

## **Package leaflet: Information for the user**

### **Zopiclone Orion 3.75 mg film-coated tablets** **Zopiclone Orion 7.5 mg film-coated tablets**

zopiclone

**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 any further 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. See section 4.

#### **What is in this leaflet**

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

#### **1. What Zopiclone Orion is and what it is used for**

Zopiclone Orion is a sleeping tablet with zopiclone as active substance.

It is used in adults as a sleeping drug for various kinds of sleeping problems, e.g. difficulty falling asleep, waking up too early or too many nightly awakenings. Zopiclone Orion is used as treatment of transient and short-term insomnia and, for a limited time, chronic insomnia.

Zopiclone Orion will only be prescribed if your sleeping problem is severe, disabling or causing you extreme distress.

#### **2. What you need to know before you take Zopiclone Orion**

##### **Do not take Zopiclone Orion**

- if you are allergic to zopiclone or any of the other ingredients of this medicine (listed in section 6)
- if you suffer from any of the following diseases:
  - a serious muscle-weakness called myasthenia gravis (an autoimmune disease)
  - respiratory insufficiency (serious breathing problem)
  - severe sleep apnoea syndrome (a sleep disorder characterized by pauses in breathing during sleep)
  - severe liver impairment
- if you have ever experienced sleepwalking or other unusual behavior (such as driving, eating, making a phone call or having sex etc.) while not being fully awake after taking Zopiclone Orion (see Warnings and precautions, Sleepwalking and associated behaviors).

##### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Zopiclone Orion.

##### General

Before treatment with Zopiclone Orion

- the cause of the sleep disturbances should be clarified
- underlying diseases should be treated.

Please tell your doctor if you have or have had any medical conditions or illnesses, especially any of the following:

- breathing problems
- liver or kidney problems
- psychoses (severe mental disorders characterized by disturbance of personality and loss of contact with reality)
- depression or anxiety linked with depression
- history of abuse of alcohol, drug or medicines
- you have recently taken Zopiclone Orion or other similar medicines for more than 4 weeks
- you do not feel you will ever be able to stop taking Zopiclone Orion or other medicines used to treat sleep problems.

Your doctor will decide whether you should take Zopiclone Orion or not or adjusts your dose. You will be also monitored closely during the treatment.

#### Dependence and withdrawal symptoms

The use of medicines like Zopiclone Orion can lead to physical and psychological dependence on these agents. The risk of dependence increases the higher the dose and the longer the period of treatment. This risk is also higher in patients with a history of alcohol, drug or medicine abuse and/or those who have marked personality disorders.

If physical dependence occurs, stopping the treatment suddenly may lead to withdrawal symptoms such as: headache, muscle pain, extreme anxiety, tension, restlessness, confusion and irritability. In severe cases following symptoms may occur: an alteration in the perception of the world so that it seems strange or unreal, loss of your own personal identity followed by feelings of unreality and strangeness, oversensitivity to sound, numbness and tingling of arms and legs, hypersensitivity to light, noise or physical contact, seeing, hearing or feeling things that don't really exist (hallucinations) and epileptic seizures.

#### Sleeplessness recurring after stopping the treatment (rebound insomnia)

After stopping the treatment with Zopiclone Orion the sleeplessness may return in a more severe form than before the treatment. This is a temporary syndrome called "rebound insomnia". Other symptoms may be mood changes, anxiety and restlessness. The risk of withdrawal or rebound symptoms can be decreased by reducing the dose gradually. Your doctor will advise you.

#### Tolerance

The effect of Zopiclone Orion may decrease after repeated use for a few weeks. This is called tolerance. Talk to your doctor, if you have the feeling that the effect of Zopiclone Orion decreases.

#### Short-term memory loss

Zopiclone Orion may cause a short-term memory loss. This occurs particularly a few hours after taking the medicine. In order to reduce this risk, make sure you will be able to have an uninterrupted sleep of 7–8 hours.

#### Psychiatric and paradoxical reactions

During the use of Zopiclone Orion, the following reactions may occur:

- restlessness, agitation
- irritability, aggression, outbursts of anger
- false beliefs, seeing, hearing or feeling things that do not really exist (hallucination)
- nightmares
- severe mental disorders characterized by disturbance of personality and loss of contact with reality (psychoses)
- unsuitable behaviour.

The risk of these reactions is higher in elderly patients. If you feel any of the symptoms listed above, you should stop taking Zopiclone Orion. Ask your doctor for advice.

### Sleepwalking and associated behaviours

Zopiclone Orion may cause sleepwalking or other unusual behaviour (such as driving, eating, making a phone call, or having sex etc.) while not being fully awake. The next morning, you may not remember that you did anything during the night. These events may occur following the first or any next dose of zopiclone.

These activities may occur whether or not you drink alcohol or take other medicines that make you drowsy with Zopiclone Orion. If you experience any of the above, stop the treatment with Zopiclone Orion immediately and contact your doctor.

The risk of such behaviours is increased

- if alcohol or certain other medicines (such as narcotic analgesics, antipsychotic agents, hypnotics or anxiolytics/sedatives) are used during treatment with zopiclone
- if zopiclone is used at doses exceeding the maximum recommended dose.

If you develop such behaviours, please inform your doctor immediately. Your doctor may discontinue the treatment with zopiclone.

### Suicidal ideation

Some studies have shown an increased risk of suicidal ideation, suicide attempt and suicide in patients taking certain sedatives and hypnotics, including this medicine. However, it has not been established whether this is caused by the medicine or if there may be other reasons. If you have suicidal thoughts, contact your doctor as soon as possible for further medical advice.

### Risk of fall

Due to the muscle relaxing effect of zopiclone, there is a risk of fall, especially in the elderly when they get up during the night.

See also section 4, Possible side effects, for more information regarding some of the above conditions.

### **Children and adolescents**

Zopiclone Orion should not be used in children and adolescents less than 18 years. The safety and efficacy of zopiclone in children and adolescents aged less than 18 years have not been established.

### **Other medicines and Zopiclone Orion**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

The following medicines may **increase the effect** of zopiclone:

- antipsychotics/neuroleptics (used to treat psychoses)
- hypnotics (used to treat sleeplessness)
- anxiolytics (used to treat anxiety)
- sedatives/tranquilizers (used to induce calmness and reduce anxiety)
- antidepressants (used to treat depression)
- narcotic analgesics/painkillers of the opioid class, such as morphine and morphine-like substances (used to relieve pain). They may additionally cause an abnormal feeling of happiness (euphoria). This may promote psychological dependence.
- antiepileptics/anticonvulsants (used to prevent epileptic seizures)
- anaesthetics (used to block pain sensation, for example during surgeries)
- calming antihistamines (used to treat allergic reactions).

Combination with the medicines above may require an adjusted dose.

Concomitant use of Zopiclone Orion and opioids (strong pain killers, medicines for substitution therapy and some cough medicines) also 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 Zopiclone Orion together with opioids the dose and duration of concomitant treatment should be limited by your doctor.

Please tell your doctor about all opioid medicines you are taking, and follow your doctor's dose recommendation closely. It could be helpful to inform friends or relatives to be aware of the signs 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 Zopiclone Orion:

- certain antibiotics (used to treat bacterial infections), e.g. erythromycin
- certain antimycotics (used to treat fungal infections), e.g. itraconazole
- HIV protease inhibitors (used to treat HIV).

To make side effects less likely, your doctor may decide to lower your dose of Zopiclone Orion.

The combination of Zopiclone Orion with muscle relaxants may **increase the muscle relaxing effect**.

The following medicines may **reduce the effect** of zopiclone:

- phenobarbital and phenytoin (used to treat seizures)
- carbamazepine (used to treat seizures and mood disorders)
- rifampicin (antibiotic to treat tuberculosis)
- products containing St. John's wort (herb used to treat depression and anxiety).

### **Zopiclone Orion with food, drink and alcohol**

Do not drink alcohol while you are taking Zopiclone Orion. Alcohol can increase the effects of Zopiclone Orion and make you sleep very deeply so that you do not breathe properly or have difficulty waking. Alcohol also increases the risk of dependence and the risk of e.g. sleepwalking (see section Warnings and precautions). In addition, alcohol can affect your ability to drive or use machines the day after.

Grapefruit and grapefruit juice should be avoided when taking Zopiclone Orion. Grapefruit may increase the effect of Zopiclone Orion.

### **Pregnancy, breast-feeding and fertility**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

#### Pregnancy

Use of Zopiclone Orion is not recommended during pregnancy.

If used during pregnancy there is a risk that the baby is affected. Some studies have shown that there may be an increased risk of cleft lip and palate in the newborn baby.

Reduced fetal movement and fetal heart rate variability may occur after taking Zopiclone Orion during the second and/or third trimester of pregnancy.

If Zopiclone Orion is taken at the end of pregnancy or during labour, your baby may show muscle weakness, a drop in body temperature, difficulty feeding and breathing problems (respiratory depression).

If this medicine is taken regularly in late pregnancy, your baby may develop physical dependence and may be at risk of developing withdrawal symptoms such as agitation or shaking. In this case the newborn should be closely monitored during the postnatal period.

#### Breast-feeding

Zopiclone passes into breast milk. Do not use Zopiclone Orion if you are breast-feeding.

### **Driving and using machines**

You should not drive or operate machines until the treatment has finished or it has been established that your performance is not impaired. Some of the side effects can affect your ability to react or in other ways affect your ability to drive (see section 4, Possible side effects).

The risk of these effects increases with alcohol intake and is even higher when the sleep duration is insufficient. **The symptoms may affect you also in the next morning.**

### **Zopiclone Orion contains lactose**

Zopiclone Orion 3.75 mg tablets contain 16 mg lactose monohydrate and 7.5 mg tablets contain 32 mg lactose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

## **3. How to take Zopiclone Orion**

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Your treatment with Zopiclone Orion should be as short as possible and not exceed 4 weeks. The lowest effective dose should be used.

### Use in adults

The recommended initial dose is 5 mg or 7.5 mg at bedtime.

Since Zopiclone Orion is not available in the strength 5 mg, another zopiclone product will be prescribed if you need a dose of 5 mg.

### Use in children and adolescents

You shall not take Zopiclone Orion if you are under 18 years of age.

### Use in elderly

The recommended initial dose is 3.75 mg zopiclone. Your doctor may later increase the dose to 5 mg and if necessary up to 7.5 mg.

### Use in patients with impaired liver or kidney function or chronic respiratory insufficiency

The recommended initial dose is 3.75 mg zopiclone.

Take Zopiclone Orion just before going to bed. Do not take the tablets lying down as the uptake in the body might be delayed. Make sure you will be able to have an uninterrupted sleep of 7–8 hours. Swallow the tablet with liquid (e.g. 1 glass of water).

### **Duration of the treatment**

Your treatment with Zopiclone Orion should be as short as possible. In general, it should last between a few days to 2 weeks. Your doctor will explain to you how to reduce the dose of Zopiclone Orion gradually at the end of the treatment (tapering off). This measure lowers the risk of withdrawal or rebound symptoms (see section 2, Warnings and precautions).

You should not take Zopiclone Orion for longer than 4 weeks including the tapering off phase. Ask your doctor for advice if your symptoms do not improve within this period.

### **If you take more Zopiclone Orion than you should**

If you have taken too many tablets, contact your doctor or nearest hospital casualty department immediately for advice.

Zopiclone overdose together with certain agents or medicines which have a suppressive effect on the central nervous system might be life-threatening. This includes alcohol.

Taking too much zopiclone (Zopiclone Orion) may cause symptoms such as:

- feeling drowsy, confused, sleeping deeply and possibly falling in to a coma
- floppy muscles
- feeling dizzy, light headed or faint. These effects are due to low blood pressure.
- falling over or losing your balance
- shallow breathing or difficulty breathing (respiratory depression).

#### **If you forget to take Zopiclone Orion**

If you still have time to sleep for 7 to 8 hours, you should take the dose immediately.

If there is less time, ignore the forgotten dose and do not take another dose until the following day before going to sleep, as needed. Do not take a double dose to make up for a forgotten tablet.

#### **If you stop taking Zopiclone Orion**

If you suddenly stop your treatment the sleeping problems may return during a transient time (rebound symptoms). You may also get withdrawal symptoms. See section 2, Warnings and precautions. The risk of withdrawal symptoms increases with dose and duration of treatment and the doctor will advise you how to gradually reduce the dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

## **4. Possible side effects**

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

**Stop** using Zopiclone Orion and contact a doctor or go to your nearest emergency department **immediately** if you develop one or more of following symptoms (very rare):

- swelling of the face, lips or tongue
- difficulty in swallowing
- difficulty in breathing.

These symptoms can be signs of severe allergic reactions which can be life-threatening.

#### **Other side effects that may occur:**

Common (may affect up to 1 in 10 people):

- bitter taste, dry mouth
- drowsiness.

Uncommon (may affect up to 1 in 100 people):

- restlessness, nightmares
- nausea, general discomfort, abdominal pain
- decreased alertness, headache, dizziness
- difficulty getting up in the morning, fatigue.

Rare (may affect up to 1 in 1 000 people):

- confusion, irritability, aggression, hallucinations, depression (existing depression may manifest itself during treatment with zopiclone), short-term memory loss
- change in sexual desire (libido disorders)
- difficulty breathing
- vomiting
- allergic skin reactions (including rash, itching, urticaria)
- fall (mainly in elderly patients).

Very rare (may affect up to 1 in 10 000 people):

- increase of certain liver enzymes seen in blood tests.

Not known (frequency cannot be estimated from the available data):

- restlessness, false beliefs, anger, abnormal behaviour (possibly associated with memory loss)
- memory impairment, inability to concentrate, speech disorder

- inability to co-ordinate muscle movements
- tingling or numbness in parts of the body, double vision
- shallow breathing or difficulty breathing
- indigestion
- muscular weakness
- sleep walking
- dependence, withdrawal syndrome.

See also section 2, Warnings and precautions, for more information regarding some of the side effects.

### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [the national reporting system listed in Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Zopiclone Orion**

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

Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## **6. Contents of the pack and other information**

### **What Zopiclone Orion contains**

The active substance is zopiclone.

3.75 mg

Each film-coated tablet contains 3.75 mg of zopiclone.

7.5 mg

Each film-coated tablet contains 7.5 mg of zopiclone.

The other ingredients are:

*Tablet core:*

calcium hydrogen phosphate dehydrate, maize starch, lactose monohydrate, pregelatinised starch, hydroxypropyl cellulose, magnesium stearate.

*Tablet coating:*

hypromellose, titanium dioxide (E171), macrogol

### **What Zopiclone Orion looks like and contents of the pack**

3.75 mg

White to off white, round, diameter 6 mm, biconvex film-coated tablets (tablets).

7.5 mg

White to off white, oval (10 mm x 5 mm), biconvex film-coated tablets with breakline on one side (tablets). The tablet can be divided into equal doses.

The tablets are provided in blister packs containing 10, 14, 20, 28, 30, 56, 60 or 100 tablets.

Not all pack sizes may be marketed.

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