

LEAFLET: INFORMATION FOR THE USER

Zopiclone Aurobindo 3.75 mg, film-coated tablets

Zopiclone Aurobindo 7.5 mg, film-coated tablets

zopiclone

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 ask your doctor or pharmacist.

Do not pass this medicine on to others. It may harm them, even if their symptoms are the same as yours.

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

Contents of this leaflet

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2. When should you not use this medicine or be extra careful?
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1. WHAT IS ZOPICLONE AUROBINDO AND WHAT IS IT USED FOR?

The name of your medicine is Zopiclone Aurobindo 3.75 mg (or 7.5 mg) film-coated tablets (referred to as zopiclone tablets or “this medicine” in this leaflet). It belongs to a group of medicines called hypnotics. It works by acting on your brain to help you sleep.

In adults:

Zopiclone, the active substance in this medicine, is used for the treatment of sleep problems, such as:

Difficulty falling asleep

Waking up in the middle of the night

Waking up too early

Severe or disruptive sleep problems caused by your mood or mental health issues.

This medicine can be used for both temporary and long-term sleep problems, but you should not use this medicine every day for an extended period. This medicine should also not be used to treat depression. Consult your doctor for advice if you are unsure.

2. WHEN SHOULD YOU NOT USE THIS MEDICINE OR BE EXTRA CAUTIOUS?

When should you not use this medicine?

You are allergic to zopiclone or any of the other ingredients in this medicine. You can find these ingredients in section 6. Signs of an allergic reaction include: rash, swallowing or breathing problems, swelling of your lips, face, throat, or tongue

If you have any of the following conditions:

- Severe muscle weakness, this is called "myasthenia gravis" (an autoimmune disease)
- Severe breathing difficulties (if you have breathing problems, the movement of air in and/or out of the lungs is restricted and difficult)
- Sleep apnea syndrome (a sleep disorder with long pauses between breaths when you sleep)
- Severe liver problems
- You have ever noticed that you sleepwalk or exhibit other strange behavior (such as driving, eating, making phone calls, or having sex) while not fully awake, after taking Zopiclone Aurobindo.

You are a child or adolescent under 18 years of age. The safety and efficacy of zopiclone have not been established in children and adolescents under 18 years.

Do not use this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking this medicine.

When should you be extra cautious with this medicine?

Contact your doctor or pharmacist before taking this medicine:

You have liver problems (see also the section "When should you not use this medicine?" above). Your doctor may need to give you a lower dose of zopiclone.

You have kidney problems. Your doctor may need to give you a lower dose of zopiclone.

You have mild breathing problems, your doctor will decide if you should receive this medicine (see also the section "When should you not use this medicine?" above).

You have a history of alcohol or drug abuse.

You have been told by a doctor that you have a personality disorder.

You have recently used this medicine or other similar medicines for more than 4 weeks.

You feel that you will never be able to stop using this medicine or other medicines used to treat sleep problems.

Before taking this medicine, it is important to ensure that you can sleep for at least 8 hours uninterrupted to reduce the risk of some side effects (see section 4).

Zopiclone Aurobindo can cause sleepwalking or other unusual behavior (such as driving, eating, making phone calls, having sex, etc.) while you are not fully awake. The next morning you may not remember doing anything during the night. These activities can occur regardless of whether you drink alcohol or use other medicines that make you drowsy with Zopiclone Aurobindo.

If you are not sure whether any of the above points apply to you, contact your doctor or pharmacist before taking this medicine.

This medicine should not be used to treat depression. If you also have depression, your doctor will inform you about this and prescribe the appropriate treatment. If depression is not treated, it can worsen and not go away, or you may be at greater risk of committing suicide.

Other considerations

Tolerance

If you notice after a few weeks that the tablets are not working as well as when you first started the treatment, you should see your doctor.

Dependence (addiction)

The use of benzodiazepines and benzodiazepine-like substances can lead to mental and physical dependence (physical and psychological dependence) on these substances. The higher the dose and the longer the treatment lasts, the greater the risk of addiction. The risk increases in patients who have had alcohol or drug problems in the past and/or if patients have a clear personality disorder (mental problems).

Suicidality (you develop thoughts of self-harm or suicide)

The risk of suicide and suicide attempts may increase in patients treated with benzodiazepines or hypnotics (sedatives and sleeping pills, including zopiclone). If you notice that you are developing thoughts of self-harm or suicide, contact your doctor immediately or go directly to a hospital.

Stopping the treatment

The treatment should be gradually (slowly, in steps) stopped. If the treatment is stopped, the symptoms that caused you to receive this medicine may temporarily return in an intensified form. It may be accompanied by other reactions, including mood swings, anxiety, and restlessness.

Short-term memory loss (anterograde amnesia)

This medicine can cause short-term memory loss (you may not remember things that happened recently, anterograde amnesia). This occurs especially a few hours after you have taken the medicine. To reduce this risk, you should ensure that you can sleep uninterrupted (continuously) for 8 hours.

Are you taking any other medicines?

Are you taking any other medicines besides Zopiclone Aurobindo, have you recently taken any, or is there a possibility that you will take other medicines in the near future? If so, tell your doctor or pharmacist.

This also applies to medicines (including herbal medicines) that you can obtain without a prescription. This is because zopiclone can affect the action of some other medicines. Also, some medicines can affect the way zopiclone tablets work.

Tell your doctor if you are using any of the following medicines.

The following medicines can enhance the effect of zopiclone:

Medicines for psychosis; mental disorder with, among other things, hallucinations, thoughts that do not match reality, and confusion (antipsychotics)

Medicines for epilepsy (antiepileptics)

Medicines to calm or reduce anxiety or sleep problems (hypnotics)

Medicines for depression

Some medicines for moderate to severe pain (narcotic analgesics), such as codeine, methadone, morphine, oxycodone, pethidine, or tramadol
Medicines used during operations (anesthetics)
Medicines for hay fever, skin rash, or other allergies. These medicines can make you drowsy (sedative antihistamines), such as chlorphenamine or promethazine.

The following medicines can increase the chance of side effects when taken with zopiclone tablets:

Some antibiotics, such as clarithromycin or erythromycin
Some medicines for the treatment of fungal infections, such as ketoconazole and itraconazole
Ritonavir, a protease inhibitor (used to treat AIDS).
To reduce the chance of this, your doctor may decide to lower your dose of zopiclone tablets.

The following medicines can reduce the effect of zopiclone tablets:

Some medicines for epilepsy, such as carbamazepine, phenobarbital, and phenytoin
Rifampicin (an antibiotic) – for the treatment of infections
Products containing St. John's wort (herb used for the treatment of depression and mood swings).

Concurrent use of zopiclone tablets and opioids (strong painkillers, substitution therapy drugs (if there is a deficiency of a certain substance in the body, it is supplemented) and some cough medicines) increases the risk of drowsiness, breathing problems (respiratory depression), coma and can be life-threatening. Therefore, concurrent use should only be considered if no other treatments are possible.

If your doctor prescribes zopiclone tablets together with opioids, your doctor should keep the dose of the concurrent treatment as low and the duration of the concurrent treatment as short as possible.

Inform your doctor about all opioid medications you are using and adhere as closely as possible to the dose your doctor has prescribed. It may be helpful to inform friends or family members of the symptoms mentioned above. Contact your doctor when you notice these symptoms.

What should you watch out for with alcohol?

Do not drink alcohol while using this medicine. Alcohol can enhance the effect of this medicine and as a result, you may fall into a very deep sleep, making it difficult to breathe properly or wake up.

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 before using this medicine.

Do not use this medicine during the last 3 months of pregnancy or during labor, as it may be harmful to your baby.

Some studies have shown a possible increased risk of cleft lip and palate (sometimes called “harelip”) in newborn babies.

In the unborn child, reduced movement and an irregular heartbeat may occur after using zopiclone during the second and/or third trimester of pregnancy.

When Zopiclone Aurobindo is used during the last stage of pregnancy or during labor, it may lead to muscle weakness, lowering of body temperature, feeding difficulties, and breathing problems (respiratory depression) in your baby.

Regular use of this medicine in the last stage of pregnancy may cause your baby to develop physical dependence and be at risk of withdrawal symptoms, such as agitation or tremors. In that case, the newborn baby should be carefully monitored in the postnatal period.

You should not take this medicine if you are breastfeeding. Zopiclone can pass into breast milk in small amounts. If you are breastfeeding or planning to breastfeed, contact your doctor or pharmacist before taking any medicine.

Driving and using machines

Like other medicines used for sleep problems, zopiclone can make you less alert than usual (central nervous system depression). The risk of psychomotor impairments (the control of movements from the brain works less well than normal), including driving ability, is greater if:

- You take this medicine within 12 hours before performing activities that require mental alertness
- You take more than the recommended dose of this medicine
- You take this medicine while you are already using another medicine that depresses the central nervous system or another medicine that increases the amount of zopiclone in your blood, or while drinking alcohol.

Do not perform hazardous activities that require full mental alertness, such as driving a vehicle or operating machinery after using this medicine, and especially within 12 hours after taking your medication.

See section 4 of this leaflet for more information on possible side effects that may affect your ability to drive.

Zopiclone Aurobindo contains lactose

If your doctor has told you that you cannot tolerate certain sugars, contact your doctor before taking this medicine.

Zopiclone Aurobindo contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per 3.75 mg/7.5 mg film-coated tablets, that is to say, it is essentially “sodium-free”.

3. HOW TO USE THIS MEDICINE?

Your treatment with this medicine should be as short as possible and should not last longer than four weeks, including the period of gradual withdrawal.

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

Use of this medicine

Take this medicine by mouth

Swallow the tablet with a sip of water

Do not crush and do not chew your tablets

Take the correct dose all at once just before bedtime and do not take it again the same night

Usually, the duration of treatment is 2 days to 3 weeks.

Adults

The recommended starting dose is 7.5 mg zopiclone just before bedtime (two tablets of 3.75 mg or one tablet of 7.5 mg). You must not take more than this dose.

Elderly

The usual starting dose is one zopiclone tablet of 3.75 mg just before going to bed. Your doctor may decide to increase your dose to one zopiclone tablet of 7.5 mg if necessary.

Patients with liver, respiratory, or kidney problems

The usual starting dose is one zopiclone tablet of 3.75 mg just before going to bed.

Use in children and adolescents

This medicine should not be used by children and adolescents under 18 years of age. The safety and efficacy of zopiclone in children and adolescents under 18 years have not been established.

Blood tests

This medicine can change the number of liver enzymes in blood tests. This may mean that your liver is not working properly.

If you need to have a blood test, it is important to tell your doctor that you are using this medicine.

Have you used too much of this medicine?

If you have taken too many tablets, contact your doctor, pharmacist, or the emergency department of the nearest hospital immediately for advice. Take the medicine packaging with you so the doctor knows what you have taken.

Overdose with this medicine can be very dangerous. The following effects may occur:

Feeling sleepy, confused, deeply asleep, and possibly falling into a coma

Floppy muscles (hypotonia)

Feeling dizzy, lightheaded, or weak. These effects are due to low blood pressure

Falling or losing your balance (ataxia)

Shallow breathing or difficulty breathing (respiratory depression).

Have you forgotten to use this medicine?

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

If you stop using this medicine

Continue using this medicine until your doctor tells you to stop. Do not suddenly stop using zopiclone, but tell your doctor if you want to stop. Your doctor will need to reduce your dose step by step.

If you suddenly stop using this medicine, your sleep problems may return and you may experience a "withdrawal symptom". If this happens, you may experience some of the effects listed below. Contact a doctor immediately if you experience any of the following side effects:

Feeling anxious, shaky, irritable, excited (agitated), confused, or having panic attacks

Sweating

Headache

Faster heartbeat or irregular heartbeat (palpitations)

A lower level of consciousness (less alert than normal) and problems concentrating

Nightmares, seeing or hearing things that are not real (hallucinations)

Being more sensitive to light, sound, and touch than usual

Sudden severe confusion (delirium)

Numbness and tingling in hands and feet

Painful muscles

Stomach problems.

In rare cases, seizures (uncontrollable body shakes, often as part of an epileptic fit (seizure)) may also occur.

Do you have any other questions about the use of this medicine? Then contact your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

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

Stop using this medicine and contact your doctor immediately if:

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

Tell your doctor as soon as possible if you experience any of the following side effects:

Rare (occur in less than 1 in 1000 users)

Tell your doctor as soon as possible if you experience any of the following side effects:

Poor memory since using zopiclone (amnesia). By sleeping uninterrupted for 7-8 hours after taking zopiclone tablets, you reduce the risk of experiencing this side effect

Seeing or hearing things that are not real (hallucinations)

Falls, especially in the elderly.

Unknown (frequency cannot be determined from the available data)nd of the available data)
Having thoughts that are not aligned with reality (delusions)
Feeling inferior or sad (depressive mood).

Contact your doctor or pharmacist if any of the following side effects become severe or last longer than a few days:

Common (occur in less than 1 in 10 users)

Bitter or metallic taste in your mouth

Feeling drowsy or sleepy

Dry mouth.

Sometimes (occur in less than 1 in 100 users)

Nausea or vomiting

Feeling dizzy

Headache

Nightmares

Mental or physical fatigue

Excitement, restlessness (agitation).

Rare (occur in less than 1 in 1,000 users)

Feeling confused

Itchy skin rash, hives (urticaria)

Feeling irritated or aggressive

Less interest in sex than usual (reduced libido)

Difficulty breathing or shortness of breath

Diarrhea.

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

Severe and life-threatening skin rash (Stevens-Johnson syndrome/toxic epidermal necrolysis)

Skin rash with irregular red spots (erythema multiforme).

Unknown (frequency cannot be determined from the available data)

Feeling restless or angry

Feeling lightheaded or having less control over your movements

Double vision

Moving restlessly or unsteadily

Muscle weakness

Indigestion

Becoming dependent on zopiclone (you become addicted)

Slower breathing than normal (respiratory depression)

Sensation of tingling, itching, or prickling without cause (paresthesia)

Mental problems, such as poor memory, difficulty concentrating, inability to speak normally.

Sleep-driving and other strange behavior

There have been some reports of people doing things in their sleep that they do not remember when they wake up after taking a sleeping pill, including sleep-driving and sleepwalking. Alcohol and some medications for depression or anxiety can increase the likelihood of this serious effect occurring.

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 (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. This can be found on the box or blister pack after "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 PACKAGE AND OTHER INFORMATION

What substances are in this medicine?

The active substance in this medicine is zopiclone.

[3.5 mg] Each film-coated tablet contains 3.75 mg zopiclone.

[7.5 mg] Each film-coated tablet contains 7.5 mg zopiclone.

The other substances in this medicine are:

Tablet core: lactose monohydrate, calcium hydrogen phosphate dihydrate, pregelatinized starch (maize starch), povidone (K-30), sodium starch glycolate (Type A) and magnesium stearate.

Tablet coating: hypromellose (6cps), macrogol, and titanium dioxide (E171).

What does Zopiclone Aurobindo look like and what is in a package?

Film-coated tablet.

Zopiclone Aurobindo 3.75 mg, film-coated tablets

White, round, biconvex, film-coated tablets. One side is imprinted with "Z1" and the other side is completely flat.

Zopiclone Aurobindo 7.5 mg, film-coated tablets

White, round, biconvex, film-coated tablets. One side is imprinted with "Z & 2" separated by a score line. The other side also contains a score line. The tablet can be divided into equal doses.

Zopiclone Aurobindo 3.75 mg and 7.5 mg, film-coated tablets are available in blister packs and Zopiclone Aurobindo 7.5 mg, film-coated tablets are also available in HDPE bottle.

Package sizes:

Blister packs: 5, 10, 14, 20, 28, 30, 50, 60, and 90 film-coated tablets.

HDPE packaging:

7.5mg: 500 film-coated tablets (for medicinal distribution systems only)

Not all mentioned package sizes are 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

Arrow Generiques

26 avenue Tony Garnier

69007, Lyon France

Generis-Farmaceutica, S.A.

Rua Joao de Deus, n° 19

2700-487, Venda Nova, Amadora

Portugal

Registered under:

Zopiclone Aurobindo 3.75 mg, film-coated tablets - RVG 121122. Zopiclone Aurobindo 7.5 mg, film-coated tablets - RVG 121124.

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

Belgium: Zopiclone AB 7.5 mg film-coated tablets

Germany: Zopiclone PUREN 3.75 mg/7.5 mg film-coated tablets

France: Zopiclone Arrow Lab 3.75 mg film-coated tablet Zopiclone Arrow Lab 7.5 mg scored film-coated tablet

Netherlands: Zopiclone Aurobindo 3.75 mg/7.5 mg, film-coated tablets

Poland: ApoDream

This leaflet was last approved in March 2023.

Transtoyou