

SOMIDEM TABLET

Zolpidem Tartrate (10mg)

What is in this leaflet

1. What SOMIDEM tablet is used for
2. How SOMIDEM tablet works
3. Before you use SOMIDEM tablet
4. How to use SOMIDEM tablet
5. While you are using it
6. Side effects
7. Storage and Disposal of SOMIDEM tablet
8. Product description
9. Manufacturer and Product Registration Holder
10. Date of revision

What SOMIDEM tablet is used for

SOMIDEM tablet is used to initiate and maintain sleep for short term in those with sleeping difficulties, also called insomnia. It is limited to 7 to 10 days of use and re-evaluation by the doctor is recommended if insomnia fails to remit after this period.

How SOMIDEM tablet works

SOMIDEM tablet contains the active ingredient zolpidem tartrate. SOMIDEM tablet belongs to a group of medicines called hypnotics. SOMIDEM tablet has a different chemical structure to other sleeping tablets.

SOMIDEM tablet works by binding to special sites in the brain which produce sleep.

Before you use SOMIDEM tablet

- When you must not use it

Do not take SOMIDEM tablet 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 tired easily)
- Severe liver problem
- Severe lung problems

Do not take SOMIDEM tablet if you are allergic to Zolpidem or any of the ingredients listed at the end of this leaflet (see section **Product Description**).

Children and adolescent

Do not give SOMIDEM tablet to a child or adolescent. There is no experience with its use in children or adolescents under 18 years of age.

Pregnancy and breastfeeding

Do not take it if you pregnant or intend to become pregnant. It may affect your developing baby if you take it during pregnancy.

Do not take it if you are breastfeeding or planning to breast-feed.

SOMIDEM tablet passes into breast milk and there is a possibility your baby may be affected. Tell your doctor if you are pregnant, planning to be pregnant, breastfeeding or planning to breast-feed. Your doctor will discuss the risks

and benefits of using it during pregnancy and breastfeeding.

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

- Before you start to use it

You must tell your doctor if:

- You have any allergies to:
 - Any other medicines
 - Any other substance, such as foods, preservatives or dyes

Tell your doctor if you have any problems with your breathing 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 tablet.

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

- Problem with your liver, kidneys or lungs
- Epilepsy
- Depression

If you have not told your doctor or pharmacist about any of the above, tell them before you start SOMIDEM tablet.

- 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 SOMIDEM tablet may interfere with each other. These include:

- Central Nervous System depressants. (medicines to treat anxiety)
- Chlorpromazine (medicines to treat psychotic disorder)
- Imipramine (medicines to treat depression)

The above medicines may be affected by SOMIDEM tablet or may affect how well it works.

You may need different amounts of your medicine, or take it at different times, or you may need to take different medicines. Your doctor will advise you.

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

How to use SOMIDEM tablet

- How much to use

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 label, ask your doctor or pharmacist for help.

The usual dose for adults is one tablet (10mg).

If you are elderly, the required dose is half a tablet (5mg).

If you have liver or kidney problems, the usual recommended dose is half a tablet (5mg). If necessary, this dose may be increased to 10mg.

Your doctor may provide different doses.

Ask your doctor if you are unsure of the appropriate dose for you. They will tell you the quantity to be taken.

If you take the wrong dose, SOMIDEM tablet will not give a good effect. If you are taking medications, your consciousness may be affected.

- When to use it

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

It helps you fall asleep quickly if you take SOMIDEM tablet.

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

- How long to use it

Continue taking SOMIDEM tablet for as long as your doctor recommends.

- If you forget to use it

If you forget to take the tablet 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.

Do not take a double dose to replace the missed dose.

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

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicines. 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 unconsciousness. It can cause loss of full control of bodily movements, slow heartbeat, disturbed vision, troubled breathing, nausea and severe vomiting.

While you are using it

- 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 while you are taking this medicine, 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

Driving and using machinery
SOMIDEM tablet will make you sleepy, you should not operate dangerous machinery or drive motor vehicles 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 Tablet before you drive a car or operate machinery. This is very important if you are taking other medicines that also make you drowsy.

Elderly and people with severe weakness

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

You may be more sensitive to some of the side effects of SOMIDEM Tablet such as confusion or falls.

Side effects

Do not be alarmed by this list of possible side effects. You may not experience any of them. Somidem Tablet helps most people with insomnia, but it may have unwanted side effects in some people. Ask your doctor or pharmacist to answer any questions you may have.

Complex sleep-related behaviours and unexpected changes in behaviour 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.

Alcohol can increase the risk of sleep walking or other 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.

Dependence

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.

If any of the following allergy reactions happen , stop taking this medicine 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

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

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers →Reporting).

Storage and Disposal of Somidem Tablet

- Storage

Keep your tablets in the pack until it is time to take them. If you take them out of their packaging, they will not keep well.

Do not take it after the expiry date 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 torn or show signs of tampering.

Keep them in a cool, dry place where the temperature stays below 25°C. Protect from moisture and heat.

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

Do not leave them in the car or on window sills. Heat and dampness can destroy some medicines.

Keep your tablets where young children cannot reach them. A locked cupboard at least one-and half metres above the ground is a good place to store medicines.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

11 mm white caplet with 'DUO' marking.

- Ingredients

Active Ingredient:

- 10mg of Zolpidem tartrate

Inactive ingredients:

- Sodium starch glycollate
- Lactose
- Starch
- Isopropyl alcohol (IPA)
- Polyvinylpyrrolidone
- Magnesium stearate
- Silicon dioxide

- Mal number:

MAL05072029A

Manufacturer

Duopharma (M) Sdn. Bhd.
(42491-M)
Lot. 2599, Jalan Seruling 59,
Kawasan 3, Taman Klang Jaya,
41200 Klang, Selangor Darul
Ehsan, Malaysia.

Product Registration Holder

Duopharma (M) Sdn. Bhd.
(42491-M)
Lot. 2599, Jalan Seruling 59,
Kawasan 3, Taman Klang Jaya,
41200 Klang, Selangor Darul
Ehsan, Malaysia.

Date of revision

29/12/2015

Serial Number

BPFK(R4/1)281215/00508