

**PACKAGE LEAFLET:
INFORMATION FOR THE USER**

**Zimovane 7.5 mg
film-coated tablets
Zimovane LS 3.75 mg
film-coated tablets
zopiclone**

Opella.



Is this leaflet hard
to see or read?

Phone 0800 035 2525
for help

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

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

The name of your medicine is Zimovane tablets or Zimovane **LS** tablets (both called Zimovane in this leaflet). Zimovane contains a medicine called zopiclone. This belongs to a group of medicines called hypnotics. It works by acting on your brain to help you sleep.

Zimovane is used for short term treatment of sleep problems (insomnia) in patients over 18 years of age, such as:

- Difficulty falling asleep
- Waking in the middle of the night
- Waking too early
- Severe or upsetting sleep problems that are caused by your mood or mental health problems

Do not take Zimovane as long-term treatment. Treatment should be as short as possible, because the risk of dependence increases with the duration of treatment. Ask your doctor for advice if you are unsure.

**2. What you need to know before you
take Zimovane**



Do not take Zimovane if:

- ✗ You are allergic (hypersensitive) to zopiclone or any of the other ingredients of Zimovane (listed in section 6 below).
Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- ✗ You have a problem that causes severe muscle weakness (myasthenia gravis).
- ✗ Your lungs do not work properly (respiratory failure).
- ✗ You have a problem where you stop breathing for short periods at night (sleep apnoea).
- ✗ You have severe liver problems.
- ✗ You are under the age of 18. The safety and efficacy of Zimovane in children and adolescents aged less than 18 years have not been established.
- ✗ You have ever experienced sleepwalking or other unusual behaviour (such as driving, eating, making a phone call or having sex etc.) while not being fully awake after taking Zimovane.

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

**Turn
Over**



Warnings and precautions

Talk to your doctor or pharmacist before taking Zimovane if:

- ▲ You have any liver problems (see also 'Do not take Zimovane if:'). Your doctor may need to give you a lower dose of Zimovane.
- ▲ You have any kidney problems. Your doctor may need to give you a lower dose of Zimovane.
- ▲ You suffer from mild breathing problems; your doctor will decide if you should receive Zimovane (see also 'Do not take Zimovane if:').
- ▲ You have ever had a mental disorder (including depression and personality disorder) or have abused or have been dependent on alcohol or drugs.
- ▲ You have recently taken Zimovane or other similar medicines for more than four weeks.

Risk of abuse and dependence

Use of Zimovane may lead to the development of abuse and/or physical and psychological dependence. The risk of dependence increases with dose and duration of treatment and is greater when Zimovane is used for longer than 4 weeks, and in patients with a history of mental disorders and/or alcohol, illicit substance or drug abuse.

Zimovane and mental health

Some people being treated with Zimovane can experience mental health problems

such as irrational thoughts (delusions), seeing or hearing things that are not there (hallucinations), feeling confused or disorientated (delirium), feeling angry, irritable, restless or depressed.

Additionally, 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.

Zimovane and unusual behaviour

Zimovane 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 activities may occur whether or not you drink alcohol or take other medicines that make you drowsy with Zimovane. If you experience any of the above, stop the treatment with Zimovane immediately and contact your doctor or healthcare provider. Before taking Zimovane, it is important to make sure that you can have at least 7 to 8 hours of uninterrupted sleep to help reduce the risk of some side effects (see section 4 – 'Possible side effects').

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking Zimovane.



Other medicines and Zimovane

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 Zimovane can affect the way some other medicines work. Also, some medicines can affect the way Zimovane works.

Tell your doctor if you are taking any of the following medicines. Zimovane may increase the effect of the following medicines:

- Medicines for mental problems (antipsychotics)
- Medicines for depression
- Medicines for epilepsy (anticonvulsants)
- 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) such as chlorphenamine or promethazine
- Some medicines for moderate to severe pain (narcotic analgesics) such as codeine, methadone, morphine, oxycodone, pethidine or tramadol.

The following medicines can increase the chance of you getting side effects when taken with Zimovane. To make this less likely, your doctor may decide to lower your dose of Zimovane:

- Some antibiotics such as clarithromycin or erythromycin
- Some medicines for fungal infections such as ketoconazole and itraconazole
- Ritonavir (a protease inhibitor) - for HIV infections
- Concomitant use of Zimovane and opioids increases the risk of drowsiness, difficulties breathing, coma and death. Zimovane and opioids should only be used concomitantly, when other treatment options are inadequate. Please tell your doctor about all opioid medicines you are taking and follow your doctor's dosage recommendations closely.

The following medicines can make Zimovane work less well:

- Some medicines for epilepsy such as carbamazepine, phenobarbital or phenytoin
- Rifampicin (an antibiotic) - for infections
- St John's Wort (a herbal medicine) - for mood swings and depression

Taking Zimovane with food and drink

Do not drink alcohol while you are taking Zimovane. Alcohol can increase the effects of Zimovane and make you sleep very deeply so that you do not breathe properly or have difficulty waking.

Pregnancy, breast-feeding and fertility

Pregnancy

Use of Zimovane is not recommended during pregnancy. If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

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 (sometimes called "harelip") in the newborn baby.

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

If Zimovane 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

Do not take Zimovane if you are breast-feeding or planning to breast-feed.

This is because small amounts may pass into mother's milk.

If you are breast-feeding or planning to breast-feed, talk to your doctor or pharmacist before taking any medicine.

Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast-feeding.

Driving and using machines

Like other medicines used for sleep problems, Zimovane can cause slowing of your normal brain function (central nervous system depression). The risk of psychomotor impairment including driving ability, is increased if:

- You take Zimovane within 12 hours of performing activities that require mental alertness.
- You take higher than the recommended dose of Zimovane.
- You take Zimovane while already taking another central nervous system depressant or another medicine that increases levels of Zimovane in your blood, or while drinking alcohol.

Do not engage in hazardous activities requiring complete mental alertness such as driving or operating machinery after taking Zimovane, and in particular during the 12 hours after taking your medicine.

For more information about possible side effects which could affect your driving see section 4 of this leaflet.

Zimovane contains

- **Lactose:** This is a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.
- **Sodium:** This medicine contains less than 1mmol sodium (23mg) per tablet, that is to say essentially 'sodium-free'.
- **Gluten:** This medicine contains only very low levels of gluten (from wheat starch) and is very unlikely to cause problems in you if you have coeliac disease. If you have wheat allergy (different to coeliac disease) you should not take this medicine.
 - One 3.75mg tablet contains no more than 3 micrograms of gluten.
 - One 7.5mg tablet contains no more than 6 micrograms of gluten.

3. How to take Zimovane

Treatment should be as short as possible and should not exceed four weeks including period of tapering off. Your doctor will give you the lowest effective dose.

Always take Zimovane exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

Taking this medicine

- Take this medicine by mouth.
- Swallow the tablet with a drink of water.
- Do not crush or chew your tablets.
- Take just before bedtime in a single intake and do not take again during the same night.
- The usual length of treatment is 2 days to 3 weeks.

Adults

The usual dose is one Zimovane tablet (7.5 mg) just before bedtime.

Elderly

The usual starting dose is one Zimovane **LS** tablet (3.75 mg) just before bedtime. Your doctor may decide to increase your dose to one Zimovane tablet (7.5 mg) if needed.

Use in children and adolescents

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

Patients with liver, respiratory or kidney problems

The usual starting dose is one Zimovane **LS** tablet (3.75 mg) just before bedtime.

Blood Tests

- Zimovane can change the levels of liver enzymes shown up in blood tests. This can mean that your liver is not working properly.

- If you are going to have a blood test, it is important to tell your doctor that you are taking Zimovane.

If you take more Zimovane than you should

If you take more Zimovane than you should, tell a doctor or go to a hospital casualty department straight away. Take the medicine pack with you. This is so the doctor knows what you have taken.

Taking too much Zimovane can be very dangerous. The following effects may happen:

- Feeling drowsy, confused, sleeping deeply and possibly falling into a coma
- Floppy muscles (hypotonia)
- Feeling dizzy, light headed or faint. These effects are due to low blood pressure
- Falling over or losing your balance (ataxia)
- Shallow breathing or difficulty breathing (respiratory depression)

If you forget to take Zimovane

Zimovane must only be taken at bedtime. If you forget to take your tablet at bedtime, then you should not take it at any other time, otherwise you may feel drowsy, dizzy and confused during the day.

Do not take a double dose to make up for a forgotten tablet.

If you stop taking Zimovane

Keep taking Zimovane until your doctor tells you to stop. Do not stop taking Zimovane suddenly, but tell your doctor if you want to stop. Your doctor will need to lower your dose and stop your tablets over a period of time.

If you stop taking Zimovane 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:

- Feeling anxious, shaky, irritable, agitated, confused or having panic attacks
- Sweating
- Headache
- Faster heartbeat or uneven heartbeat (palpitations)
- A lower level of awareness and problems with focusing or concentrating
- Nightmares, seeing or hearing things that are not real (hallucinations)
- Being more sensitive to light, noise and touch than normal
- Relaxed grip on reality
- Numbness and tingling in your hands and feet
- Aching muscles
- Stomach problems

In rare cases fits (seizures) may also occur.

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

4. Possible side effects

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

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

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

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

Rare (affects 1 to 10 users in 10,000)

- Poor memory since taking Zimovane (amnesia). By having 7-8 hours of uninterrupted sleep after taking Zimovane, this is less likely to cause you a problem.
- Seeing or hearing things that are not real (hallucinations)
- Falling, especially in the elderly

Not known (frequency cannot be estimated from available data)

- Thinking things that are not true (delusions)
- Feeling low or sad (depressed mood)

Tell your doctor or pharmacist if any of the following side effects get serious or lasts longer than a few days:

Common (affects 1 to 10 users in 100)

- A mild bitter or metallic taste in your mouth or a dry mouth
- Feeling drowsy or sleepy

Uncommon (affects 1 to 10 users in 1,000)

- Feeling sick (nausea) or being sick (vomiting)
- Feeling dizzy or sleepy
- Headache
- Nightmares
- Feeling physically or mentally tired
- Agitation

Rare (affects 1 to 10 users in 10,000)

- Feeling confused
- Itchy, lumpy rash (urticaria)
- Feeling irritable or aggressive
- Reduced sex drive
- Difficulty breathing or being short of breath

Not known (frequency cannot be estimated from available data)

- Feeling restless or angry
- Feeling light-headed or having problems with your coordination
- Double vision
- Moving unsteadily or staggering
- Muscular weakness
- Indigestion
- Becoming dependent on Zimovane
- Slower breathing (respiratory depression)
- Unusual skin sensations such as numbness, tingling, pricking, burning or creeping on the skin (paraesthesia)



- Mental problems such as poor memory
- Difficulty paying attention
- Disrupted normal speech
- Zimovane may cause sleepwalking or other unusual behaviour (such as driving, eating, making a phone call, or having sex etc.) while not being fully awake.
- Delirium (a sudden and severe change in mental state that can cause a combination of confusion, disorientation and/or attention deficit)

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Zimovane

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

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

Zimovane LS 3.75mg: Store below 30°C.
Zimovane 7.5mg: None.
Keep the blister in the outer carton in order to protect from light and moisture.

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 Zimovane and Zimovane LS contain

- Each tablet of Zimovane contains 7.5 mg of the active substance zopiclone
- Each tablet of Zimovane **LS** contains 3.75 mg of the active substance zopiclone

Other ingredients are lactose monohydrate, calcium hydrogen phosphate dihydrate, wheat starch, sodium starch glycolate, magnesium stearate, hypromellose, titanium dioxide and macrogol 6000.

What Zimovane looks like and contents of the pack

Zimovane is a white, elliptical (oval), biconvex shaped film-coated tablet with a score line on one side contained within PVC/aluminium foil blisters containing 56, 28, 14, 7 or 3 tablets, and in a starter pack containing 3 tablets.

Zimovane **LS** is a white, round, biconvex shaped film-coated tablet within PVC/aluminium foil blisters containing 112, 56, 28, 14, 10, 7 or 3 tablets, and in a starter pack containing 3 tablets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Sanofi, 410 Thames Valley Park Drive, Reading, Berkshire, RG6 1PT, UK.
Tel: 0800 035 2525

email:

uk-medicalinformation@sanofi.com

Manufacturer

Opella Healthcare International SAS
56, Route de Choisy
60200 Compiègne, France

This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

This leaflet was last revised in December 2024

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