

## LEAFLET: INFORMATION FOR THE USER

Zolpidem Tartrate Aurobindo 5 mg, film-coated tablets  
Zolpidem Tartrate Aurobindo 10 mg, film-coated tablets  
zolpidem tartrate

Read the entire 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.

Do you have any further questions? Please contact your doctor or pharmacist.

Do not pass this medicine on to others, as it has been prescribed for you only. It may harm them, even if their symptoms are the same as yours.

Do you experience any side effects listed in section 4? Or do you experience a side effect not listed in this leaflet? Then contact your doctor or pharmacist.

### Contents of this leaflet

1. What is Zolpidem Tartrate Aurobindo and what is it used for?
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## 1. WHAT IS ZOLPIDEM TARTRATE AUROBINDO AND WHAT IS IT USED FOR?

Zolpidem Tartrate Aurobindo belongs to a group of medicines known as benzodiazepine-like agents.

This medicine is a sleeping tablet (hypnotic) that works in the brain to induce sleepiness. It is used for the short-term treatment of insomnia in adults, when the condition is severe, disabling you physically or mentally (you can no longer do everything you used to) or causes severe distress.

## 2. WHEN SHOULD YOU NOT USE THIS MEDICINE OR BE EXTRA CAREFUL WITH IT?

When should you not use this medicine?

You are allergic to any of the ingredients in this medicine. You can find these ingredients in section 6.

An allergic reaction can be recognized by a skin rash, itching, difficulty breathing, or swelling of the face, lips, throat, or tongue.

If you have severe liver problems.

If you have sleep apnea (a condition where you stop breathing for very short periods during sleep).

If you suffer from severe muscle weakness (myasthenia gravis).

If you have sudden and severe breathing problems.

If you are under 18 years of age.

When should you be extra careful with this medicine?

Contact your doctor or pharmacist before using this medicine if you:

are elderly or debilitated. Be careful when getting up at night. This medicine can weaken your muscles. Combined with the sedative effect, the risk of falling increases, as does the risk of a hip fracture.

suffer from liver or kidney problems.

have had breathing problems in the past. Your breathing may weaken when using this medicine.

have had mental illnesses, anxiety, or psychoses in the past (serious mental illness where control over one's own thinking, behavior, and actions is disturbed; contact with reality is also disturbed). Zolpidem can trigger or worsen symptoms.

suffer from or have suffered from depression (feeling sad/depressed for more than 2 weeks).

suffer from or have suffered from alcohol or drug addiction or are sensitive to it. The risk of developing a dependence on this medicine (physically or mentally unable to do without the medicine, caused by a compulsion to continue using it) is greater, especially with higher dosages or prolonged use of zolpidem.

the risk of suicide and suicide attempts may increase in patients treated with benzodiazepines or sleeping pills (hypnotics), including zolpidem. If you have thoughts of self-harm or suicide, contact your doctor immediately or go directly to a hospital.

have long QT syndrome. This is a heart condition; a type of heart rhythm disorder.

Before treatment with this medication:

- it must be clear what is causing the sleep problems;
- diseases you already had must be treated.

Is the treatment of your sleep problems not working after 7 to 14 days? Then you should be further examined for other mental (psychological) or physical (somatic) diseases.

Is your liver functioning much worse due to liver failure? Then this medicine should not be used. Because toxic substances accumulate in the body, the brain may function worse (encephalopathy).

Children and adolescents up to 18 years

Do not give this medicine to children and adolescents up to 18 years.

Other considerations:

Tolerance - If you notice after a few weeks that the tablets are not working as well as at the beginning, you should contact your doctor.

Dependence (not being able to do without the medicine) - If you use this type of medicine, there is a risk of developing dependence. This risk increases with higher dosage and longer use. The risk is greater if you have a history of mental (psychological) disorders, drug addiction, alcohol or drug abuse, but dependence can also occur at doses normally used for treatment or if you do not show risk factors such as a history of alcohol or drug abuse.

Withdrawal symptoms (symptoms that can occur when you stop using a certain medicine)  
- The treatment should be gradually reduced. A temporary syndrome may occur during withdrawal, where the symptoms that led to your treatment with this medicine return in an aggravated form. It may be accompanied by other reactions, including mood swings, anxiety, and restlessness.

Memory loss - this medicine can lead to memory loss. To reduce this risk, you should ensure that you can sleep uninterrupted for at least 8 hours.

Psychiatric and 'paradoxical' reactions (opposite reactions that do not match the effect of the medicine) - this medicine can cause behavioral problems, such as restlessness, excitement and/or agitation, irritation, aggression, delusions (seeing, feeling, or hearing things that are not there), rage attacks, nightmares, hallucinations, psychoses (hallucinations; when you see, hear, or feel things that are not there), inappropriate behavior, and increased drowsiness.

Sleepwalking and behavior that resembles it - this medicine can cause people to do things during their sleep that they do not remember when they wake up, including sleepwalking, sleep-driving (operating a vehicle while not well-rested), preparing and eating food, having phone conversations, or having sex. The use in combination with alcohol and other medicines for the treatment of depression or anxiety, or using more of this medicine than the recommended maximum dose seems to increase the risk of this behavior.

Careful consideration should be given to the risks and benefits of this medicine if you have long QT syndrome (a heart abnormality, a type of arrhythmia).

Like other sleeping pills (hypnotics) and sedative medications, zolpidem has a suppressive effect on the central nervous system.

Impairment of psychomotor skills (conscious, brain-controlled movement) the next day (see also 'Driving ability and use of machines') - The day after you have taken this medicine, the risk of impairment of psychomotor skills, including impaired driving ability, may be higher when:

- you take this medicine less than 8 hours before performing activities that require alertness
- you take a higher dose than the recommended dose
- you take zolpidem while already using other central nervous system depressants or other medicines that increase the level of zolpidem in your blood, or when you drink alcohol or use illegal drugs

This medicine can make you drowsy and less aware. This can cause you to fall and become seriously injured.

Take the medicine all at once immediately before going to bed. Do not take another dose during the same night.

Are you using any other medicines?

Are you using any other medicines besides this one, have you done so recently, or is there a possibility that you will use other medicines in the near future? Then tell your doctor or pharmacist.

This medicine can affect the action and/or side effects of other medicines.

Rifampicin, a medicine used for the treatment of tuberculosis, can reduce the effect of this medicine.

When you use zolpidem with the following medicines, sedation, drowsiness, and impairment of psychomotor skills (conscious, brain-controlled movement) the next day, including reduced driving ability, may be increased:

Medicines for certain mental health problems (antipsychotics)

Medicines for sleep problems (hypnotics)

Medicines to calm or reduce anxiety

Medicines for depression including St. John's Wort (an herbal medicine used for the treatment of depression)

Medicines for moderate to severe pain (narcotic analgesics) such as codeine and morphine. Feelings of excitement (euphoria) may increase, which in turn increases the risk of physical or mental dependence (not being able to do without the medicine; addiction).

Medicines for epilepsy such as phenytoin and carbamazepine

Medicines used for anesthesia. If you need to undergo surgery under full anesthesia, tell your doctor which medicines you are using.

Medicines for hay fever, rash, or other allergies that can make you drowsy (sedative antihistamines).

Muscle relaxants; the muscle-relaxing effect and the risk of falling, especially in older patients, could be increased.

Medicines that inhibit liver enzymes (certain types of proteins made in the liver). Ask your doctor or pharmacist which medicines have this effect (for example, ketoconazole, a medicine against fungal infections).

Grapefruit juice can also inhibit liver enzymes.

No interaction has been observed when using zolpidem together with warfarin (an anticoagulant), digoxin (for treating heart failure), or ranitidine (for treating stomach problems).

Concurrent use of this medicine and opioids (strong painkillers, medicines for substitution therapy (replacement of the medicine by the same or another medicine), and some medicines against cough) increases the risk of drowsiness, breathing difficulties (respiratory depression), coma (unconsciousness), and can be life-threatening. Therefore, concurrent use should only be considered if there are no other treatment options.

If your doctor prescribes this medicine together with opioids, the dose and duration of the concurrent treatment should be limited by your doctor.

Inform your doctor about all opioid medications you are using and follow your doctor's dosage recommendation carefully. It may be helpful to inform friends or family members about the signs and symptoms mentioned above. Contact your doctor when you experience these symptoms.

When you take zolpidem with antidepressants such as bupropion, desipramine, fluoxetine, sertraline, and venlafaxine, you may see things that are not there (hallucinations).

It is not recommended to take zolpidem together with fluvoxamine or ciprofloxacin.

What should you watch out for with alcohol?

You should not drink alcohol while using this medicine as it may enhance the sleep-inducing effect.

Pregnancy and breastfeeding

Are you pregnant, do you think you might be pregnant, do you want to become pregnant, or are you breastfeeding? Then contact your doctor or pharmacist before using this medicine.

This medicine can be harmful to the fetus if used during pregnancy.

Results from some studies show that there may be a higher risk of a cleft lip and palate (sometimes called "harelip").

Is this medicine given during the second and/or third trimester of pregnancy? Then it is possible that the unborn child moves less and has an irregular heartbeat.

This medicine should not be used during pregnancy, especially not during the first 3 months. If, for urgent medical reasons, this medicine is used during the last months of pregnancy or during labor, your baby may suffer from low body temperature, limp muscles, feeding problems, and breathing difficulties, and your baby may experience withdrawal symptoms such as being restless, trembling after birth due to physical dependence (physically unable to do without the medicine). Does this happen? Then the child should be closely monitored in the period after birth (postpartum period).

Do not breastfeed your baby, as small amounts of zolpidem can pass into breast milk.

Driving ability and the use of machines

This medicine has a significant impact on driving ability, such as sleep-driving, and on the ability to operate machines. On the day after you have taken this medicine (as with other sleeping pills), you should be aware that:

You may feel drowsy, sleepy, dizzy, or confused

You may be less able to make quick decisions

You may have blurred or double vision

You may be less attentive.

A period of at least 8 hours is recommended between taking zolpidem and driving a vehicle, operating machines, and working at heights. This is necessary to minimize the chance of the effects mentioned above.

Do not drink alcohol or take other psychoactive substances (substances that affect mental processes) while using this medicine, as this can enhance the effects mentioned above.

Zolpidem tartrate Aurobindo contains lactose

If your doctor has told you that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Zolpidem tartrate Aurobindo contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say, essentially “sodium-free”.

### 3. HOW TO USE THIS MEDICINE?

Always use this medicine exactly as your doctor or pharmacist has told you. If you are unsure about the correct use, contact your doctor or pharmacist.

This medicine is taken orally.

This medicine works quickly and should be taken just before going to bed or when you are lying down.

#### Adults:

The recommended dose is 10 mg Zolpidem tartrate Aurobindo per 24 hours. Some patients may be prescribed a lower dose.

This medicine should be taken:

in one go;

just before bedtime.

Ensure there are at least 8 hours between taking this medicine and performing activities that require alertness.

Do not take more than 10 mg per 24 hours.

Elderly (over 65 years) and debilitated patients: The recommended dose is 5 mg. You should not take more than the recommended dose.

Patients with liver problems: The usual starting dose is 5 mg. Your doctor may decide to increase this to 10 mg if it is safe. Do not use this medicine if you have severe liver problems. Be extra cautious in elderly patients whose liver function is impaired.

Patients with a history of breathing problems (chronic respiratory insufficiency): a lower dose is recommended.

Use in children and adolescents under 18 years

This medicine should not be used in children and adolescents under 18 years of age.

#### Duration of treatment

The duration of treatment should be as short as possible. This can range from a few days to 2 weeks. The maximum duration of treatment, including the stepwise reduction period, is four weeks.

Your doctor will choose a stepwise reduction period for you based on your personal needs. In certain situations, you may need to use this medicine for more than 4 weeks.

Have you used too much of this medicine?

If you (or someone else) take several tablets at once or if you think a child has swallowed tablets, you must contact your doctor or the emergency department of the nearest hospital immediately. Take the packaging and any remaining tablets with you. Do not go to a medical service without supervision. Taking an overdose can make you very sleepy very quickly, with higher doses potentially leading to a coma (unconsciousness) or even death.

Is this medicine used together with other medications that depress the central nervous system (such as alcohol)? Then this can cause serious problems and can even be fatal. Signs of moderate overdose may include: being sleepy, confused, feeling tired and sluggish, having little energy, and wanting to sleep a lot (lethargy). If the overdose is severe, the following symptoms may occur: movement problems (ataxia), weak muscles (hypotonia), low blood pressure (hypotension), reduced breathing, cases of reduced consciousness to coma, and more severe symptoms, such as a fatal outcome.

Have you forgotten to use this medicine?

If you forgot to take your dose just before bedtime, but you discover this when you can still sleep for 8 hours, you may still take the dose when you discover you forgot to take it. If it is not possible to sleep for another 8 hours, you should not take the missed dose but take it the next evening. Do not take a double dose to make up for a forgotten tablet. In case of doubt, consult your doctor or pharmacist.

If you stop using this medicine

The dosage should be reduced slowly because otherwise the symptoms for which you are being treated may return in a more severe form (rebound insomnia). In addition to insomnia, anxiety, restlessness, and mood swings may also occur. These symptoms are temporary and will disappear on their own.

If you have become physically dependent on this medicine (if your body can no longer do without the medicine), symptoms such as headache, muscle pain, anxiety, tension, restlessness, confusion, irritability (feeling irritated or annoyed), and insomnia will occur when you suddenly stop the treatment. In severe cases, the following may also occur: hypersensitivity to light, sound, and touch, an unusually good ability to hear with a painful hypersensitivity to sound, hallucinations (seeing, feeling, or hearing things that are not there), numbness and tingling in the limbs, a feeling of unreality (as if the environment is not real), loss of personality (the feeling that your mind is no longer connected to your body), or epileptic seizures (severe convulsions or jerks). These symptoms can also occur between doses, especially at higher dosages.

If you have any other questions about the use of this medicine, please contact your doctor or pharmacist.

#### 4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everyone gets them.

Side effects of this medicine depend on the dose. This is especially true for side effects that affect the central nervous system. These side effects are less severe if this medicine is taken just

before going to sleep or just before going to bed. Side effects are more common in older patients.

If any of the following situations occur, stop using this medicine and contact your doctor immediately or go to the emergency department of the nearest hospital:

allergic reactions such as rash or itching, with swelling of the face, lips, throat or tongue and difficulty breathing or swallowing (angioedema)

These side effects are serious, but the frequency (how often it occurs) is not known (cannot be estimated from the available data). You need medical help.

Tell your doctor or pharmacist if any of the following side effects occur or worsen:

Common (occur in less than 1 in 10 users):

Infections of the upper or lower respiratory tract  
hallucinations, excitement and/or restlessness (agitation), nightmares  
drowsiness, headache, dizziness, worsened insomnia, memory loss (possibly associated with inappropriate behavior)  
'dizzy' feeling  
drowsiness the next day, showing less emotion (flattened emotions), being less attentive, confusion, double vision  
diarrhea, nausea, vomiting  
skin reactions  
fatigue  
back pain  
abdominal pain

The risk of memory loss is higher at higher doses. If you ensure you can sleep uninterrupted for 8 hours, the risk of memory loss is reduced.

Sometimes (occur in less than 1 in 100 users):

itching or tingling without cause (paresthesia)  
joint pain, muscle pain, muscle cramps and neck pain  
involuntary trembling (tremor)  
problems with speaking  
you cannot concentrate on something  
eating disorder  
blurred vision  
skin rash, itching  
excessive sweating  
double vision  
very happy (euphoric) mood  
muscle weakness  
confusion, irritability  
worsened insomnia  
a disorder in balance and coordination of movements (coordination disorders)

elevated levels of certain liver enzymes (which would be detected by your doctor during a blood test).

Rare (occur in less than 1 in 1000 users):

decreased or increased interest in sex (libido)

liver damage (hepatocellular, cholestatic, or mixed forms)

you are less aware

impaired vision

skin rash with pink bumps and severe itching (hives)

you walk differently than usual

falls, especially in the elderly

Opposite reactions (restlessness, excitement and/or agitation, irritability, aggressiveness, seeing, feeling, or hearing things that are not there (delusions), anger, nightmares, hallucinations, severe mental illness where control over one's own thinking, behavior, and actions is disturbed; contact with reality is also disturbed (psychoses), inappropriate behavior and other adverse effects on behavior). These occur more often if you are older.

Very rarely (occur in less than 1 in 10,000 users):

you believe or think things that are not true (delusions)

you physically need this medicine (physical dependence): using this medicine (even at recommended dosages) can lead to physical dependence; suddenly stopping the treatment can cause withdrawal symptoms (complaints when stopping) and the return of problems.

you mentally need this medicine (psychological dependence): this happens if you think you can never sleep again without using this medicine.

Unknown (cannot be determined from the available data)

various forms of liver damage

breathing problems

restlessness, aggression, anger, psychosis (hallucinations, when you see, hear, or feel things that are not there), inappropriate behavior

depression (feeling sad)

Sleepwalking

the need to take increasingly higher doses of a drug to achieve the same effect

Reporting side effects

If you experience side effects, contact your doctor or pharmacist. This also applies to possible side effects not listed in this leaflet. You can also report side effects directly via the Netherlands Pharmacovigilance Centre Lareb, website: [www.lareb.nl](http://www.lareb.nl). By reporting side effects, you can help us obtain more information about the safety of this medicine.

## 5. HOW TO STORE THIS MEDICINE

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date. It can be found on the packaging after “Do not use after” or “Exp.:”. It includes a month and a year. The last day of that month is the expiry date.

There are no special storage conditions for this medicine.

Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. They will then be destroyed responsibly and will not enter the environment.

## 6. CONTENTS OF THE PACKAGING AND OTHER INFORMATION

What substances are in this medicine

- The active substance in this medicine is zolpidem tartrate.  
Zolpidem Tartrate Aurobindo 5 mg: each film-coated tablet contains 5 mg zolpidem tartrate.  
Zolpidem Tartrate Aurobindo 10 mg: each film-coated tablet contains 10 mg zolpidem tartrate.
- The other substances in this medicine are:  
Tablet core: Lactose monohydrate, microcrystalline cellulose (PH-101), sodium starch glycolate (type A), magnesium stearate  
Tablet coating: Hypromellose (5cps), macrogol 400, titanium dioxide (E171)

What Zolpidem Tartrate Aurobindo looks like and how much is in a package?

Film-coated tablets.

Zolpidem Tartrate Aurobindo 5 mg, film-coated tablets

White to off-white, round, film-coated tablets that are convex on both sides, with the inscription “E” on one side and “78” on the other side.

Zolpidem Tartrate Aurobindo 10 mg, film-coated tablets

White to off-white, oval, film-coated tablets that are convex on both sides, with the inscription “E” on one side and “80” with a score line between the “8” and the “0” on the other side. The tablet can be divided into equal doses.

Zolpidem tartrate Aurobindo film-coated tablets are available in blister and HDPE packs.

Blister packs: 7, 8, 10, 14, 15, 20, 28, 30, 50, 56, 60 and 100 film-coated tablets HDPE packs: 30, 100, 250 & 500 film-coated tablets

Not all pack sizes may be marketed.

Marketing authorization holder and manufacturer

Marketing authorization holder:

Aurobindo Pharma B.V.

Baarnsche Dijk 1

3741 LN Baarn

Manufacturer:  
APL Swift Services (Malta) Limited  
HF26, Hal Far Industrial Estate  
BBG 3000, Birzebbugia, Malta

Generis Farmaceutica, S.A.  
Rua Joao de Deus, n° 19  
2700-487, Venda Nova, Amadora, Portugal

Registered under:  
Zolpidem tartrate Aurobindo 5 mg, film-coated tablets is registered under RVG 121164. Zolpidem tartrate Aurobindo 10 mg, film-coated tablets is registered under RVG 121165.

This medicine is registered in EEA member states under the following names:

Czech Republic: Zolpidem Aurovitas  
Germany: Zolpidem PUREN 10 mg film-coated tablets  
Poland: ApoZolpin  
Spain: Zolpidem Aurovitas 10 mg film-coated tablets EFG  
Netherlands: Zolpidem tartrate Aurobindo 5 mg/10 mg, film-coated tablets

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