

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.** Keep this leaflet. You may need to read it again. If you have more questions, ask your doctor or pharmacist. This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours. If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

▲ **ZASAN film tablets 5 mg**

▲ **ZASAN film tablets 10 mg**

Zolpidem

**In this leaflet:**

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**1. What ZASAN is and what it is used for**

**ZASAN** (zolpidem) are film tablets. Zolpidem contains active substance called zolpidem tartrate. It belongs to a group of medicines called hypnotics and sedatives, benzodiazepines related medications. It works by acting on your brain to help you sleep. Your doctor has prescribed **ZASAN** to you for short-term treatment of insomnia. **ZASAN** reduces sleep latency, increases total sleep time, prevents early morning awakening and reduces the frequency of awakenings during the night. Treatment should be as short as possible. There should be no more than a few days to two weeks, maximum four weeks, including the time of gradual dose reduction. If you still have problems sleeping after you have taken your tablets, consult your doctor again.

**2. Before you take ZASAN**

**Do not take ZASAN if:**

- You are allergic (hypersensitive) to zolpidem tartrate or any of the other ingredients of **ZASAN** (listed in Section 6 below)
- 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)
- Your lungs do not work properly (respiratory failure)
- You have severe liver problems
- Children under 18 years should not take this medicine, as well as patients with severe mental illnesses.
- Consult your doctor if you are not sure whether to start treatment with **ZASAN** tablets.

Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue. In this case you should immediately consult a doctor.

**Take special care with ZASAN**

- Notify your doctor about all health problems you have or have had, as well as any allergies.
- Notify your doctor if you have :
- You have depression or have had another mental illnesses in the past
  - You have liver problems, because the doctor will prescribe a lower dose. Patients with severe liver failure should not take this medicine.
  - You have a history of alcohol or drug abuse caution is needed, because of the possible development of psychological and physical dependence
  - You have recently taken **ZASAN** or other similar medicines for more than four weeks, because there is the possibility of developing addiction
  - You have impaired function of breathing, because of the possible deterioration in breathing function you must take special caution when using this drug
  - You have renal impairment, because you will occasionally need to do laboratory tests.
- During treatment with **ZASAN** tablets you should not consume alcoholic beverages or take medications that reduce the effect of the central nervous system.

Take **ZASAN** before going to bed, because the medicine acts rapidly. Long-term use of **ZASAN** may reduce the effectiveness of the drug. Take **ZASAN** tablets only when sleeping time for 7-8 hours is enabled. **ZASAN** can cause mental and physical dependence, and also sudden withdrawal of the drug can lead to crises: headaches or pain in the area of muscle, extreme anxiety and tension, restlessness, confusion and irritability. Considering it is possible feedback insomnia after stopping use of **ZASAN**, it is recommended that you avoid abrupt discontinuation of therapy. If your doctor told you have an intolerance to some sugars, before you start taking **ZASAN** consult your doctor. This medicine contains lactose, and this should be taken into account if you have diabetes.

**Taking Zasan with other drugs**

Tablets **ZASAN** can usually be used together with other medicines. Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. The effect of **ZASAN** tablets with coadministration of some drugs that act on the central nervous system can be enhanced and it can make you sleepier than it should. While taking **ZASAN** with the following medicines, drowsiness and

next-day psychomotor impairment effects, including impaired driving ability, may be increased.

- Medicines for some mental health problems (antipsychotics)
- Medicines for sleep problems (hypnotics)
- Medicines to calm or reduce anxiety
- Medicines for depressions
- Medicines for moderate to severe pain (narcotic analgesics)
- Medicines for epilepsy
- Medicines used for anesthesia
- Medicines for hay fever, rashes or other allergies that can make you sleepy (sedatives antihistamines)

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

It is not recommended to take **ZASAN** with fluvoxamine or ciprofloxacin. Pharmacodynamic effect of **ZASAN** tablets is reduced when administered with rifampicin.

Ketoconazole (medicament for the treatment of fungal infections) and ritonavir (medicament for the treatment of HIV infection) can increase sedating effect of **ZASAN** tablets because they reduce its degradation and excretion.

**Taking ZASAN with food and drink**

If fast onset of action is desired, **ZASAN** tablets should not be taken during meals or immediately after it, because food reduces and slows the absorption of the drug.

**Do not drink alcohol while you are taking ZASAN.**

Alcohol can increase the effects of **ZASAN** and make you sleep very deeply so that you do not breathe properly or have difficulty waking.

**Pregnancy**

Use of **ZASAN** is not recommended in pregnant women. If you are pregnant or plan to become pregnant, you must tell your doctor before starting treatment with **ZASAN** so that alternative treatments can be considered.

**Breast-feeding**

**ZASAN** in smaller quantities passes into breast milk. Its effects on the infant are not known. If treatment with **ZASAN** is considered to be necessary, should be also considered cessation of breastfeeding and switch to artificial infant feeding.

**Driving and using machines**

▲ Trigonik, a drug with a powerful effect on ability. While you are on therapy with **ZASAN**, it is forbidden to operate motor vehicles or machines, if at least 12 hours of use of the drug are not passed!

**3. How to take ZASAN**

Always take **ZASAN** exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. The dose ordered to you by your doctor depends on the disease, about your response to treatment, and other medications you are taking at the same time. It is important that you follow the dosage and instructions given to you by a doctor. You may not modify the dose or interrupt treatment, whereas previously you consult with a physician. The doctor will determine how long will the treatment last.

**How to take ZASAN tablets:**

- Take this medicine by mouth, swallow the tablet whole with a drink of water
- just before bedtime
- 7 to 8 hours after taking the drug you should sleep undisturbedly
- The usual length of treatment is 2 days to 4 weeks, including the time of gradual dose reduction.

**Recommended daily dose**

The recommended dose per 24 hours is 10 mg of **ZASAN**.

A lower dose may be prescribed to some patients.

**ZASAN** 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. Do not exceed 10mg per 24 hours.

Elderly and frail people, patients with liver problems

The usual dose is tablet (5mg) just before bedtime. Just in case that effect is not sufficient and if the patient tolerates drug well, the dose can be increased to 10 mg.

**Children and Adolescents**

**ZASAN** should not be used in people under 18 years old. The maximum daily dose is 10 mg and can not be exceeded. Treatment should be as short as possible. There should be no more than a few days to two weeks, maximum four weeks, including the time of gradual dose reduction. If you still have problems sleeping after you have taken your tablets, consult your doctor again.

In exceptional cases, treatment may be longer than the maximum recommended duration of treatment, but only after the doctor again, carefully estimated your condition.

Dose reduction should be adapted to each patient.

If you think that the effect of **ZASAN** tablets is too strong or too weak, talk to your doctor or pharmacist.

#### **If you take more ZASAN than you should**

If you take more **ZASAN** than you should, tell a doctor or go to a hospital casualty department straight away. The following effects are most likely to happen: Feeling drowsy, confused, sleeping deeply and possibly falling into a fatal coma.

#### **If you forget to take ZASAN**

**ZASAN** must only be taken at bedtime, as your doctor prescribed.

If you forget to take your tablet at bedtime, then you should not take it at any other time. Do not take a double dose to make up for a forgotten tablet. Just continue with the usual regimen.

#### **If you stop taking ZASAN**

If you are taking tablets **ZASAN** for a long time in larger doses, abrupt discontinuation of treatment may cause the so-called abstinence syndrome (withdrawal symptoms) with symptoms such as headache, muscle aches, abdominal pain, anxiety, depression, restlessness sweating, sleep disturbances, confusion or irritability. Severe withdrawal syndrome occurs very rarely. If you experience these symptoms, consult your doctor. Also, sudden discontinuation of hypnotics (drugs tranquilizer) can cause a condition known as "feedback insomnia". This means, that a few days after discontinuation of the drug the patient can have a greater sleeping problems than they had before treatment. If a feedback insomnia occurs, do not be concerned. These symptoms tend to disappear after the 1-2 days.

Abstinence syndrome and insomnia feedback rarely occur in patients treated with zolpidem.

If you took **ZASAN** or any other medicines for sleep producing more than one or two weeks, do not suddenly stop taking them.

Gradually decrease the dosage until completely interrupt administration of the drug. Always take the drug exactly as the doctor prescribed. If at the end of the scheduled duration of treatment you still do not feel well or during treatment feel worse, tell your doctor. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

#### **4. Possible side effects**

Like all medicines, **ZASAN** can cause side effects, although not everybody gets them.

Stop taking **ZASAN** and see a doctor or go to a hospital straight away if:

- You have an allergic reaction. The signs may include: a rash, swelling of your lips, face, throat or tongue
- swallowing or breathing problems.

Side effects can be:

- very common (affects more than 1 in every 10 people),
- common (affects less than 1 in every 10 people),
- uncommon (affects less than 1 in every 100 people),
- rare (affects 1 to 10 in every 10000 people) and
- very rare (affects less than 1 in every 10000 people).

#### **Other side effects**

##### **Very common**

-Hallucinations (seeing things), agitation (motor restlessness and psychic anxiety), nightmares

-Daytime sleepiness, emotional instability, reduced alertness, headache, dizziness, worsening of insomnia, dizziness, ataxia (impaired muscle coordination), anterograde amnesia (transient loss of memory) which may be accompanied by inappropriate behavior

-Fatigue

-Diarrhea

##### **Common**

-Confusion, irritability, euphoria (excessive mood), anxiety

-Migraine (headache types), paresthesia (numbness or tingling feeling in your fingers or feet), tremor (shaking), dizziness, decreased level of consciousness, trouble concentrating

-Diplopia (double vision)

-Tachycardia (increased heart rate)

-Cerebrovascular disorders (disorders of blood circulation in the brain), hypertension (high blood pressure), hypotension (low blood pressure), orthostatic hypotension (blood pressure in the upright body position)

-Bronchitis (inflammation of the bronchi), cough, dyspnoea (shortness of breath)

-Nausea, vomiting, constipation, dysphagia (difficulty swallowing), flatulence (gas emission), hiccups, gastroenteritis (inflammation of the stomach and intestines)

-Rash, pruritus (itching), increased sweating

-Muscle weakness, arthritis (joint inflammation)

-Cystitis (inflammation of the bladder), incontinence (urinary incontinence)

-Menstrual disorders, vaginitis (inflammation of the vagina)

-Weakness, disturbances in gait and falls, trauma (injury), edema (swelling), fever.

##### **Rare**

Aggression, delusions (believing things that are not there), psychosis, somnambulism (sleepwalking), abnormal behavior - often observed in the elderly, impaired libido (sexual desire)

-Increased levels of liver enzymes (ALT)

-Paleness, angioedema (swelling of the face, tongue or throat)

##### **Very rare**

-anger.

With long-term use may occur addiction, abstinence syndrome, feedback of insomnia and habituation or decrease in the effectiveness of tablets **ZASAN**.

#### **Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse.

This includes any possible side effects including those not listed in this leaflet.

#### **5. How to store ZASAN film coated tablets**

Keep out of the reach and sight of children.

Do not store above 25°C.

Store in the original package.

#### **Shelf life**

3 years. The expiry date of the drug is indicated on the package.

The expiry date refers to the last day of that month.

#### **6. Further information**

##### **What ZASAN contains**

**ZASAN** 5 mg

Each tablet of **ZASAN** contains 5 mg of the active substance zolpidem tartrate.

**Other ingredients are** (tablet core): microcrystalline cellulose, lactose monohydrate, povidone, sodium starch glycolate, talc, magnesium stearate.

Film coating : Opadry II pink, purified water

**ZASAN** 10 mg

Each tablet of Zasan contains 10 mg of the active substance zolpidem tartrate.

**Other ingredients are** (tablet core) : microcrystalline cellulose, lactose monohydrate, povidone, sodium starch glycolate, talc, magnesium stearate.

Film coating : Opadry II white, purified water

##### **Contents of the pack**

Cardboard box with 20 (2 x 10) tablets of 5 mg propafenone (as hydrochloride) in blister.

Cardboard box with 20 (2 x 10) tablets of 10 mg propafenone (as hydrochloride) in blister.

Anatomical Therapeutic Chemical Classification System-(ATC): N05CF02

##### **Marketing Authorisation Holder and Manufacturer:**

ZADA Pharmaceuticals d.o.o.

Donji Bistarac bb

75300 Lukavac, Bosna i Hercegovina.

Classification :

- Prescription only.

Additional information can be obtained from your doctor or pharmacist, who have more detailed information about **ZASAN** and your health.

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▲ **ZASAN** film-coated tablets 5 mg, 20x5 mg: Date: 07.03.2017.

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▲ **ZASAN** film-coated tablets 10 mg, 20x10 mg: Date: 07.03.2017.

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