

SOMIDEM

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

SOMIDEM is used to initiate and maintain sleep in those with sleeping difficulties, also called insomnia. It is not recommended for use for more than 4 weeks at a time.

SOMIDEM has a different chemical structure to other sleeping tablets. It works by binding to special sites in the brain which produce sleep.

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

Your doctor may have prescribed SOMIDEM for another reason.

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 have an allergy to:

- any medicine containing zolpidem
- any ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

Do not take SOMIDEM if you have:

- been drinking alcohol or you believe that you may have alcohol in your bloodstream

- severe and/or 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 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
- heart 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)

Tell your doctor if you have ever been addicted to alcohol or any drug or medicine, or if you have ever suffered from mental illness. If you have, 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 them before you start taking SOMIDEM.

Taking other medicines

Tell your doctor or pharmacist 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 interfere with SOMIDEM. These include:

- other sleeping tablets, sedatives or tranquillisers

- medicines for depression, anxiety, and other mental illnesses including imipramine (Tofranil) and chlorpromazine (Largactil)
- St John's Wort (also known as Hypericum), a herbal remedy used to treat depression
- medicines used to relieve pain, including strong pain killers such as opioids
- 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 infections such as rifampicin, ciprofloxacin
- medicines to treat fungal infections such as ketoconazole

These medicines may be affected by SOMIDEM, or may affect how well it works, i.e. by increasing drowsiness. This may affect your ability to drive a car or operate dangerous machinery. You may need to use different amounts of your medicine, or take different 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

SOMIDEM should only be taken when you are able to get a full night's sleep (7 to 8 hours) before you need to be active again. It should be taken in one dose and not be re-administered during the same night.

The usual dose of SOMIDEM is one 10 mg tablet 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. If necessary, this can be increased to 10 mg.

Your doctor may have prescribed a different dose. The lowest effective daily dose should be used and must not exceed 10 mg.

Ask your doctor if you are unsure of the correct dose for you.

They will tell you exactly how much to take.

Follow the instructions they give you.

If you take the wrong dose, SOMIDEM may not work as well. If you take too much your consciousness may be impaired (see 'Overdose' below).

SOMIDEM should not be given to children or adolescents less than 18 years of age.

How to take it

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 it

Take SOMIDEM immediately before you go to bed or while you are in bed.

It helps put you to sleep quite quickly. If you take SOMIDEM on an empty stomach it may work faster.

If you are not sure when to take it, ask your doctor or pharmacist.

How long to take it

Usually, SOMIDEM or any other medicines to treat sleeping disorders, should only be used for short periods (e.g., 2 to 4 weeks). Continuous long-term use is not recommended unless advised by your doctor.

Ask your doctor or pharmacist if you are not sure how long to take this medicine for.

If you forget to take it

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 it.

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 are not sure what to do, 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 SOMIDEM.

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

You may need urgent medical attention.

If you take too much SOMIDEM, your consciousness may be impaired, ranging from drowsiness to light coma.

While you are taking it

Things you must do

If you are about to be started on any new medicine, remind your doctor or pharmacist that you are taking SOMIDEM.

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

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

If you become pregnant while taking SOMIDEM, stop taking it and tell your doctor immediately.

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.

Things you must not do

Do not take more than the recommended dose unless your doctor tells you to.

This can increase the risk of side effects.

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

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

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

This can increase the risk of side effects. 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).

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.

Things to be careful of

As SOMIDEM will make you sleepy, you should not drive or operate machinery for 8 hours after you take it. You should also be careful the next morning when you wake up.

Make sure you know how you react to SOMIDEM before you drive a car or operate machinery. This is very important if you are taking other drugs that also make you drowsy.

Be careful if you are over 65 and unwell or taking other medicines.

You may be more sensitive to some of the side effects of SOMIDEM. Some patients may be particularly susceptible to the sedative effects of this medicine, which may increase the possibility of a fall.

You should not drink alcohol while you are taking SOMIDEM.

The effects of alcohol could be made worse while taking 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 with insomnia, 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 the following list of 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:

- drowsiness
- dizziness

- headache
- fatigue
- worsened insomnia
- nightmares
- hallucinations
- agitation
- abdominal pain
- nausea, vomiting
- diarrhoea
- back pain
- muscle weakness
- infections of the nose, throat and chest

The above list includes the more common 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
- fainting
- unexpected changes in behaviour. These have included rage reactions, confusion 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 sleep walking and other related behaviours. These side effects can also occur without the presence of alcohol.

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

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.

Sleep medicines should, in most cases, be used only for short periods of time (2 to 4 weeks). If your sleep problems continue, consult your doctor.

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.

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

Tell your doctor or pharmacist 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 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°C.

Do not store SOMIDEM or any other medicine in the bathroom or near a sink. Do not leave it in the car or on a window sill.

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 this medicine or the expiry date has passed, ask your pharmacist what to do with any that is 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 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

Alphapharm Pty Limited

(ABN 93 002 359 739)

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

Phone: (02) 9298 3999

www.mylan.com.au

Australian registration number:

AUST R 119196

This leaflet was prepared in

December 2017

somidem_cmi\Dec17/00