Emergency Department at the nearest hospital, if you think that you or anyone else may have taken too much temazepam.

Do this even if there are no signs of discomfort or poisoning.

Also report any other medicine or alcohol which has been taken with temazepam.

You may need urgent medical attention.

If you take too much temazepam, you may feel drowsy or excitable, confused, tired, dizzy, have difficulty breathing or speaking, feel weak, uncoordinated, or become unconscious.

While you are taking temazepam

Things you must do

Tell any other doctors, dentists, and pharmacists who are treating you that you are taking temazepam.

Tell your doctor if you are about to have an operation.

Temazepam and some anaesthetics can interfere with each other.

Tell your doctor immediately if you become pregnant.

Go to your doctor regularly for a check-up.

Your doctor needs to check your progress and see whether you need to keep taking temazepam.

Tell your doctor if you feel temazepam is not helping your condition.

Always discuss with your doctor any problems or difficulties during or after taking temazepam.

Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed.

Otherwise your doctor may think that it was not effective and change your treatment unnecessarily.

Things you must not do

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Do not take your medicine to treat any other complaints unless your doctor or pharmacist tells you to.

Do not stop taking your medicine suddenly, or change the dosage, without checking with your doctor.

Stopping this medicine suddenly may cause some unwanted effects. Your doctor will slowly reduce your dose of temazepam before you can stop taking it completely.

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

Temazepam may cause drowsiness or dizziness in some people and therefore may affect alertness.

Make sure you know how you react to temazepam before you drive a car, operate machinery, or do anything else that could be dangerous if you are drowsy, dizzy or not alert.

Even if you take temazepam at night, you may still be drowsy or dizzy the next day.

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

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

Do not suddenly stop taking temazepam if you suffer from epilepsy.

Stopping this medicine suddenly may make your epilepsy worse.

Things to be careful of

Be careful while driving or operating machinery until you know how temazepam affects you.

Be careful when drinking alcohol while taking temazepam.

Combining temazepam 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 while asleep.

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

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 of temazepam

All medicines may have some unwanted side effects. Sometimes they are serious, but most of the time, they are not. Your doctor has weighed the risks of using this

medicine against the benefits they expect it will have for you.

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

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

If side effects do happen, they are more likely to happen when you first start taking temazepam. These side effects may go away during treatment as your body adjusts to the dose.

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

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

- * dizziness, giddiness
- * headache
- * mild daytime drowsiness or tiredness

The above list includes the more common side effects. Mostly, these are mild.

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

- * feeling weak, unsteady or uncoordinated, slurred speech
- * feeling dizzy, confused or disorientated
- * faintness, shaking or tremors
- * leg cramps
- * skin rashes, hair loss
- * yellowing of the skin and/or eyes, also called jaundice
- * indigestion, constipation, feeling sick or vomiting
- * dry mouth, loss of taste
- * outbursts of anger, aggression, hostility, rage and increased excitement
- * feeling depressed, anxious, agitated or irritable
- * vivid dreams, nightmares, insomnia
- * hallucinations

- * memory loss, or doing things whilst not fully awake, and not remembering (e.g. sleep walking, making phonecalls, driving)
- * blurred or double vision
- * sexual problems
- * low blood pressure or body temperature
- * signs of frequent or worrying infections such as fever, severe chills, sore throat or mouth ulcers
- * feeling out of breath, or sleep apnoea getting worse
- * fast or irregular heartbeats

These may be serious side effects. You may need medical attention. Most of these side effects are rare.

If any of the following happen, do not take any more of your medicine and either tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- * allergic reaction, such as rash, itching or hives on the skin; swelling of the face, lips, tongue, mouth, throat or other parts of the body; shortness of breath, wheezing or difficulty swallowing or breathing
- * convulsions (fits)
- * thinking about or trying to commit suicide

These are very serious side effects. You may need urgent medical attention or hospitalisation.

Other side effects not listed above may occur in some patients.

Tell your doctor if you notice anything else that is making you feel unwell when you are taking, or soon after you have finished taking, temazepam.

Ask your doctor or pharmacist if you don't understand anything in this list.

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

After taking this medicine

Storage

Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it may not keep well.

Keep your medicine in a cool, dry place where the temperature will stay below 30 degrees C.

Do not store your medicine, or any other medicine, in a bathroom or near a sink.

Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it 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.

Disposal

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

Where to go for further information

Pharmaceutical companies are not in a position to give people an individual diagnosis or medical advice. Your doctor or pharmacist is the best person to give you advice on the treatment of your condition.

Product description

What Apo-Temazepam looks like

APO-Temazepam 10 mg tablets are orange, round, biconvex tablets, with stylised "S" on one side and plain on the other side. The tablets come in blister packs of 25.

Ingredients

Each tablet contains 10 mg of temazepam as the active ingredient.

It also contains the following inactive ingredients:

- * lactose
- * microcrystalline cellulose
- * maize starch
- * magnesium stearate
- * sunset yellow

This medicine is gluten-free, sucrose-free and tartrazine-free.

Australian Registration Numbers

APO-Temazepam 10 mg tablets

Blister packs

AUST R 153123

Distributor

Apotex Pty Ltd

66 Waterloo Road

North Ryde, NSW 2113

Australia

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This leaflet was prepared in:

July 2009.