Package leaflet: Information for the user

Zopiclone Grindeks 3.75 mg film-coated tablets
Zopiclone Grindeks 5 mg film-coated tablets
Zopiclone Grindeks 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 ate the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This also includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What [Invented name] is and what it is used for

[Invented name] is a sleeping tablet with zopiclone as active substance. It is used in adults as a sleeping medicine for various kinds of sleeping problems, e.g., difficulty falling asleep, waking up too early or too many night awakenings. [Invented name] is used for short-term sleep disorders.

[Invented name] 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 [Invented name]

Do not take [Invented name]
- If you are allergic to zopiclone or any of the other ingredients of this medicine (listed in section 6).
- If you have any of the following diseases:
  - a severe liver disease;
  - sleep apnoea syndrome (sleep disturbance with temporary pauses in breathing during sleep);
  - a serious muscle-weakness called myasthenia gravis (an autoimmune disease);
  - severe difficulty breathing (severe respiratory failure).
- 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.

Warnings and precautions
General
Talk to your doctor or pharmacist before taking [Invented name].

Before starting treatment with [Invented name], the cause of your sleep problems should be investigated, and any other underlying disease treated.

Tell your doctor if you have or have had any illness or any other medical condition, especially if you have any of the following:

- liver or kidney problems;
- breathing problems;
- impaired general condition;
- is elderly (in older people, medicines stay longer in the body);
- depression or anxiety linked with depression;
- history of abuse of alcohol, drug, or medicines;
- you have recently taken [invented name] or other similar medicines for more than 4 weeks.

Your doctor will decide whether you should take [invented name] or not or adjusts your dose. You will be also monitored closely during the treatment.

Dependence and withdrawal symptoms
The use of medicines like [Invented name] may lead to a physical or mental dependence or abuse of these medicines. The risk of dependence increases the higher the dose and the longer the period of treatment. The 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: insomnia, 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)
If treatment is stopped abruptly after prolonged use, it sometimes leads sleeplessness for a few nights. This is a temporary syndrome called "rebound insomnia". To avoid any problems with discontinuation after long-term treatment, it is recommended to gradually reduce the dose. See also the section on side effects.

Tolerance
The effect of [Invented name] may be reduced if the medicine is used repeatedly for a few weeks. This is called tolerance. Talk to your doctor if you have the feeling that the effect of [Invented name] decreases.

Short-term memory loss, so-called anterograde amnesia
[Invented name] may cause a short-term memory loss, especially a few hours after taking the tablet. To reduce the risk of this, take [Invented name] just before or after going to bed and make sure you will be able to have an uninterrupted sleep of 7–8 hours.

Psychiatric and "paradoxical reactions"
When using [Invented name], certain mental reactions, such as restlessness and anxiety, nightmares, irritability, aggression, inappropriate behaviour, hallucinations (seeing and hearing things that are not real), confusion, and difficulty concentrating may occur.

Sleepwalking, so-called somnambulism, and associated behaviours
Sleepwalking and other associated behaviours such as 'sleep driving', cooking and eating or making phone calls in your sleep, with memory loss of the event, have been reported in patients who have taken zopiclone and were not fully awake.

The risk of such behaviour increases if [Invented name] is combined with alcohol or certain other specific medications (e.g., opioid-class painkillers, antipsychotics, hypnotics or anti-anxiety / sedatives). The risk also increases if [Invented name] is taken in higher doses than the highest recommended dose. Contact a doctor immediately if you experience any of the above symptoms.

Depression/suicidal thoughts
This medicine is not intended to treat depression. If you also have a depression, your doctor will prescribe appropriate treatment. If depression is left untreated, it can worsen, become persistent or increase possible risk of suicide.

Some studies have shown an increased risk of suicidal thoughts, suicide attempts and suicides in patients taking certain sedatives and hypnotics, including this medicine. However, it has not been established if this is due to the medicine or if there are other reasons. If you have suicidal thoughts, contact your doctor as soon as possible for 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.

Children and adolescents
[Invented name] should not be used by children and adolescents under 18 years of age. Safety and efficacy in children and adolescents under 18 years of age have not been established.

Other medicines and [Invented name]
The treatment effect can be affected if [Invented name] is taken at the same time as certain other medicines, which means that the dose of [Invented name] may need to be adjusted.
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. In particular any of the following medicines:
- Medicines for certain mental disorders (antipsychotics/neuroleptics)
- Sleeping pills (hypnotics)
- Medicines used to treat anxiety (anxiolytics)
- Medicines used to calm (sedatives)
- Treatment of depression (antidepressants)
- Strong opioid class painkillers, e.g., morphine and morphine-like substances
- Medicines used in surgery (anaesthetics)
- Medicines used to treat allergy (antihistamines)
- Some medicines used to treat bacterial and fungal infections such as erythromycin or itraconazole
- Medicines used to treat HIV infections
- Medicines used to treat epilepsy such as phenytoin, phenobarbital and carbamazepine
- Medicines used to treat tuberculosis (e.g., rifampicin)
- Products containing St. John's wort (traditional herbal medicine).

Concomitant use of [Invented name] 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 [Invented name] 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.

[Invented name] with drink and alcohol
Alcohol should be avoided when taking [Invented name] as alcohol may increase the effects of [Invented name]. The effect may persist until the next morning, which may adversely affect your ability to drive or use machines.
Grapefruit and grapefruit juice should be avoided while taking [Invented name]. Grapefruit can increase the effect of [Invented name].

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 or pharmacist for advice before taking this medicine.

Pregnancy
Use of [Invented name] is not recommended during pregnancy since it crosses the placenta.
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 [Invented name] during the second and/or third trimester of pregnancy.

If [Invented name] 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 [Invented name] if you are breast-feeding.

Driving and using machines
You should not drive or use machines until your treatment with [Invented name] has ended, or until it has been established that your ability is not impaired. The effect can also persist until the next day.
Side effects of [Invented name] that may affect your ability to drive are:
- Fatigue and drowsiness the following day (residual somnolence)
- Dizziness
- Memory loss (anterograde amnesia)
- Decreased ability to concentrate.

The risk of suffering from the above side effects is greater if you have drunk alcohol and if you have not had enough sleep.

[Invented name] contains Cochineal red A
5 mg film-coated tablet contains Cochineal red A (E124) that may cause allergic reactions.

[Invented name] contains sodium
This medicine contains less than 1 mmol (23 mg) sodium per tablet, i.e., is essentially 'sodium-free'.

3. How to take [Invented name]

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 recommended initial dose for adults is one 5 mg or 7.5 mg tablet, taken at bedtime.

For some patients, e.g. elderly or if you have kidney, liver or breathing problems, a lower starting dose at 3.75 mg will be used. Your doctor may later increase the dose to 5 mg and if necessary up to 7.5 mg. The maximum daily dose is 7.5 mg per day.

<u>How to take [Invented name]</u>
Take [Invented name] 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. 1/2 glass of water).
<u>Duration of treatment</u>

Your treatment with [Invented name] should be as short as possible (a few days to 2 weeks). To reduce the risk of withdrawal symptoms or recurring sleep problems when treatment is stopped, your doctor will explain how to gradually reduce the dose at the end of treatment, so-called tapering. You should not take [invented name] 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 [Invented name] than you should
If you have taken too many tablets or if e.g., a child has ingested the medicine by mistake, contact your doctor or nearest hospital casualty department immediately for advice.
Zopiclone overdosage together with certain agents or medicines which have a suppressive effect on the central nervous system might be life-threatening. This also includes alcohol.
Taking too much zopiclone may cause symptoms such as:

- feeling drowsy, confused, sleeping deeply and possibly falling into a coma
- floppy muscles
- feeling dizzy, lightheaded, 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 [Invented name]
Do not take a double dose to make up for a forgotten dose.
If you still have time to sleep for 7 to 8 hours, you should take the dose immediately. If you do not have the opportunity for a full night's sleep, skip the missed dose and do not take a new dose until you go to bed next night.

If you stop taking [Invented name]
If you suddenly stop taking [Invented name], your sleep problems may return for a temporary period. You may also have withdrawal symptoms. Withdrawal symptoms include difficulty sleeping, headaches, sweating, hallucinations and increased heart rate. In more severe and very rare cases, seizures may occur.
The risk of withdrawal symptoms increases with the dose and the duration of treatment and therefore the doctor may give you information on 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 [Invented name] and contact a doctor or go to your nearest emergency department **immediately** if you experience any of the following symptoms (very rare, may affect up to 1 in 10,000 people):

- Swelling of the face, tongue, or throat; difficulty swallowing; hives and breathing difficulties (angioedema).
- Symptoms of severe allergic reaction: itchy rash, swelling of your mouth, which can cause breathing and swallowing difficulties, wheezing (anaphylactic reaction).

<u>Other side effects</u>
Common (may affect up to 1 in 10 people):

- drowsiness
- bitter or metallic taste in the mouth
- dry mouth.

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

- nervous excitement (agitation), nightmares
- feeling sick (nausea), general discomfort, abdominal pain
- decreased alertness, headache, dizziness

- difficulty getting up in the morning, fatigue (asthenia).

Rare (may affect up to 1 in 1,000 people):
- feeling confused, 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
- 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 available data)
- restlessness, false beliefs, anger, abnormal behaviour (possibly associated with memory loss), sleepwalking or other unusual behaviour during sleep (such as driving, eating, making a phone call, or having sex etc.) while not being fully awake
- physical and psychological dependence, withdrawal syndrome or rebound insomnia upon discontinuation of zopiclone
- you lose some contact with reality (psychosis); this might involve seeing or hearing things that you cannot see or hear and believing things that are not actually true
- memory impairment, inability to concentrate, speech disorder
- difficulty coordinating certain movements, numbness or tingling in some parts of body
- double vision
- shallow breathing or difficulty breathing
- indigestion, vomiting
- muscular weakness.

If treatment is stopped abruptly after long-term treatment, so-called withdrawal symptoms may occur. Withdrawal symptoms vary and include difficulty sleeping, tremor, sweating, confusion (delirium), headaches, palpitations and increased heart rate, nightmares, and hallucinations. You may also feel anxious, irritated, and upset (agitation). In very rare cases, seizures have also occurred.

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 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 [Invented name]

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.

This medicinal product 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 to protect the environment.

6. Contents of the pack and other information

What [Invented name] contains
The active substance in [Invented name] is zopiclone. Each tablet contains 3.75 mg, 5 mg or 7.5 mg zopiclone, respectively.

The other ingredients are:
Tablet core: maize starch, hypromellose (type 2910) (E464), calcium hydrogen phosphate (E341), sodium starch glycolate (type A), cellulose, microcrystalline (E460), magnesium stearate (E572).

Tablet film-coating
5 mg tablets:
Macrogol poly(vinyl alcohol) grafted copolymer (E1209); talc (E553b); titanium dioxide (E171); glycerol monocaprylocaprate (E471); poly(vinyl alcohol) (E1203); indigo carmine (E132); cochineal red A (E124); quinoline yellow (E104).

3.75 mg and 7.5 mg tablets:
Macrogol poly(vinyl alcohol) grafted copolymer (E1209); talc (E553b); titanium dioxide (E171); glycerol monocaprylocaprate (E471); poly(vinyl alcohol) (E1203).

What [Invented name] looks like and contents of the pack
[Invented name] 3.75 mg are white round biconvex film-coated tablets with plain surfaces; size of tablet is approximately 5 mm in diameter.
[Invented name] 5 mg are blue round biconvex film-coated tablets with plain surfaces; size of tablet is approximately 6 mm in diameter.
[Invented name] 7.5 mg are white round film-coated tablets, convex on one side and dimple with break-line on other with plain surfaces; size of tablet is approximately 7 mm in diameter. Tablet can be divided in equal doses.

[Invented name] is available in PVC/PVDC//Alu blisters containing 10, 20, 30 or 100 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

[To be completed nationally]

Manufacturer

[To be completed nationally]

This medicine is authorised in the Member States of the European Economic Area under the following names:

Sweden	Zopiclone Grindeks 3,75 mg, 5 mg, 7,5 mg filmdragerade tabletter
Austria	Zopiclon Grindeks 3,75 mg, 5 mg, 7,5 mg Filmtabletten
Belgium	Zopiclone Grindeks 3,75 mg, 5 mg, 7,5 mg comprimés pelliculés
Bulgaria	Зопиклон Гриндекс 3,75 mg, 5 mg, 7,5 mg филмирани таблетки
	Zopiclone Grindeks 3,75 mg, 5 mg, 7,5 mg film-coated tablets
Croatia	Zopiklon Grindeks 3,75 mg filmom obložene tablete
	Zopiklon Grindeks 5 mg filmom obložene tablete
	Zopiklon Grindeks 7,5 mg filmom obložene tablete
Czech Republic	Zopiclone Grindeks
Denmark	Somnols 3,75 mg, 5 mg, 7,5 mg filmovertrukne tabletter
Estonia	Sonareta
Finland	Zopiclone Grindeks 3,75 mg, 5 mg, 7,5 mg tabletti, kalvopäällysteinen

France	ZOPICLONE GRINDEKS 3,75 mg, comprimé pelliculé ZOPICLONE GRINDEKS 5 mg, comprimé pelliculé ZOPICLONE GRINDEKS 7,5 mg, comprimé pelliculé sécable
Germany	Zopiclon Grindeks 3,75 mg, 5 mg, 7,5 mg Filmtabletten
Greece	Zopiclone/Grindeks
Hungary	Zopiclone Grindeks 3,75 mg, 5 mg, 7,5 mg filmtabletta
Ireland	Zopiclone Grindeks 3.75 mg, 5 mg, 7.5 mg film-coated tablets
Italy	Zopiclone Grindeks
Latvia	Zopiclone Grindeks 3,75 mg, 5 mg, 7,5 mg apvalkotās tabletes
Lithuania	Zopiclone Grindeks 3,75 mg plėvele dengtos tabletės Zopiclone Grindeks 5 mg plėvele dengtos tabletės Zopiclone Grindeks 7,5 mg plėvele dengtos tabletės
Luxembourg	Zopiclone Grindeks 3,75 mg, 5 mg, 7,5 mg filmbeschichtete Pëllen
The Netherlands	Zopiclon Grindeks 3,75 mg filmomhulde tabletten Zopiclon Grindeks 5 mg filmomhulde tabletten Zopiclon Grindeks 7,5 mg filmomhulde tabletten
Norway	Sonlax
Poland	Zopiclone Grindeks
Portugal	Zopiclona Grindeks 3,75 mg, 5 mg, 7,5 mg comprimidos revestidos por película
Romania	Zopiclonă Grindeks 3,75 mg, 5 mg, 7,5 mg comprimate filmate
Slovakia	Somnols 3,75 mg, 5 mg, 7,5 mg filmom obalené tablety
Slovenia	Zopiklon Grindeks 3,75 mg, 5 mg, 7,5 mg filmsko obložene tablete
Spain	Zopiclona Grindeks 3,75 mg, 5 mg, 7,5 mg comprimidos recubiertos con película EFG

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