

Package leaflet: Information for the patient

Zopiclone Actavis 5 mg and 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.
- Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Please note that your doctor may have prescribed a different use and/or dose of the film-coated tablets than specified in the information for the patient.

What is in this leaflet

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

1. What Zopiclone Actavis is and what it is used for

Zopiclone Actavis is a sleeping drug, which affects the centers in the brain that make us able to sleep. It helps you fall asleep sooner and sleep longer. Zopiclone Actavis is used in adults as a sleeping drug for various kinds of sleeping problems, e.g. difficulty falling asleep, waking up too early or to many nightly awakenings. Zopiclone Actavis is used as treatment of transient and short-term insomnia and, for a limited time, chronic insomnia. Zopiclone Actavis usually works within 30 minutes and leaves the body relatively fast. This means that risk of feeling drowsy on the day after having taken the tablet is small.

2. What you need to know before you take Zopiclone Actavis

Do not take Zopiclone Actavis:

- if you are allergic to zopiclone or any of the other ingredients of this medicine (listed in section 6).
- if you have severe liver disease
- if you have severe muscle weakness (myasthenia gravis)
- if you have breathing problems (respiratory impairment)
- if you have severe respiratory arrest during sleep (sleep apnoea).

Warnings and precautions

Talk to your doctor or pharmacist before taking Zopiclone Actavis. Let your doctor know before treatment if you:

- have liver problems
- have breathing problems (respiratory problems)
- have history of alcohol or drug abuse
- have recently taken Zopiclone Actavis or other similar medicines for more than four weeks

- feel you will not be able to stop taking Zopiclone Actavis or other medicines used to treat sleep problems
- have a reduced general condition

Sleepwalking and similar behaviours

Sleep walking and other similar behaviours, such as sleep-driving and sleep-eating, with memory loss (amnesia) for the event, have been reported in patients who have taken zopiclone and were not fully awake.

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.

Elderly

Caution should be exercised in treatment of elderly patients.

Children and adolescents

Zopiclone Actavis 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 Actavis

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines you buy without a prescription, including herbal medicines. This is because Zopiclone Actavis can affect the way some other medicines work. Also some medicines can affect the way Zopiclone Actavis works.

Zopiclone Actavis may increase the effect of the following medicines:

- Medicines for mental problems (antipsychotics)
- Medicines for depression
- 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)
- Some medicines for moderate to severe pain (narcotic analgesics)

The following medicines can increase the effect of Zopiclone Actavis therefore your doctor may decide to lower your dose of Zopiclone Actavis:

- Some antibiotics such as erythromycin
- Some medicines for fungal infections such as itraconazole

Concomitant use of Zopiclone Actavis 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 Zopiclone Actavis 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.

Some antibiotics for infections such as rifampicin can make Zopiclone Actavis work less well.

Zopiclone Actavis with alcohol

Do not drink alcohol while you are taking Zopiclone Actavis. Alcohol can increase the effects of Zopiclone Actavis and make you sleep very deeply so that you do not breathe properly.

Pregnancy and breastfeeding

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.

In pregnancy there is a risk that the foetus may be affected. Zopiclone Actavis should therefore not be used during pregnancy.

Zopiclone Actavis passes into breast milk. Using Zopiclone Actavis while you are breast-feeding is not recommended.

Driving and using machines

Zopiclone Actavis may impair the ability to react. You should take this into consideration when alertness is required, e.g. when driving or performing precision work. For more information about possible side effects which could affect your driving see section 4 of this leaflet. If you are unsure, talk to your doctor or pharmacist.

Zopiclone Actavis contains lactose

If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicinal product

3. How to take Zopiclone Actavis

The duration of treatment should be as short as possible. Including the gradual tapering off, it should not exceed 4 weeks. Always take use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Taking this medicine

- Take this medicine by mouth
- Take this medicine in an upright position as the effect may otherwise be delayed.
- Take just before bedtime or before going to sleep Zopiclone Actavis usually works within 30 minutes.

The recommended dose for adults is 1 tablet at bedtime (5 mg). Your doctor may decide to increase your dose to one Zopiclone Actavis tablet (7.5 mg) if needed.

If you take more Zopiclone Actavis than you should

If you have taken too much Zopiclone Actavis, contact the doctor or go to the hospital straight away. Take the medicine pack with you. This is so the doctor knows what you have taken.

Taking too much Zopiclone Actavis can have the following effects:

- Feeling drowsy, confused, sleeping deeply and possibly falling into a coma
- Tiredness (Fatigue)
- Heart beats too fast
- Feeling dizzy, light headed or faint
- Changes to blood test results
- Symptoms from stomach and intestine
- Shallow breathing or difficulty breathing (respiratory depression)

If you forget to take Zopiclone Actavis

Do not take a double dose to make up for a forgotten tablet. Zopiclone Actavis must only be taken at bedtime.

If you stop taking Zopiclone Actavis

If you stop taking Zopiclone Actavis 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:

- Headaches
- Aching muscles (Myalgia)
- Muscle tension
- Extreme anxiety
- Irritability
- Hallucinations (seeing or hearing things that are not real)
- Being more sensitive to light, noise and touch than normal
- Numbness and tingling in your hands and feet
- Epileptic seizures

4. Possible side effects

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

Common: may affect more than 1 in 100 people:

- Dry mouth (careful mouth hygiene is therefore important)
- Bitter taste in the mouth (often transient)
- Drowsiness

These side effects depend on the size of the dose and will generally disappear or be reduced when the dose is lowered.

Uncommon: may affect up to 1 in 100 people:

- Headache
- Abnormal dreams
- General discomfort
- Agitation
- Dizziness

Rare: may affect up to 1 in 1000 people:

- Aggressiveness
- Confusion
- Irritation
- Difficulty in concentrating
- Memory loss
- Hallucinations
- Anxiety
- Skin rash
- Severe allergic reactions
- Effect on liver enzymes

Not known: Frequency cannot be estimated from the available data

- Sleep-walking and other similar behaviour, see section 2 "Warnings and precautions".

Reporting of side effects

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

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

Store below 25 °C. Keep the film-coated tablets in the original packaging. Do not use this medicine after the expiry date which is stated on the packaging. 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 Actavis contains

The active substance is zopiclone

The other ingredients are:

Lactose monohydrate,

calcium hydrogen

phosphate dehydrate

maize starch

carmellose sodium

magnesium stearate

titanium dioxide (E171)

hypromellose.

5 mg film-coated tablets also contain yellow iron oxide (E172) and macrogol.

What Zopiclone Actavis looks like and contents of the pack

5 mg film-coated tablets: yellow, marked 'ZOC5'.

7.5 mg film-coated tablets: White, scored on both sides, marked 'ZOC7.5'.

PVC/PVDC/aluminium blister: 10, 30, 100 and 50x1 film-coated tablets (single dose)

HDPE plastic container: 500 film-coated tablets (only for dose dispensing and hospital use)

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

[To be completed nationally]

This package leaflet was last revised in 9 October 2018