Package leaflet: Information for the patient

Zopiklon Mylan 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 Zopiklon Mylan is and what it is used for

Zopiklon Mylan is a sleeping pill (a hypnotic) that contains the active substance zopiclone. Zopiklon Mylan works by acting on the brain to help you to fall asleep and stay asleep.
Zopiklon Mylan may be used in adults for the short term treatment of sleeping difficulties which are severe, disabling or causing great distress.

2. What you need to know before you take Zopiklon Mylan

Do not take Zopiklon Mylan if you:

- are allergic to zopiclone or any of the other ingredients of this medicine (listed in section 6)
- suffer from a disease of the muscles causing drooping eyelids, double vision, difficulty speaking or swallowing and sometimes muscle weakness in the arms and legs (myasthenia gravis)
- have severe liver problems
- stop breathing for short periods of time while asleep (sleep apnoea syndrome)
- have severe breathing problems (respiratory failure).

Warnings and precautions

Before treatment

Before treatment with Zopiklon Mylan, the cause of your sleep disturbances should be investigated and any underlying diseases should be treated.

Talk to your doctor or pharmacist before taking Zopiklon Mylan if you:
- are elderly
- are in poor general health
- suffer from renal or liver problems
- have or ever had a history of breathing problems

- have or ever had a history of alcohol or drug abuse.
- suffer from psychosis (severe mental disorders characterized by disturbance of personality and loss of contact with reality)
- suffer from depression or anxiety associated with depression

If any of the above applies to you, the doctor will decide whether you should take this medicine or not, or if you should take a reduced dose.

During treatment

Short-term memory loss
Zopiklon Mylan may cause short-term memory loss (anterograde amnesia). This occurs particularly a few hours after taking the medicine. To reduce this risk, take this medicine when you go to bed and ensure you will have a full night's (7-8 hours) uninterrupted sleep.

Sleep walking (somnambulism) and similar behaviours
Sleep walking or performing activities while asleep such as driving, preparing and eating food or making phone calls, without remembering the event afterwards, have been reported in patients who have taken Zopiklon Mylan and were not fully awake, see section 4.

The risk of such behaviour increases if alcohol or certain other medicines (such as narcotic analgesics, antipsychotic agents, hypnotics or anxiolytics/sedatives) are used during treatment with Zopiklon Mylan. The risk is also increased if Zopiklon Mylan is used at doses exceeding the maximum recommended dose.

Contact your doctor immediately if you experience any of the above symptoms. Your doctor may discontinue the treatment.

Tolerance
The effect of Zopiklon Mylan 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 Zopiklon Mylan decreases.

Dependence
When taking this type of medicine there is a risk that you may develop some physical or psychological addiction (dependence). This risk increases with the time for which you have been taking Zopiklon Mylan and your dosage. There is also a greater risk in those patients who have history of alcohol or drug abuse, or when Zopiklon Mylan is taken at the same time as alcohol or other medicines that are used to treat psychiatric disease. If a physical dependence occurs, stopping treatment suddenly may lead to withdrawal symptoms (see below examples of withdrawal symptoms on "Sleeplessness recurring after stopping treatment (rebound insomnia) and other withdrawal symptoms").

Sleeplessness recurring after stopping treatment (rebound insomnia) and other withdrawal symptoms
When stopping treatment with Zopiklon Mylan you may find that your symptoms of difficulty sleeping reoccur in a more severe form than before the treatment. This is a temporary syndrome called 'rebound insomnia'. The risk of rebound symptoms can be decreased by reducing the dose gradually. Your doctor will advise you.

Treatment with Zopiklon Mylan should be temporary or intermittent, to reduce the risk of withdrawal symptoms such as disturbed sleep, headache, extreme anxiety, shaking, muscle pain, increased sweating, agitation, confusion and irritability, hearing, seeing or feeling things that do not really exist (hallucinations), palpitations, increased heart rate, numbness and tingling of arms and legs, oversensitivity to sound, light and physical contact, 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, delirium (characterised by confusion, inattentiveness, disorientation, delusions, hallucination and agitation), nightmares or epileptic seizures. Your doctor will advise you.

Psychiatric and paradoxical reactions

During the use of Zopiklon Mylan, the following reactions may occur:

- restlessness, agitation
- irritability, aggression, rage
- hearing, seeing or feeling things that do not really exist (hallucination)
- nightmares
- delusion
- psychosis (severe mental disorders characterized by disturbance of personality and loss of contact with reality)
- unsuitable behaviour

The risk of these reactions is higher in elderly patients. If you experience any of the above symptoms stop taking Zopiklon Mylan and contact your doctor. Your doctor may discontinue the treatment.

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

Children and adolescents

Zopiklon Mylan should not be given to children and adolescents under the age of 18 years. The safety and efficacy of Zopiklon Mylan in children and adolescents aged less than 18 years have not been established.

Other medicines and Zopiklon Mylan

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Zopiklon Mylan may affect or be affected by certain medicinal products, for example:

- Medicines used to treat certain mental and emotional conditions (antipsychotics/neuroleptics)
- Other sleeping pills or medicines used to treat anxiety or induce calmness (hypnotics, anxiolytics or sedatives)
- Medicines used to treat depression (antidepressants)
- Medicines used to treat severe pain (strong analgesics)
- Medicines used to treat allergies that can cause drowsiness (antihistamines)
- Products containing St John’s wort (an herbal remedy used for depression).
- Medicines used to treat seizures or epilepsy (antiepileptics) such as carbamazepine, phenobarbital, phenytoin).
- Medicines used to treat bacterial infections (antibiotics such as erythromycin and clarithromycin).
- Medicines used to treat fungal infections (antimycotics such as itraconazole and ketoconazole).
- Certain medicines used to treat HIV infections (HIV protease inhibitors, especially when given with ritonavir or cobicistat).
- Rifampicin (an antibiotic used to treat tuberculosis)

The combination of Zopiklon Mylan with the medicines above may require an adjusted dose. Your doctor will decide if your dose needs to be adjusted.

Concomitant use of Zopiklon Mylan 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 Zopiklon Mylan 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.

If you are going to have an operation or dental surgery, let your doctor, hospital staff or dentist know you are taking Zopiklon Mylan.

Zopiklon Mylan with food, drink and alcohol

You should not drink alcohol while being treated with this medicine, because this may increase the sedative effects of Zopiklon Mylan. This may persist to the following morning and affect your ability to drive (see 'Driving and using machines' below).

Avoid eating grapefruit or drinking grapefruit juice while taking this medicine as these may increase the effects of Zopiklon Mylan.

Pregnancy and breast-feeding

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

Pregnancy
Zopiklon Mylan should not be taken during pregnancy. If Zopiklon Mylan is taken during the last trimester or during labour there may be a risk that the newborn baby is affected. Symptoms such as muscle weakness, breathing problems or low body temperature (hypothermia) may occur. Withdrawal symptoms may occur in the new newborns. This has been observed in children of mothers who have used this medicine for long periods during the last months of pregnancy.

Breast-feeding
Do not breast-feed your baby, as small amounts of this medicine can pass into breast milk.

Driving and using machines

Do not drive or operate machinery until your treatment with Zopiklon Mylan is completed, or until it is established that your ability is not impaired. The effects of Zopiklon Mylan can last into the following day.

Possible side effects of Zopiklon Mylan that can affect your ability to drive are:
- Drowsiness
- Dizziness
- Short-term memory loss (anterograde amnesia)
- Difficulty concentrating

The risk of experiencing these side effects is greater if you consume alcohol. The risk is even higher if you do not sleep for long enough.

Zopiklon Mylan contains lactose

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

3. How to take Zopiklon Mylan

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

The tablet should be taken with a glass of liquid, immediately before going to bed. Make sure you will

be able to have a full night's uninterrupted sleep (7-8 hours). You should take the tablet when standing or sitting upright, and not when lying down.

The recommended dose in adults is 1 tablet (5 mg) immediately before going to bed. This dose should not be exceeded unless advised by your doctor.

Use in elderly patients
The recommended starting dose for elderly patients is 3.75 mg, which may be increased by your doctor if needed.

Use in patients with kidney or liver problems, or with sever breathing problems (respiratory failure)
The recommended starting dose is 3.75 mg.

How long should you take Zopiklon Mylan for

The duration of treatment with Zopiklon Mylan should be as short as possible. Treatment should not exceed 4 weeks, including a period of tapering off.

If you take more Zopiklon Mylan than you should

Contact your doctor or nearest hospital emergency department immediately, do not go unaccompanied to seek medical help. If an overdose has been taken you may become increasingly drowsy very quickly. Take the container and any remaining tablets with you.

Overdose with Zopiklon Mylan together with certain substances or medicines that have a suppressive effect on the central nervous system might be life-threatening. This includes alcohol.

Taking too much Zopiklon Mylan may cause symptoms such as::
- drowsiness, confusion, lack of energy (lethargy), coma
- problems with your balance or coordination, muscle weakness
- low blood pressure (symptoms include feeling dizzy, light headed or faint)
- shallow breathing or difficulty breathing (respiratory depression).

If you have poor general health or another medical condition the severity of the above symptoms may increase and in very rare cases result in death.

If you forget to take Zopiklon Mylan

If you forget to take a dose immediately before going to bed but remember during the night only take the missed dose if you are still able to have 7-8 hours uninterrupted sleep. If this is not possible, take the next dose before bed time the following night. Do not take a double dose to make up for a forgotten dose.

If you stop taking Zopiklon Mylan

Treatment of Zopiklon Mylan should be gradually withdrawn, otherwise your original symptoms that Zopiklon Mylan was used to treat will return with a higher intensity (rebound insomnia). For other possible signs of withdrawal see section 2 'During treatment'. These will however disappear with time. 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.

If any of the following happen, stop taking Zopiklon Mylan and tell your doctor immediately or go to your nearest hospital emergency department:

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

- Serious allergic reaction with any of the following symptoms (angioedema, anaphylaxis, hypersensitivity):
  - swelling of the face, tongue or throat
  - difficulty swallowing
  - hives and breathing difficulties
  - fall in blood pressure

Other possible side effects may include:

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

- Dry mouth
- Bitter or metallic taste
- Drowsiness

Uncommon (may affect up to 1 in 100 people)

- Agitation
- Nightmares
- Feeling sick (nausea)
- Headache
- Dizziness
- Fatigue

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

- Short term memory loss (anterograde amnesia)
- Inappropriate behaviour possibly associated with memory loss
- Indigestion
- Vomiting
- Diarrhoea
- Difficulty concentrating
- Confusion
- Sleepwalking
- Anxiety
- Irritability
- Aggressiveness
- Hearing, seeing or feeling things that do not really exist (hallucinations)
- Itching
- Rash, possibly with raised lumps (known as hives or nettle rash)
- Raised liver enzyme levels in the blood which can be seen in a blood test
- Restlessness
- Changes in sexual drive (libido disorder)
- Rage
- Psychosis (severe mental disorders characterized by disturbance of personality and loss of contact with reality
- Sweating
- Falls, there is a risk of falls and consequently fractures in older people

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

- Seizures (fits)

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

- Dependence (physical and psychological)
- Delusions
- Affective blunting (reduced ability to express emotions)
- Reduced alertness
- Inability to co-ordinate muscle movements (ataxia)
- Double vision
- Muscle weakness
- Unsteadiness

Drowsiness, affective blunting (reduced ability to express emotions), reduced alertness, confusion, fatigue, headache, dizziness, muscle weakness, inability to co-ordinate muscle movements (ataxia) or double vision occurs predominantly at the start of the therapy and usually disappear with repeated administration. 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 [to be completed nationally]. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Zopiklon Mylan

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

Do not store above 25ºC.

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 Zopiklon Mylan contains

The active substance is zopiclone. Each film-coated tablet contains 5 mg zopiclone.
The other ingredients in the tablet core are lactose (see section 2, ‘Zopiklon Mylan contains lactose’), anhydrous calcium hydrogen phosphate, maize starch, povidone and magnesium stearate. The tablet coating contains hypromellose, titanium dioxide (E171) and macrogol.

What Zopiklon Mylan looks like and contents of the pack

Your medicine comes as a white film-coated, round tablet. The tablets are marked ‘Z05’ on one side and ‘G’ on the other.

Zopiklon Mylan is available in blisters of 10, 30 and 100 film-coated tablets and in unit dose blisters of 100×1 film-coated tablets.
Zopiklon Mylan is also available in packs of 100, 250 and 500 film-coated tablets in a plastic container with plastic cap.

Not all pack sizes may be marketed

Marketing Authorisation Holder

[To be completed nationally]

Manufacturer

[To be completed nationally]

This medicinal product is authorised in the Member States of the EEA under the following names:

Finland – Zopiklon Mylan 5 mg tabletti, kalvopaallysteinen
Sweden - Zopiklon Mylan 5 mg filmdragerad tablett

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