

Proprietary name:	ZOLTAB 5; ZOLTAB 10
Dosage form:	Tablets
Active Ingredient:	Zolpidem (as tartrate)
Strength per dosage unit:	5 mg or 10 mg of zolpidem per tablet

1.3.2 PATIENT INFORMATION LEAFLET (FINAL)

SCHEDULING STATUS

S5

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

ZOLTAB 5 Film-coated Tablets

ZOLTAB 10 Film-coated Tablets

5 mg or 10 mg of zolpidem.

Contains Sugar.

ZOLTAB 5 contains 42,30 mg of lactose monohydrate.

ZOLTAB 10 contains 84,60 mg of lactose monohydrate.

Please read this leaflet carefully before taking ZOLTAB.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- **ZOLTAB** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What **ZOLTAB** is and what it is used for
2. What you need to know before you take **ZOLTAB**
3. How to take **ZOLTAB**
4. Possible side effects
5. How to store **ZOLTAB**
6. Contents of the pack and other information

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1. WHAT ZOLTAB IS AND WHAT IT IS USED FOR

ZOLTAB contains a medicine called zolpidem tartrate. This belongs to a group of medicines called hypnotics. It works by acting on your brain to help you sleep.

ZOLTAB is used for temporary sleep problems in adults that are causing you severe distress or that are affecting your everyday life. This includes sleep problems in adults such as:

- Difficulty falling asleep.
- Waking in the middle of the night.
- Waking too early.

Your doctor will identify your sleep problem wherever possible and the underlying factors before prescribing **ZOLTAB** for you. The failure of your sleep problems to stop after a 7 – 14-day course of treatment may indicate you have an underlying disorder; your doctor will assess you at regular intervals.

ZOLTAB is used for short-term treatment of insomnia in adults. Do not use long-term.

Treatment should be as short as possible because the risk of dependence increases with the duration of treatment. Ask your doctor for advice if you are unsure.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ZOLTAB

Do not take ZOLTAB if:

- you are allergic (hypersensitive) to zolpidem tartrate or any of the other ingredients of this medicine (listed in section 6).
- you have signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- you have a problem where you stop breathing for short periods at night (sleep apnoea).
- you have a problem that causes severe muscle weakness (myasthenia gravis).

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- you have breathing difficulties (hypoventilate).
- you have severe liver problems.
- you are under the age of 18.
- safety in pregnancy and breastfeeding has not been established.

Do not take ZOLTAB if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking **ZOLTAB**.

Take special care with ZOLTAB if:

- you have a history of alcohol or drug abuse.
- your lungs do not work properly.
- you have any liver problems.
- you have depression or have had another mental illness in the past.
- you have recently taken zolpidem or other similar medicines for more than 4 weeks.

Use of **ZOLTAB** may lead to the development of abuse and/or physical and psychological dependence.

The risk of dependence is greater when **ZOLTAB** is used for longer than 4 weeks, and in patients with a history of mental disorders and/or alcohol, illicit substances, or drug abuse. Tell your healthcare provider if you have ever had a mental disorder or have abused or have been dependent on alcohol, illicit substances, or medicines.

ZOLTAB can cause drowsiness and decrease your level of alertness. This could cause you to fall, sometimes leading to severe injuries.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking **ZOLTAB**.

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Next day psychomotor impairment (see also ‘Driving and using machines’)

The day after taking **ZOLTAB**, the risk of psychomotor impairment, including impaired driving ability may be increased if:

- you take this medicine less than 8 hours before performing activities that require your alertness.
- you take a higher dose than recommended.
- you take **ZOLTAB** while you are already taking other central nervous system depressants or other medicines that increase zolpidem in your blood, or while drinking alcohol, or while taking illicit substances.

Take the single intake immediately at bedtime. Do not take another dose during the same night.

Children and adolescents

Do not give **ZOLTAB** to children below the age of 18 years.

Other medicines and ZOLTAB:

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

The use of **ZOLTAB** with these medicines may cause undesirable interactions. Consult your doctor or pharmacist if you are taking any other medicines, including any medicine you have bought at your pharmacy, supermarket or health food shop.

Always inform your doctor if you take any medication as this may interact with **ZOLTAB**. This is because **ZOLTAB** can affect the way some other medicines work. Also, some medicines can affect the way **ZOLTAB** works.

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*Zolpidem, as in **ZOLTAB** may increase the effect of the following medicines:*

While taking zolpidem with the following medicines, drowsiness and next-day psychomotor impairment effects, including impaired driving ability, may be increased:

- Medicines for mental problems (antipsychotics).
- Medicines for depression such as sertraline.
- Some medicines for moderate to severe pain (narcotic analgesics).
- Medicines for epilepsy (anticonvulsants).
- Medicines used in surgery (anaesthetics).
- Medicines to calm or reduce anxiety or for sleep problems (hypnotics).
- Medicines for hay fever, rashes or other allergies that can make you sleepy (sedative antihistamines) such as chlorphenamine or promethazine.

While taking **ZOLTAB** with antidepressants including bupropion, desipramine, fluoxetine, sertraline and venlafaxine, you may see things that are not real (hallucinations).

It is not recommended to take **ZOLTAB** with fluvoxamine, ciprofloxacin or St. John's Wort (a herbal medicine) used for mood swings and depression.

Risks from concomitant use with opioids:

Concomitant use of zolpidem and opioids (strong pain killers, medicines for substitution therapy and some cough medicines) increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life-threatening.

Because of this, concomitant use should only be considered when other treatment options are not possible.

However, if your doctor does prescribe zolpidem together with opioids the dosage and duration of concomitant treatment should be limited by your doctor.

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Please tell your doctor about all opioid medicines you are taking; and follow your doctor's dosage recommendation closely. It could be helpful to inform friends or relatives to be aware of sign and symptoms stated above. Contact your doctor when experiencing such symptoms.

*The following medicines can increase the chance of you getting side effects when taken with zolpidem as in **ZOLTAB**. To make this less likely, your doctor may decide to lower your dose of **ZOLTAB**:*

- Some medicines for fungal infections such as ketaconazole.

The following medicines can make ZOLTAB work less well:

- Rifampicin (an antibiotic) – for infections.

ZOLTAB with alcohol:

Do not drink alcohol while you are taking zolpidem. Alcohol can increase the effects of zolpidem as in **ZOLTAB** and make you sleep very deeply so that you do not breathe properly or have difficulty waking.

Not all the medicines that may interact with ZOLTAB are listed above.

Pregnancy and Breastfeeding

Pregnancy:

Use of **ZOLTAB** is not recommended during pregnancy.

If you discover that you are pregnant or are planning to have a baby, consult your doctor right away. If taken regularly in late pregnancy, your baby may get withdrawal symptoms. In this case the newborn should be closely monitored during the postnatal period.

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Breastfeeding:

Do not take **ZOLTAB** if you are breast-feeding or planning to breast-feed. This is because small amounts may pass into mothers' milk.

Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast-feeding.

Driving and using machines

After taking **ZOLTAB**, do not drive or use machinery or tools if you feel sleepy, dizzy, or confused. Zolpidem, as in **ZOLTAB** has a major influence on the ability to drive and use machines such as 'sleep driving'. On the day after taking zolpidem (as with other hypnotic medicines), you should be aware that:

- you may feel drowsy, sleepy, dizzy, or confused.
- you may take longer to make quick decisions.
- you may have double or blurred vision.
- you may be less alert.

A period of at least 8 hours is recommended between taking zolpidem and driving, using machinery, and working at heights to minimize the above listed effects.

Do not drink alcohol or take other psychoactive substances while you are taking **ZOLTAB** as it can increase the above listed effects.

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3. HOW TO TAKE ZOLTAB

Do not share medicines prescribed for you with any other person.

Always take **ZOLTAB** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are not sure.

ZOLTAB is taken by mouth. Swallow the tablet whole with a drink of water. **ZOLTAB** should be taken as a single intake just before bedtime.

Make sure you have a period of at least 8 hours after taking this medicine before performing activities that require your alertness.

Adults over 18 years of age:

- The recommended dose is one 10 mg tablet (or two 5 mg tablets) just before bedtime.
- A lower dose may be prescribed to some patients.

Do not exceed 10 mg per 24 hours.

Elderly:

- The usual dose is one 5 mg tablet just before bedtime.

Patients with liver problems:

- The usual starting dose is one 5 mg tablet just before bedtime. This may be increased to two 5 mg tablets (or one 10 mg tablet) by your doctor if necessary.

The usual length of treatment is 2 days to 4 weeks.

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Blood tests:

ZOLTAB can change the levels of liver enzymes shown up in blood tests. This can mean that your liver is not working properly.

If you are going to have a blood test, it is important to tell your doctor that you are taking **ZOLTAB**.

If you take more ZOLTAB than you should:

If you take more zolpidem than you should, tell a doctor or go to a hospital casualty department straight away. Take the medicine pack with you. This is so the doctor knows what you have taken.

Taking too much zolpidem can be dangerous. The following effects may happen:

Feeling drowsy, confused, sleeping deeply and possibly falling into a coma.

If you forget to take ZOLTAB:

ZOLTAB must only be taken at bedtime. If you forget to take your tablet at bedtime, then you should not take it at any other time, otherwise you may feel drowsy, dizzy, and confused during the day. Do not take a double dose to make up for a forgotten tablet.

If you stop taking ZOLTAB:

Keep taking the medicine until your doctor tells you to stop. Do not stop taking **ZOLTAB** suddenly but tell your doctor if you want to stop. Your doctor will need to lower your dose and stop your tablets over time.

If you stop taking **ZOLTAB** suddenly, your sleep problems may come back, and you may get a 'withdrawal effect'. If this happens you may get some of the effects listed below.

See a doctor straight away if you get any of the following effects:

- Feeling anxious, shaky, irritable, agitated, or confused.
- Feeling restless.

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- Headache.
- Limp or weak muscles.
- A lower level of awareness and problems with focusing or concentrating.
- Nightmares, seeing or hearing things that are not real (hallucinations).
- Being more sensitive to light, noise, and touch than normal.
- Relaxed grip on reality.
- Numbness and tingling in your hands and feet.
- Aching muscles.
- Changes in your behaviour.
- Fits (seizures).

4. POSSIBLE SIDE EFFECTS

ZOLTAB can have side effects.

Not all side effects reported for **ZOLTAB** are included in this leaflet.

Should your general health worsen while taking **ZOLTAB** please consult your doctor, pharmacist, or other healthcare professional for advice.

If any of the following happens, stop taking **ZOLTAB** and tell your doctor immediately or go to the casualty department at your nearest hospital:

Severe allergic reaction, including an itchy, lumpy rash (hives) or nettle rash (urticaria), swelling of the hands, feet, ankles, face, lips or throat and difficulty in swallowing or breathing.

These are all serious side effects. You may need urgent medical attention or hospitalisation. Tell your doctor if you notice any of the following:

Frequent side-effects:

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- Poor memory while taking **ZOLTAB** (amnesia) and strange behaviour during this time. This is more likely to affect you in the few hours after you take this medicine. By having 7- 8 hours sleep after taking **ZOLTAB** this is less likely to cause you a problem.
- Sleeping problems that get worse after taking this medicine.
- Seeing or hearing things that are not real (hallucinations).
- Diarrhoea.
- Feeling sick (nausea) or being sick (vomiting).
- Abdominal pain.
- Respiratory infection.
- Headache.
- Feeling tired or agitated.
- Nightmares.
- Depression.
- Feeling dizzy.
- Feeling sleepy or drowsy.
- Back pain.

Less frequent side-effects:

- Any changes in vision such as blurred eyesight or 'seeing double', loss of vision.
- Being less aware of your environment.
- Falling, especially in the elderly.
- Sleep-driving and other sleep-related behaviour.
- Itching skin or skin rash.
- Excessive sweating.

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- Feeling restless, aggressive, confused, or irritable.
- Feeling overly happy/confident (euphoric).
- Unusual skin sensations such as numbness, tingling, pricking, burning, or creeping on the skin (paraesthesia).
- Tremor.
- Lack of concentration.
- Speech problems.
- Changes in the amount of liver enzymes – shown up in the results of blood tests.
- Changes in appetite or behaviour concerning appetite.
- Muscle pain, muscle spasms and limp or weak muscles.
- Itchy, lumpy rash (urticaria).
- Thinking things that are not true (delusions).
- Changes in sex drive (libido).
- You have discolouration of the skin or eyes, pain in the abdomen (stomach) or a bloated feeling, severe itching, pale or bloody stools, extreme weakness, nausea, or loss of appetite. This could be caused by an infection or injury to the liver.
- An illness where removal of bile from the liver is blocked (cholestasis). Signs include jaundice, rash or fever and the colour of your water (urine) becomes darker.
- Changes in the way you walk.
- Slower breathing (respiratory depression).
- Becoming dependent on **ZOLTAB**.

Frequency unknown:

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- A feeling of being out of touch with reality and being unable to think or judge clearly (psychosis).
- Feeling angry or showing unusual behaviour.
- Needing to take more **ZOLTAB** in order to sleep.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects:

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of **ZOLTAB**. Alternatively, all adverse events can be reported to Alkem Laboratories via the e-mail: pharmacist.rsa@Alkem.com.

5. HOW TO STORE ZOLTAB

Store at or below 25 °C. Protect from light and moisture.

Keep sealed blister in outer container until required for use.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date stated on the carton and the blister. Do not throw away any medicines in drains or sewage systems.

Return all unused medicine to the pharmacist.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What ZOLTAB contains:

The active substance: 5 mg or 10 mg of zolpidem (as tartrate).

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The other ingredients are: hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, sodium starch glycolate and coating solution (hypromellose, macrogol and titanium dioxide).

What ZOLTAB looks like and contents of the pack:

ZOLTAB 5: White to off-white round biconvex film coated tablets, plain on both sides.

ZOLTAB 10: White to off-white capsule shaped film coated tablets having a break line on one side and plain on other sides.

Aluminium/ PVC blister strips containing 14 tablets. The blister strips are packed in an outer carton.
White HDPE bottles and caps containing 30 tablets each.

Holder of certificate of registration

Alkem Laboratories (Pty) Ltd.
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121 Sovereign Drive, Block A, Office 202
Irene Ext. 30, Centurion, 0157

This leaflet was last revised in

Application Numbers:

ZOLTAB 5: 550136

ZOLTAB 10: 550137

Access to the corresponding Professional Information

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The professional information will be included in each unit pack of the product.