

STILDEM

Zolpidem tartrate

Consumer Medicine Information

Warning: Zolpidem 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 zolpidem and particular caution is needed with other drugs that may also act on the brain; before you take zolpidem refer to the "Taking other medicines" section below or ask your doctor or pharmacist. You must not drink alcohol when you take zolpidem. Do not take zolpidem 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 STILDEM

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

STILDEM is used to initiate and maintain sleep in those with sleeping difficulties, also called insomnia.

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

In general, sleeping tablets such as STILDEM are not recommended for use for more than 4 weeks at a time.

Ask your doctor if you have any questions about why STILDEM was prescribed for you.

STILDEM is only available with a prescription.

Before you take it

When you must not take STILDEM

Do not take STILDEM if you are allergic to zolpidem or any of the 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 STILDEM if you have been drinking alcohol or you believe that you may have alcohol in your bloodstream.

Do not take STILDEM if you have the following medical conditions:

- severe muscle weakness known as myasthenia gravis
- a sleeping disorder known as obstructive sleep apnoea
- severe liver problems
- acute or severe lung problems.

Do not take STILDEM if you are pregnant or breastfeeding, unless you and your doctor have discussed the risks and benefits involved.

Do not take STILDEM if the expiry date (Exp) printed on the pack has passed or the packaging is torn or shows signs of tampering.

Do not give STILDEM to children or adolescents under 18 years of age unless advised by your child's doctor.

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

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 plan to become pregnant or to breastfeed.

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

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 STILDEM.

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

- kidney problems
- liver problems
- lung disease
- 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 start taking STILDEM.

Taking other medicines

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

Some medicines may be affected by STILDEM, or may affect how well it works. 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
- rifampicin and ciprofloxacin, medicines to treat bacterial infections
- ketoconazole, a medicine to treat fungal infections.

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 STILDEM.

How to take STILDEM

How much to take

STILDEM 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. The usual adult dose of STILDEM is 10 mg (one tablet). If you are over 65 years of

age, the dose is 5 mg (half a STILDEM tablet).

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

Follow all directions given to you by your doctor and pharmacist carefully.

How to take it

Swallow the tablet with water or other liquid. STILDEM tablets can be broken in half.

Take STILDEM immediately before you go to bed.

It helps puts you to sleep quite quickly. It works more quickly if you take it on an empty stomach.

If you forget to take your dose

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

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

If you take too much (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much STILDEM.

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

You may need urgent medical attention.

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

While you are taking it

Things you must do

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

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

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

Tell your doctor if you become pregnant or intend to become pregnant while taking STILDEM.

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 use STILDEM to treat any other complaints unless your doctor says so.

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

Do not drink alcohol before or after taking this medicine.

This can increase the risk of side effects.

Things to be careful of

Because STILDEM will make you sleepy, you should not operate dangerous machinery or drive a motor vehicle for 8 hours after you take it. You should also be careful the next morning when you wake up.

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

You may be more sensitive to some of the side effects of STILDEM.

You should not drink alcohol while taking STILDEM.

The effects of alcohol could be made worse while you are taking STILDEM.

Side Effects

Like all medicines, STILDEM can have unwanted side effects in some people. Sometimes they are serious, most of the time they are not. You may need medical treatment 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.

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 or vomiting
- abdominal pain
- back pain
- muscle weakness
- infections of the nose, throat, or chest.

These are the most common side effects of STILDEM.

Less common side effects include:

- 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.

While these effects can occur at prescribed doses, drinking alcohol or taking more than the recommended dose, increases the risk of sleep walking or other behaviours such as driving or eating food whilst asleep.

Some sleep medicines may cause short-term memory loss. When this occurs, a person may not remember what 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 for only 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 taking STILDEM.

Tell your doctor immediately or go to Accident and Emergency at the nearest hospital if you notice any of the following soon after taking STILDEM:

- 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. All of these side effects are very rare.

Other side effects not listed above may also occur in some people. Tell your doctor if you notice anything that is making you feel unwell.

After taking it

Storage

Keep STILDEM where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good way to store medicines.

Keep your STILDEM in the pack until it is time to take them.

If you take the tablets out of the pack, they may not keep as well.

Keep STILDEM in a cool dry place where the temperature stays below 25°C.

Do not store STILDEM or any other medicines in the bathroom or near a sink.

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

Heat and dampness can destroy some medicines.

Disposal

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

Product description

What it looks like

White, capsule-shaped tablets embossed 'Z | 10' on both sides.

STILDEM comes in blister packs of 7 and 14 tablets.

Ingredients

The active ingredient in STILDEM is zolpidem tartrate. Each STILDEM tablet contains 10 mg of zolpidem tartrate.

The tablet also contains

- lactose monohydrate
- microcrystalline cellulose
- sodium starch glycollate
- purified talc
- magnesium stearate
- hypromellose
- hyprolose
- titanium dioxide.

The tablets do not contain gluten, sucrose, tartrazine or any azo dyes.

Supplier

STILDEM is supplied by:

Arrow Pharma Pty Ltd
15 – 17 Chapel Street
Cremorne VIC 3121

Australian registration numbers:
STILDEM - AUST R 120379

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