

Package leaflet: Information for the patient

Lunivia® 1 mg film-coated tablets

Lunivia® 2 mg film-coated tablets

Lunivia® 3 mg film-coated tablets

eszopiclone

For use in adults

This medicine contains eszopiclone, which can cause dependence, tolerance and addiction. You can get withdrawal symptoms if you stop taking it or reduce the dose suddenly.

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

1. What Lunivia is and what it is used for

This medicine has been prescribed for you to help you sleep. Lunivia contains eszopiclone, which belongs to a class of medicine called z-drugs. This medicine has been prescribed to you and should not be given to anyone else. Lunivia is used in adults to treat insomnia, usually for short term duration. Lunivia is used only when the disorder is severe, disabling or causing great distress.

Z-drugs can cause dependence, tolerance and addiction, and you may get withdrawal symptoms if you stop taking it or reduce the dose suddenly. Your prescriber should have explained how long you will be taking it for and, when it is appropriate to stop, how to do this safely. When your treatment is stopped, it is usually done gradually over a period which is specific to you and may occur over a period of weeks to months.

2. What you need to know before you take Lunivia

Do not take Lunivia:

- if you are allergic to eszopiclone, zopiclone or any of the other ingredients of this medicine (listed in section 6).
- if you have myasthenia gravis (an autoimmune condition which causes muscles to tire easily and become weak).
- if you have severe breathing problems.
- if you have severe sleep apnoea (a sleep disorder where you stop breathing for short periods while asleep).
- if you have severe liver problems.
- if you have experienced sleepwalking or other unusual behaviours, such as driving, eating, making a phone call or having sex while not being fully awake, after taking other hypnotics.
- if you are aged 65 or over and are taking CYP3A4 inhibitors such as certain antibiotics or antifungals (e.g. ketoconazole). Talk to your doctor or pharmacist.

Warnings and precautions

Talk to your prescriber before taking Lunivia if you:

- are taking any other medicines to help you sleep, such as benzodiazepines and benzodiazepine-like-substances. There is a chance that you become dependent on them. It is more likely to occur if you have a history of alcohol abuse or drug abuse or with a diagnosis of a personality disorder.
- are or have ever been addicted to opioids, alcohol, prescription medicines, or illegal drugs, or if you have ever had a history of struggling to control your alcohol or drug intake.
- have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or drugs.
- feel you need to take more of Lunivia to get the same level of symptom control, this may mean you are developing tolerance to the effects of this medicine or are becoming addicted to it. Speak to your prescriber who will discuss your treatment and may change your dose or switch you to an alternative medication.
- are feeling anxious or depressed. Your doctor may need to review your medicine. Eszopiclone does not treat depression.
- have breathing problems (see section 2, 'Do not take Lunivia').
- have liver problems (see section 2, 'Do not take Lunivia').
- have kidney problems.
- are aged 65 or over (see section 3, 'How to take Lunivia').

Taking this medicine regularly, particularly for a long time, can lead to physical dependence and addiction. Your prescriber should have explained how long you will be taking it for and, when it is appropriate to stop, how to do this safely. When your treatment is stopped, it is usually done gradually over a period which is specific to you and may occur over a period of weeks to months.

Physical dependence and addiction can cause withdrawal symptoms when you stop taking this medicine. Withdrawal symptoms can include:

- feeling anxious, shaky, irritable, agitated, confused, having panic attacks, sweating, headache, faster heartbeat or uneven heartbeat (palpitations), lower level of awareness or problems with focussing or concentrating, nightmares, seeing of 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.

Your prescriber will discuss with you how to gradually reduce your dose before stopping the medicine. It is important that you do not stop taking the medicine suddenly as you will be more likely to experience withdrawal symptoms. Your prescriber will ensure that your plan for stopping treatment is tailored to you and can be adapted according to your needs and experience of any withdrawal symptoms.

Z-drugs should only be used by those they are prescribed for. Do not give your medicine to anyone else. Taking higher doses or more frequent doses of Z-drugs, may increase the risk of addiction. Overuse and misuse can lead to overdose and/or death.

Before taking Lunivia:

- It is important that you have 8 hours to devote to sleep.
- Lunivia can cause memory loss. To reduce the risk, you should ensure that you are able to have at least 8 hours of uninterrupted sleep.

During treatment with Lunivia:

- If you do not get 8 hours of sleep after taking Lunivia, you may feel unsteady on your feet. If you are aged 65 or over, you may be more likely to fall and injure yourself.
- Tell your doctor if you start acting in a way which is unusual for you, for example, more outgoing or aggressive behaviour than normal, confusion, agitation, restlessness, nightmares, feeling or hearing things that are not there (hallucinations), worsening of depression, and suicidal thoughts or actions while taking Lunivia.
- Sleep walking and other associated behaviours may occur. After taking Lunivia, you may get up out of bed

while not being fully awake and do an activity that you do not know you are doing. The next morning, you may not remember that you did anything during the night. You have a higher chance for doing these activities if you drink alcohol or take other medicines that make you sleepy with Lunivia. Reported activities include: driving a car ("sleep driving"), making and eating food, talking on the phone, having sex, sleep-walking.

– The day after taking Lunivia, the risk of psychomotor impairment, including impaired driving ability may be increased:

- if you take this medicine less than 12 hours before performing activities that require your alertness.
- if you take a higher dose than the recommended dose.
- if you take Lunivia while you are already taking another central nervous system depressants or other medicines that increase Lunivia in your blood, or while drinking alcohol, or while taking illicit substances. (see section 2, 'Driving and using machines').

Children and adolescents

Do not give eszopiclone to children and adolescents under the age of 18 years.

Other medicines and Lunivia

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is because Lunivia may affect or be affected by certain medicines.

These include:

- Medicines you buy without a prescription, including herbal medicines
- CYP3A4 inhibitors such as some antibiotics (medicines used to treat bacterial infections), some antifungals (medicines used for fungal infections, e.g. ketoconazole) or grapefruit juice. The dose of Lunivia may need to be reduced or discontinued. (See section 3, how to take Lunivia).
- Inducers of cytochrome P450-enzymes such as carbamazepine, phenytoin and St John's Wort
- Medicines used to treat your mood or behaviour (how you feel or act), e.g. medicines for depression or anxiety (antipsychotics, hypnotics, anxiolytics/sedatives, antidepressants)
- Medicines used for strong pain relief (narcotic analgesics)
- Medicines used for the treatment of seizures/convulsions or fits (antiepileptic medicines)
- Medicines used in surgery (anaesthetics)
- Medicines used for allergies (sedative antihistamines)

Combination with the medicines above may result in increased chance of getting side effects. Tell your doctor if you are taking any of the medicines above. Your doctor may need to adjust the dose of Lunivia.

Concomitant use of Lunivia and opioids (strong pain killers, medicines for substitution therapy (e.g., levomethadone, methadone or buprenorphine) 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 Lunivia 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.

Lunivia with food, drink and alcohol

Lunivia may take longer to work if you take it with or immediately after eating a high-fat or large meal.

Do not drink alcohol while taking Lunivia because alcohol can increase the side effects of Lunivia.

The consumption of grapefruit juice should be avoided (see section 2, 'Other medicines and Lunivia').

Pregnancy and breast-feeding

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

Lunivia is not recommended during pregnancy because it may be harmful to your baby.

Do not take Lunivia if you are breast-feeding, as it may pass into breast milk.

Driving and using machines

Do not drive, operate machinery or do any hazardous activities requiring complete mental alertness for 12 hours after you take Lunivia. Drowsiness, blurred vision, and difficulty with concentration, memory and coordination may affect your ability to perform such activities.

Lunivia contains sodium

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

3. How to take Lunivia

Duration of treatment

The duration of treatment should be as short as possible and usually should not exceed four weeks including the stepwise withdrawal process (see section 'If you stop taking Lunivia').

In certain cases, you may be required to take Lunivia for longer than 4 weeks. In this case, your doctor will tell you how long you need to take Lunivia.

Your prescriber should have discussed with you how long the course of tablets will last. They will arrange a plan for stopping treatment. This will outline how to gradually reduce the dose and stop taking the medicine. Your

prescriber will ensure that your plan for stopping treatment is tailored to you and can be adapted according to your needs and experience of any withdrawal symptoms.

Taking this medicine

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

Take Lunivia by mouth just before you go to bed. Swallow the tablets whole. Do not crush or break the tablet.

Do not take more than one dose in a single night.

Adults

The usual starting dose of eszopiclone is 1 mg at night. The dose may be increased to 2 or 3 mg if needed.

Elderly aged 65 or older

The recommended starting dose of eszopiclone is 1 mg at night. The dose may be increased to 2 mg if needed.

Patients with severe kidney problems

The maximum recommended dose of eszopiclone is 2 mg each night.

Patients taking CYP3A4 inhibitors such as certain antibiotics or antifungals

The maximum recommended dose of eszopiclone is 2 mg each night. If you are 65 years or older, you must not take Lunivia with CYP3A4 inhibitors.

If you take more Lunivia than you should

If you have taken too many tablets, you should seek medical advice urgently. Take the Lunivia pack with you, so the doctor knows what you have taken.

Eszopiclone overdose can be very dangerous. If you take too much Lunivia, the following effects may happen:

- Feeling very sleepy, confused and possibly fall into a coma.
- Shallow breathing or difficulty breathing (respiratory depression)
- Falling over or losing your balance (ataxia)

If you forget to take Lunivia

Eszopiclone must only be taken at bedtime. If you forget to take your tablet at bedtime, you should not take it at any other time. Just take your next tablet at the usual time the

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

If you stop taking Lunivia

Do not suddenly stop taking Lunivia. If you want to stop taking this medicine, discuss this with your prescriber first. They will tell you how to do this, usually by reducing the dose gradually so that any unpleasant withdrawal effects are kept to a minimum. This may occur over a period of weeks to months. Your prescriber will ensure that your plan for stopping treatment is tailored to you and can be adapted according to your needs and experience of any withdrawal symptoms.

Withdrawal symptoms such as:

- feeling anxious, shaky, irritable, agitated, confused, having panic attacks, sweating, headache, faster heartbeat or uneven heartbeat (palpitations), lower level of awareness or problems with focussing or concentrating, nightmares, seeing of 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, increased appetite.

It is also possible that your difficulty in sleeping may return for one or two nights when you stop taking Lunivia. In rare cases, seizures may occur after you stop taking medicines like Lunivia. Tell your doctor if any of these happen to you.

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 taking Eszopiclone and see a doctor or go to a hospital straight away if you have any of the following side effects:

Uncommon side effects (may affect 1 to 10 users in 1000):

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

Rare side effects (may affect 1 to 10 users in 10000):

– Angioedema (swelling of face, lips, tongue or throat), anaphylactic reaction (severe allergic reaction with rash, swallowing or breathing problems)

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

Common side effects (may affect 1 to 10 users in 100):

– Loss or difficulty with memory, abnormal thinking

Uncommon side effects (may affect 1 to 10 users

in 1000):

– Feeling or hearing things that are not there (hallucination), euphoria

Rare side effects (may affect 1 to 10 users in 10000):

– Fall (predominantly in patients 65 years or older)

Side effects of **not known** frequency (frequency cannot be estimated from the available data):

– Becoming dependent, withdrawal symptoms, dampened emotions

– Slower breathing (respiratory depression)

– Dependence and addiction (see section “How do I know if I am tolerant or addicted?”)

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

Very common side effect (may affect more than 1 in 10 people):

– Unpleasant taste

Common side effects (may affect 1 to 10 users in 100):

– Nervousness, depression, anxiety

– Blurred vision (predominantly in patients 65 years or older)

– Sore throat

– Dry mouth, diarrhoea, feeling sick (nausea), being sick (vomiting), indigestion, stomach pain

– Rash

– Back pain, muscle pain

– Weakness, pain

– Headache, migraine, sleepiness, dizziness, abnormal dreams

Uncommon side effects (may affect 1 to 10 users

in 1000):

– Infection

– Anaemia, change in white blood cells

– Over-active thyroid

– Swelling of the ankles, feet or fingers, anorexia, thirst, increased appetite, low blood potassium

– Vertigo, difficulty in coordination and walking, disturbed or decreased bodily movement, pins and needles, stupor, tremor

– Dry eyes

– Ringing in the ears, ear pain

– High blood pressure, fainting

– Difficulty breathing, runny nose, hiccup

– Bad breath, mouth ulcer, colon inflammation, gastric flu (gastroenteritis), tongue swelling

– Sensitivity of the skin to light, sweating, acne, dry skin, eczema

– Leg cramps, muscle twitching, muscle weakness, joint problems

– Frequent need to urinate, urinary tract infection,

incontinence, kidney pain, kidney stone, presence of the protein albumin in the urine

– Painful, irregular or light menstrual periods, breast pain,

impotence

– Fever, tiredness

– Gaining weight, losing weight

– Emotional lability, reduced sex drive, confusion, agitation, sleeplessness, apathy

Rare side effects (may affect 1 to 10 users in 10000):

– Emotional upset, aggression, anger, restlessness, thinking things that are not true (delusions), abnormal behaviour, poor memory since taking eszopiclone (amnesia), sleep walking or sleep driving and other

strange behaviour

– Pruritus (common in patients 65 years or older)

Very rare side effects (may affect less than 1 in 10000

people):

– Mild to moderate increased transaminases and/or blood alkaline phosphatase

Side effects of **not known** frequency (frequency cannot be estimated from the available data):

– Loss of smell, disturbance in attention, prolonged reaction time

– Double vision

– Muscular weakness

Drug Withdrawal

When you stop taking Lunivia, you may experience drug withdrawal symptoms, which include:

– feeling anxious, shaky, irritable, agitated, confused, having panic attacks, sweating, headache, faster heartbeat or uneven heartbeat (palpitations), lower level of awareness or problems with focussing or concentrating, nightmares, seeing of 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, increased appetite.

How do I know if I am tolerant or addicted?

If you notice any of the following signs whilst taking Lunivia, it could be a sign that you have become addicted.

– You may feel the need to keep taking the medication for longer than your doctor recommended

– You feel you need to use more than the recommended dose

– You are using the medicine for reasons other than prescribed

– When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again

If you notice any of these signs, it is important you talk to your prescriber.

Sleep-driving, sleep-walking and other strange behaviours

There have been some reports of people doing things while asleep that they do not remember when waking up after taking a sleep medicine. This includes sleep-driving and sleep-walking. Alcohol and some medicines for depression or anxiety can increase the chance that this serious effect will happen.

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 Yellow Card Scheme

Website: 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 Lunivia

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 and blister after EXP. The expiry date refers to the last day of that month.

For 1 mg packed in PVC/PVdC/PVC-Aluminium blisters

Do not store above 30°C.

For 2 mg and 3 mg packed in PVC/PCTFE-Aluminium, OPA/Alu/PVC-Aluminium and PVC/PVdC/PVC-Aluminium blisters

This medicine does not require any special storage conditions.

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 Lunivia contains

– The active substance is eszopiclone.

Lunivia 1 mg film-coated tablets

Each film-coated tablet contains 1 mg eszopiclone.

Lunivia 2 mg film-coated tablets

Each film-coated tablet contains 2 mg eszopiclone.

Lunivia 3 mg film-coated tablets

Each film-coated tablet contains 3 mg eszopiclone.

– The other ingredients are:

Tablet core: cellulose, microcrystalline, calcium hydrogen phosphate, croscarmellose sodium, silica, colloidal anhydrous, magnesium stearate.

Film-coating: hypromellose, talc, titanium dioxide (E171), macrogol 3350.

1 mg and 3 mg tablets also contain indigo carmine aluminium lake (E132).

What Lunivia looks like and contents of the pack

Lunivia 1 mg film-coated tablets are light blue, round, biconvex and marked with “1” on one side.

Lunivia 2 mg film-coated tablets are white, round, biconvex and marked with “2” on one side.

Lunivia 3 mg film-coated tablets are blue, round, biconvex and, marked with “3” on one side.

Lunivia is available in blisters; packs containing 10, 14, 20 or 30 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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Packmittel/Packaging: PIL
Format/Size: 148 x 428 mm
Schriftgröße: 8 pt (ZAB 8,5 pt) – 14 pt
Hersteller Artikelnr.: ---
LaetusCode: ---
Flattermarken: ---
1. Farbe/Colour: ■ Schwarz 100% 70% 100%
2. Farbe/Colour: -
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