

Somidem

contains the active ingredient zolpidem tartrate

CONSUMER MEDICINE INFORMATION

WARNING: SOMIDEM MAY BE ASSOCIATED WITH UNUSUAL AND POTENTIALLY DANGEROUS BEHAVIOURS WHILST APPARENTLY ASLEEP. THESE HAVE INCLUDED SLEEP WALKING, DRIVING MOTOR VEHICLES AND OTHER BIZARRE BEHAVIOURS. SOME MEDICINES MAY INTERACT WITH SOMIDEM AND PARTICULAR CAUTION IS NEEDED WITH OTHER DRUGS THAT MAY ALSO ACT ON THE BRAIN; BEFORE YOU TAKE SOMIDEM REFER TO THE "TAKING OTHER MEDICINES" SECTION BELOW OR ASK YOUR DOCTOR OR PHARMACIST. YOU MUST NOT DRINK ALCOHOL WHEN YOU TAKE SOMIDEM. DO NOT TAKE SOMIDEM FOR MORE THAN 4 WEEKS. IF YOUR SLEEP PROBLEMS CONTINUE, CONSULT YOUR DOCTOR.

What is in this leaflet

This leaflet answers some common questions about Somidem.

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 Somidem 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 is Somidem used for

The name of your medicine is Somidem. It contains the active ingredient zolpidem tartrate.

Somidem is used in adults to initiate sleep in those with sleeping difficulties, also called insomnia. It works by binding to special sites in the brain which produce sleep. The

cause of the sleeping problem should be known, if possible. The causes should be treated before Somidem, or any hypnotics, is prescribed.

In general, sleeping tablets such as Somidem should be taken for short periods only (for a maximum of 4 weeks). Continuous long term use is not recommended unless advised by your doctor. The use of Somidem may lead to dependence on the medicine.

If you have any concerns, discuss this with your doctor.

Your doctor may have prescribed Somidem for another reason. Ask your doctor if you have any questions about why Somidem was prescribed for you.

It is available only with a doctor's prescription.

Before you take Somidem

When you must not take it

Do not take Somidem if you are allergic to zolpidem tartrate (Stilnox) 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.

Do not take Somidem if you have:

- * severe and acute lung disease
- * sleep apnoea, a condition where you temporarily stop breathing while you are asleep
- * myasthenia gravis, a condition where there is severe muscle weakness, most commonly affecting the eyes, face, throat and limbs
- * severe liver disease.

Do not give Somidem to children and adolescents under 18 years of age.

The safety and effectiveness of Somidem in this age group have not been established.

Do not take this medicine if you are pregnant or intend to become pregnant.

It may affect your developing baby if you take it during pregnancy. Your doctor will discuss the risks and benefits of taking it if you are pregnant.

Do not take this medicine if you are breastfeeding or planning to breastfeed.

Somidem passes into breast milk and there is a possibility your baby may be affected. Your doctor will discuss the risks and benefits of using it if you are breastfeeding or planning to breastfeed.

Do not drink any alcohol before or while you are taking this medicine.

The effects of alcohol could be made worse while taking Somidem. You may feel more sleepy, dizzy or light-headed.

Do not take this medicine 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 have, or have had, any medical conditions, especially the following:

- * kidney problems
- * liver problems
- * lung disease, problems with your breathing or if you often snore while you are asleep
- * epilepsy or seizures
- * mental illness such as depression, psychosis or schizophrenia (disturbed thinking, emotional reactions and behaviour)
- * drug or alcohol dependence.

If you have ever been addicted to alcohol or any drug or medicine, or if you have ever suffered from mental illness, you may be at risk of getting into a regular pattern or habit of taking Somidem.

If you have not told your doctor about any of the above, tell him/her before you start taking

Somidem.

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 Somidem, or may affect how well it works. These include:

- * other sleeping tablets, sedatives or tranquillisers
- * medicines for depression and other mental illnesses including imipramine (Tofranil) and chlorpromazine (Largactil)
- * medicines used to relieve pain, strong pain killers
- * anaesthetics including some dental anaesthetics
- * barbiturates, medicines used to treat epilepsy
- * muscle relaxants
- * medicines for allergies and hayfever, such as antihistamines or cold tablets
- * medicines to treat bacterial infections such as rifampicin, erythromycin and clarithromycin
- * medicines to treat fungal infections such as ketoconazole.

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 Somidem.

How to take Somidem

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 usual adult dose is 10 mg at bedtime.

If you are over 65 years of age, the dose of Somidem is 5 mg (half a tablet).

If you have a liver problem, you should start with 5 mg of Somidem, taken at night. If necessary, this can be increased to 10 mg.

If you need to break Somidem, hold tablet with both hands and snap along break line.

How to take Somidem

Swallow the tablets with a glass of water.

Somidem tablets can be divided in half along the breakline if advised by your doctor or pharmacist.

When to take Somidem

Take Somidem just before you go to bed because it puts you to sleep quite quickly.

Somidem works more quickly on an empty stomach.

How long to take Somidem for

Somidem is to be used 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 Somidem

If you forget to take Somidem before you go to bed and you wake up late in the night or early morning, do not take any Somidem 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 unwanted side effects.

If you have any questions about this, ask your doctor or pharmacist.

If you take too much Somidem (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 Somidem. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Some signs and symptoms of taking too much Somidem include severe drowsiness, clumsiness or unsteadiness, mental or mood changes, unusual tiredness or weakness and unconsciousness.

While you are taking Somidem

Things you must do

Before starting any new medicine, remind your doctor or pharmacist that you are taking Somidem.

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

If you become pregnant while taking Somidem, tell your doctor immediately.

Always follow your doctor's instructions carefully.

Somidem will add to the effects of alcohol and other central nervous system (CNS) depressant medicines that cause drowsiness.

Some examples of CNS depressants are sedating antihistamines or

medicine for hay fever, other allergies, or colds; sedative tranquilisers or sleeping medicines; prescription pain medicines or narcotics; barbiturates; medicine for seizures; muscle relaxants; or anaesthetics including some dental anaesthetics.

Check with your doctor or pharmacist before taking any of the above or any other medicines with or without a prescription while you are using Somidem.

Keep all your doctor's appointments so that your progress can be monitored.

Discuss with your doctor any problems or difficulties during or after taking Somidem.

After taking Somidem for insomnia, you may have difficulty sleeping (rebound insomnia) for the first few nights after you stop taking it.

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.

If you develop any unusual and strange thoughts or behaviour while you are taking Somidem, be sure to discuss it with your doctor. Some changes that have occurred in people taking this medicine are like those seen in people who drink alcohol and then act in a manner that is not normal. Other changes may be more unusual and extreme, such as aggressiveness, hallucinations (seeing, hearing, or feeling things that are not there), and unusual excitement, nervousness, or irritability.

Things you must not do

Do not stop taking Somidem, or change the dose, unless advised by your doctor.

Stopping this medicine suddenly, especially when you are on a high dose or have been taking it for a long time, may cause some unwanted

effects such as mood changes, anxiety and restlessness. Your doctor will advise you to slowly reduce your dose of Somidem before you can stop taking it completely

Do not take Somidem for longer than your doctor has prescribed.

When sleep medicines are used every night for more than a few weeks, they may lose their effectiveness to help you sleep. Sleep medicines should, in most cases, be used only for short periods of time (2 to 4 weeks) unless advised by your doctor.

Do not drink any alcohol before or while you are taking this medicine.

The effects of alcohol could be made worse while taking Somidem. You may feel more sleepy, dizzy or light-headed. Alcohol can also increase the risk of sleep walking and some other related sleep behaviours (see Side effects).

If your sleep problems continue, consult your doctor.

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

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

Things to be careful of

Some sleep medicines may cause a special type of memory loss "anterograde amnesia". 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.

Do not drive motor vehicles or operate dangerous machinery after you take Somidem. You should also be careful the next morning when you wake up.

Somidem may cause drowsiness, dizziness or lightheadedness. Make

sure you know how Somidem affects you before you drive a car, operate machinery or do things that could be dangerous. This is very important if you are taking other drugs that also make you drowsy.

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.

Some medicines can cause dependence, especially when they are used regularly for longer than a few weeks. People who have been dependent on alcohol or other drugs in the past may have a higher chance of becoming addicted to sleep medicines. If you have been addicted to alcohol or drugs in the past, it is important to tell your doctor before starting Somidem.

Side effects

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

Somidem helps most people, 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 attention if you get some of the 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.

This is not a complete list of all possible side effects.

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

- * drowsiness during the day
- * dizziness
- * headache
- * nausea, vomiting, dry mouth
- * diarrhoea
- * muscle weakness.

The above list includes the more common and mild side effects of Somidem.

If any of the following happen, stop taking Somidem and tell your doctor immediately, or go to Accident and Emergency at your nearest hospital:

- * skin rashes or hives, swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing
 - * confusion
 - * unexpected changes in behaviour. These have included rage reactions, worsened insomnia, confusion, agitation, hallucinations and other forms of unwanted behaviour.
 - * sleep walking, driving motor vehicles and other unusual and on some occasions dangerous behaviours whilst apparently asleep. These have also included preparing and eating food, making phone calls or having sexual intercourse. People experiencing these effects have had no memory of the events.
- Consumption of alcohol can also increase the risk of such behaviours.

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

These are very serious side effects. You may need urgent medical attention. All of 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 people.

After taking Somidem

Storage

Keep Somidem 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 may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 25 degrees C.

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

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

Heat and dampness can destroy some medicines.

Disposal

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

Product description

What it looks like

Somidem is a white to off-white, capsule-shaped breakable tablet, marked "ZM breakline 10" on one side and "G" on the other side.

Each blister pack contains 7 tablets.

Ingredients

The active ingredient in Somidem is zolpidem tartrate.

Each Somidem tablet contains 10 mg of zolpidem tartrate (equivalent to zolpidem 8.03 mg).

The tablets also contain the following inactive ingredients:

- * lactose
- * cellulose - microcrystalline
- * starch - pregelatinised maize
- * magnesium stearate
- * Opadry White YS-1R-7003.

Somidem tablets do not contain sucrose, gluten or tartrazine.

Supplier

Somidem is supplied in Australia by:

Alphapharm Pty Limited

(ABN 93 002 359 739)

Chase Building 2

Wentworth Park Road

Glebe NSW 2037

Phone: (02) 9298 3999

Medical Information

Phone: 1800 028 365

More recent information on Somidem may be available. Please check with your pharmacist for the latest Consumer Medicine Information or go to www.alphapharm.com.au.

Australian registration number:

AUST R 119196 (blister pack).

This leaflet was prepared on

27 January 2009.