

APO-TEMAZEPAM

temazepam 10 mg tablets

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about APO-TEMAZEPAM. It does not contain all of the available information.

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

All medicines have risks and benefits. Your doctor has weighed the risks of you taking APO-TEMAZEPAM against the benefits this medicine is expected to have for you.

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

Keep this leaflet with the medicine.

You may need to read it again.

What APO-TEMAZEPAM is used for

APO-TEMAZEPAM is used to treat sleeping problems, also called insomnia.

Your doctor, however, may have prescribed APO-TEMAZEPAM for another purpose. Ask your doctor if you have any questions about why APO-TEMAZEPAM has been prescribed for you.

APO-TEMAZEPAM belongs to a group of medicines called benzodiazepines. They are thought to work by their action on brain chemicals.

In general, benzodiazepines such as APO-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 may lead to dependence on the medicine.

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

Before you take it

When you must not take it

Do not take APO-TEMAZEPAM if:

- 1. you are allergic to:**
 - APO-TEMAZEPAM or any of the ingredients listed at the end of this leaflet.
 - any other medicine from the benzodiazepine group of medicines. Some of the symptoms of an allergic reaction may include skin rash, itching, hives or other serious allergic reaction which is rare and its symptoms can include swelling of the face, tongue, throat or voice box and difficulty in breathing. If any of these symptoms occur, you should seek medical attention as soon as possible.
- 2. you have severe lung disease or breathing difficulties.**
- 3. you have sleep apnoea, a condition where you have breathing problems when you sleep.**

Do not take APO-TEMAZEPAM if the packaging is torn or shows signs of tampering.

Do not take APO-TEMAZEPAM after the expiry date (EXP) printed on the pack.

If you take it after the expiry date has passed, it may not work as well or have no effect at all.

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

The safety and effectiveness of APO-TEMAZEPAM in children under 16 years have not been established.

Before you take it

You must tell your doctor if:

- 1. you have any allergies to:**
 - any other medicines
 - any other substances, such as foods, preservatives or dyes.
- 2. you are pregnant or planning to become pregnant**

Do not take APO-TEMAZEPAM if you are pregnant or planning to become pregnant unless you and your doctor have discussed the risks and benefits involved.
- 3. you are breastfeeding or planning to breastfeed**

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

APO-TEMAZEPAM may pass into breast milk and cause drowsiness and/or feeding difficulties in the baby.
- 4. you have or have had any other medical conditions including:**
 - liver, kidney or lung disease

- blood disorders
- fits or convulsions
- severe muscle weakness known as myasthenia gravis
- low blood pressure
- glaucoma (high pressure in the eye)
- depression, psychosis or schizophrenia.

5. you drink alcohol regularly.

Alcohol may increase the effects of APO-TEMAZEPAM.

6. You plan to have surgery

If you have not told your doctor about any of the above, tell them before you take any APO-TEMAZEPAM.

Taking other medicines

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

Some medicines may interfere with APO-TEMAZEPAM. These include:

- other sleeping tablets, sedatives or tranquillisers
- medicines for depression, schizophrenia and other mental illnesses
- medicines for allergies for example antihistamines or cold tablets
- medicines used to treat Parkinson's disease
- theophylline, a medicine used to treat asthma
- pain relievers
- muscle relaxants
- medicines to control fits

Your doctor will advise you what to do if you are taking any of these medicines.

Check with your doctor or pharmacist if you are not sure whether you are taking any of these medicines.

Your doctor or pharmacist may have more information on medicines to be careful with or

avoid while taking APO-TEMAZEPAM.

How to take it

How much to take

The dose of APO-TEMAZEPAM may be different for each person. Your doctor will decide the right dose for you.

The recommended dose is 10 to 30 mg taken 30 minutes before going to bed

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

How to take it

Swallow APO-TEMAZEPAM tablets whole with a glass of water. Do not chew them.

APO-TEMAZEPAM may be taken with or without food.

When to take it

Take APO-TEMAZEPAM 30 minutes before going to bed in the evening.

How long to take it

Do not take APO-TEMAZEPAM for longer than your doctor says.

APO-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.

Continue taking APO-TEMAZEPAM as long as your doctor recommends it.

If you forget to take it

If you forget to take APO-TEMAZEPAM before you go to bed and you wake up late in the night or early morning, do not take any APO-TEMAZEPAM as you may have trouble waking in the morning. If you have any questions

about this, ask your doctor or pharmacist.

Do not try to make up for missed doses by taking more than one dose at a time.

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

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) for advice or go to casualty at your nearest hospital if you think that you or anyone else may have taken too much APO-TEMAZEPAM. Do this even if there are no signs of discomfort or poisoning. Also report any other medicine or alcohol which has been taken.

You may need urgent medical attention.

If you take too much APO-TEMAZEPAM you may feel drowsy, confused, tired, dizzy, have difficulty breathing, feel weak or become unconscious.

While you are taking it

Things you must do

Take APO-TEMAZEPAM exactly as your doctor has prescribed.

Tell all doctors, dentists and pharmacists who are treating you that you are taking APO-TEMAZEPAM.

If you become pregnant while you are taking APO-TEMAZEPAM, tell your doctor immediately.

Visit your doctor regularly.

Your doctor needs to check your progress and see whether you need

to keep taking APO-TEMAZEPAM.

Tell your doctor if you feel APO-TEMAZEPAM is not helping your condition.

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

Keep enough APO-TEMAZEPAM to last weekends and holidays.

Things you must not do

Do not drive or operate machinery until you know how APO-TEMAZEPAM affects you.

APO-TEMAZEPAM may cause drowsiness or dizziness in some people and therefore may affect alertness.

Make sure you know how you react to APO-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 APO-TEMAZEPAM at night, you may still be drowsy or dizzy the next day.

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

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

Do not stop taking APO-TEMAZEPAM or change the dose, without first checking with your doctor.

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

Do not suddenly stop taking APO-TEMAZEPAM if you suffer from epilepsy.

Stopping this medicine suddenly may make your epilepsy worse.

Do not use this medicine to treat any other complaints unless your doctor says to.

Do not give APO-TEMAZEPAM to anyone else, even if their symptoms seem similar to yours.

Things to be careful of

Be careful when drinking alcohol while taking APO-TEMAZEPAM.

Combining APO-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 APO-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

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using APO-TEMAZEPAM.

APO-TEMAZEPAM helps most people with insomnia, but it may have unwanted side effects in some people.

All medicines may 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.

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 APO-TEMAZEPAM. These side effects may go away during treatment as your body adjusts to the dose. However, tell your doctor if you notice any of the following and they worry you:

- dizziness
- headache
- mild daytime drowsiness
- feeling tired

These are the more common side effects of APO-TEMAZEPAM.

Less common or rare side effects of APO-TEMAZEPAM include:

- unsteadiness
- confusion and loss of memory
- faintness
- shaking or tremors and weakness
- leg cramps
- skin rashes
- swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing
- feeling sick or vomiting
- dry mouth
- irritability
- outbursts of anger and increased excitement
- depression
- sleep disturbances
- hallucinations
- blurred vision
- low blood pressure
- wheezing or shortness of breath
- fast or irregular heartbeats
- unpleasant dreams
- slurred speech
- change in libido or sex drive
- signs of frequent infections such as fever, chills, sore throat or mouth ulcers
- yellowing of the eyes and skin (jaundice).

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, APO-TEMAZEPAM.

Some people may get other side effects while using APO-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 it

Storage

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

If you take the tablets out of their container they may not keep well.

Keep APO-TEMAZEPAM tablets in a cool, dry place where the temperature stays below 30°C.

Do not store APO-TEMAZEPAM tablets or any other medicines, in a bathroom or near a sink. Do not leave it in the car or on window sills.

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

Product description

What it looks like

APO-TEMAZEPAM comes in one tablet strength.

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

Ingredients

The active ingredient in APO-TEMAZEPAM is temazepam.

Each APO-TEMAZEPAM 10 mg tablet contains 10 mg temazepam

APO-TEMAZEPAM 10 mg tablets also contain:

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

APO-TEMAZEPAM tablets do not contain gluten, sucrose, tartrazine or any other azo dyes.

Distributor

Apotex Pty Ltd
16 Giffnock Avenue
Macquarie Park NSW 2113

Australian Registration Number:

APO-TEMAZEPAM 10 mg tablets
AUST R 153123

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