

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 risks and benefits. Your doctor has weighed the risks of you taking SOMIDEM against the benefits they expect it will 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 SOMIDEM is used for

SOMIDEM is used to initiate and maintain sleep in those with sleeping difficulties, also called insomnia in patients over 18 years of age. 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 or pharmacist if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

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

Before you take SOMIDEM

When you must not take it

Do not take SOMIDEM if you have:

- been drinking alcohol or you believe that you may have alcohol in your bloodstream
- sleep apnoea (a condition where you temporarily stop breathing while you sleep)
- myasthenia gravis (a condition in which the muscles become weak and tire easily)
- severe liver problems
- acute and/or severe lung problems
- previously experienced complex sleep behaviours after taking this medicine including sleepwalking, sleep-driving, and/or engaging in other activities while not fully awake.

Do not take SOMIDEM if you are allergic to it or any of the ingredients listed at the end of this leaflet.

Some symptoms of an allergic reaction include skin rash, itching, shortness of breath or swelling of the face, lips or tongue, which may cause difficulty in swallowing or breathing.

Do not give SOMIDEM to a child or adolescent.

There is no experience with its use in children or adolescents under 18 years of age.

Talk to your doctor or pharmacist if you have ever had a mental disorder or have abused or have been dependent on alcohol or drugs.

Do not take it 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.

Do not take it if the packaging is damaged or shows signs of tampering.

Before you start to take it

Tell your doctor if you have allergies to any of the ingredients listed at the end of this leaflet.

Contains lactose.

Tell your doctor if you are pregnant, suspect that you are pregnant or intend to become pregnant.

Like most medicines of this kind, SOMIDEM is not recommended to be used during pregnancy. Your doctor will discuss the risks and benefits of taking it if you are pregnant.

Tell your doctor if you are breast-feeding or planning to breast-feed.

SOMIDEM can pass into breast milk. Your doctor will discuss the risks and benefits of using it if you are breast-feeding or planning to breast-feed.

Tell your doctor if you have any problems with your breathing or if you often snore while you are asleep.

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

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

- problems with your heart, liver, kidneys or lungs
- epilepsy
- depression
- mental illness, for example, schizophrenia

Tell your doctor if you plan to have surgery.

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

Taking other medicines

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

Some medicines may interfere with SOMIDEM. These include:

- medicines to treat depression, anxiety and mental illness
- medicines to treat epilepsy
- pain relievers
- muscle relaxants
- antihistamines
- St John's Wort (also known as Hypericum), a herbal remedy used to treat depression
- medicines to treat infections, such as rifampicin or ciprofloxacin
- ketoconazole, a medicine to treat antifungal infections

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. Your doctor will advise you.

Your doctor or pharmacist has more information on medicines to be careful with or to avoid while taking SOMIDEM.

How to take SOMIDEM

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 adult dose of SOMIDEM is one tablet (10 mg).

If you are over 65 years of age the dose is half a SOMIDEM tablet (5 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 tablet whole with a full glass of water, unless your doctor has told you to take half a tablet.

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 this medicine, 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 very early in the morning, do not take it.

You may have trouble waking at your normal time.

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

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone Australia 13 11 26), 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 SOMIDEM

Things you must do

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

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

If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking this medicine.

If you become pregnant or suspect that you are pregnant while you are taking SOMIDEM, stop taking it and tell your doctor or pharmacist immediately.

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 complaints unless your doctor tells you to.

Do not drink alcohol before or after taking this medicine.

This can increase the risk of side effects.

Things to be careful of

Because SOMIDEM will make you sleepy, you should not operate dangerous machinery or drive motor vehicles 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 medication, 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

All medicines have some unwanted side effects. Sometimes they are serious, but most of the time they are not. Your doctor or pharmacist has weighed the risks of using this medicine against the benefits they expect it will have for you.

Do not be alarmed by the following list of side effects.

You may not experience any of them.

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

This medicine helps most people with insomnia, but it may have unwanted side effects in some people.

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

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

These are the most common side effects of this medicine.

Less common adverse effects include:

- unexpected changes in behaviour. These have included rage reactions, worsened insomnia, confusion, agitation, depression, hallucinations, delirium, and other forms of unwanted behaviour
- alcohol can increase the risk of sleep walking and other related behaviours. These side effects can also occur without the presence of alcohol

Although these side effects can occur at the usual recommended doses, the risk of these behaviours occurring may also be increased if you take more than the recommended dose.

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.

Sleep medicines should, in most cases, be used only for short periods of time. 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.

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

- swelling of the face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- hives
- fainting
- 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.

These are very serious side effects. If you have them, you may have had a serious allergic reaction to SOMIDEM. You may need urgent medical attention or hospitalisation.

These side effects are very rare.

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

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

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.

After using SOMIDEM

Sometimes when medicines are stopped suddenly, after being used for a long time, withdrawal symptoms may occur. Symptoms of withdrawal may include abdominal and muscle cramps, vomiting and sweating.

In some cases, your insomnia may appear worse for a short time which may be accompanied with other reactions including mood changes, anxiety and restlessness; speak to your doctor if this occurs.

Patients taking part in trials have not had any problems when they stopped taking SOMIDEM.

However, let your doctor know if you have any problems when you stop taking SOMIDEM.

If you have any queries about any aspect of your medicine, or any questions regarding the information in this leaflet, discuss them with your doctor or pharmacist.

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.

Return any unused medicine to your pharmacist.

Product description

What it looks like

SOMIDEM is a white to off-white, capsule-shaped breakable tablet, marked "ZM break line 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 monohydrate
- microcrystalline cellulose
- pregelatinised maize starch
- magnesium stearate
- Opadry White YS-1R-7003 (ARTG PI No: 1625)

Supplier

SOMIDEM is supplied in Australia by:

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond
30-34 Hickson Road
Millers Point NSW 2000
www.viatris.com.au

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Somidem® is a Viatris company trade mark.

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