

# STILDEM

*Zolpidem (as 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 common questions about STILDEM. 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 risk of taking STILDEM against the benefits it is expected to 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 STILDEM is used for

STILDEM is a prescription medicine that your doctor has prescribed for you. Do not share it with anyone.

STILDEM is the brand name of a medicine called Zolpidem tartrate.

STILDEM is used to initiate sleep in those with sleeping difficulties, also called insomnia. The cause of sleeping problems should be known, if possible. The causes should be treated before STILDEM, or any hypnotic is prescribed.

**It should not be used for more than 4 weeks at a time.**

Continuous long term use is not recommended unless advised by your doctor.

The use of STILDEM may lead to dependence on the medicine.

STILDEM has a different chemical structure to any other sleeping tablet that is currently available in Australia.

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

Your doctor will have explained why you are being treated with STILDEM and told you what dose to take. Follow these instructions carefully. They may differ from the information contained in this leaflet.

### Before you take STILDEM

#### *When you must not take it*

Do not take STILDEM if:

- You are allergic to the active ingredient or any of the inactive ingredients mentioned 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

- It is past its expiry date or the packaging appears to have been tampered with
- You are pregnant or breastfeeding, unless permitted by your doctor
- You suffer from severe muscle weakness known as myasthenia gravis.
- You suffer from a sleeping disorder known as obstructive sleep apnoea
- You have severe liver problems
- You have acute or severe lung problems
- You have taken alcohol

**Do not give STILDEM to children and adolescents under 18 years of age unless advised by your child's doctor. The safety and effectiveness of STILDEM in this age group has not been established.**

#### *Before you start to take it*

**Tell your doctor if you have allergies to:**

- **Any other medicines, especially if they are in the same medicine class as STILDEM.**
- **Any other substances, including foods, preservatives or dyes.**

**Tell your doctor if you plan on becoming pregnant or will be**

**breastfeeding while you are using STILDEM.**

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

- Kidney problems
- Liver problems
- Lung disease
- Fits or convulsions
- Depression, psychosis or schizophrenia
- Drug and/or alcohol addiction
- If you have any problems with your breathing or if you often snore while you are asleep

### *Taking other medicines*

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

Some medicines may affect the way other medicines work.

**In particular, tell your doctor if you take any of the following:**

- Other sleeping tablets, sedatives or tranquilizers
- Medicines for depression including imipramine
- Medicines to treat anxiety and mental illness
- Medicines to treat bacterial infections such as rifampicin, erythromycin and clarithromycin
- Medicines to treat fungal infections such as ketoconazole
- Pain relievers

These medicines may be affected by STILDEM or may affect how well it works. You may need to use different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

**Let your doctor know if you have used STILDEM before and if you had any problems with it.**

Some medicines can cause dependence, especially when they

are used regularly for longer than a few weeks.

People who have been dependant 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 STILDEM.**

**Use with caution in the elderly or debilitated patient**

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## How to take ZOLPIDEM-PS

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

They may differ from the information contained in this leaflet.

**If you do not understand the instructions on the box, ask your doctor or pharmacist for help.**

### *How much to take*

The usual adult dose of STILDEM is 10 mg.

If you are over 65 years of age the dose is 5mg (half of the 10mg) STILDEM at night.

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

### *How to take it*

STILDEM should be taken just before you go to bed because it puts you to sleep quite quickly. It works more quickly if you take it on an empty stomach.

### *How long to take it*

**It should not be used for more than 4 weeks at a time.**

Continuous long term use is not recommended unless advised by your doctor.

### *If you forget to take your dose*

**If you forget to take ZOLPIDEM-PS 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 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 an unwanted side effect.

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

### *If you take too much (overdosage)*

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

**If you or someone else has taken too much STILDEM, immediately telephone your doctor or the Poisons Information Centre (13 11 26), or go to Accident and Emergency at your nearest hospital. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention**

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## While you are taking STILDEM

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### *Things you must do*

**Always follow your doctors instructions carefully.**

**Tell your doctor if you become pregnant while taking STILDEM.**

**If you are about to start taking a new medicine, tell your doctor and pharmacist that you are taking STILDEM.**

STILDEM 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
- Medicines for seizures
- Muscle relaxants
- 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 STILDEM.**

**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 STILDEM.**

**After taking STILDEM 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 it was not effective and change your treatment unnecessarily.

If you develop any unusual and strange thoughts or abnormal behaviour while you are taking STILDEM, 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 aggression, hallucinations (seeing, hearing, or feeling things that are not there), and unusual excitement, nervousness, or irritability.

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. If your sleep problems continue, consult your doctor.**

### *Things you must not do*

**Do not stop taking STILDEM or lower the dose without checking with 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 side effects such as mood changes, anxiety and restlessness.

Your doctor will advise you to slowly reduce your dose of STILDEM before you can stop taking it completely.

**Do not use STILDEM to treat any other complaint unless your doctor says so.**

**Do not give this medication to anyone else, even if their symptoms seem similar to yours.**

**Do not take STILDEM for a longer time than your doctor has prescribed.**

STILDEM should be taken for short periods only (maximum 4 weeks), unless advised by your doctor.

**STILDEM will make you sleepy, dizzy or light-headed and may therefore affect alertness. Do not drive motor vehicles or operate dangerous machinery for 8 hours after you take it.**

You should also be careful the next morning when you wake up. Even if you take STILDEM at night, you may still be drowsy or dizzy early the next day.

**Do not take STILDEM with alcohol, as combining STILDEM and alcohol can increase the risk of sleep walking and other associated behaviours (see SIDE EFFECTS).**

### *Things to be careful of*

**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.

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## Side Effects

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

**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 or light-headedness
- Headache
- Nausea and vomiting
- Diarrhea
- Muscle weakness

These are more common side effects of STILDEM. Mostly, these are mild and short-lived.

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.

Less common side effects include:

- Unexpected changes in behavior. 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. 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.

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

- Skin rashes or hives
- Excessive sweating
- swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing
- fainting

**These are very serious side effects. If you have them, you may have had a serious allergic reaction to STILDEM. You may need urgent medical attention or hospitalization.** 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 any other effects and they worry you.**

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## After taking STILDEM

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### *Storage*

**Keep your tablets in the blister pack until it is time to take them.**

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

**Keep your tablets in a cool dry place where the temperature stays below 25°C and protect from light.**

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

**Do not leave it in the car or on window sills.**

Heat and dampness can destroy some medicines.

**Keep it where children cannot reach it.**

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

### *Disposal*

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

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## Product Description

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### *What it looks like*

STILDEM 10 mg tablets (AUST R 131917) are white, oval, biconvex, film-coated tablets, scored on both sides and embossed with "ZIM" and "10" on one side.

STILDEM tablets are available in pack sizes of 14 tablets.

### *Ingredients*

#### **Active Ingredient:**

Zolpidem tartrate

#### **Other Ingredients:**

- lactose monohydrate
- microcrystalline cellulose
- hypromellose
- sodium starch glycollate
- magnesium stearate.

The coating contains

- hypromellose
- titanium dioxide
- macrogol 400

#### **Name and Address of the Sponsor**

Arrow Pharma Pty Ltd  
15 – 17 Chapel street  
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#### **Date of Preparation**

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