

**PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE
PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986**

The medicine is dispensed with a doctor's prescription only

Zopiclone Grindeks 7.5 mg

Film-coated Tablets 7.5 mg

Composition:

Each tablet contains: Zopiclone 7.5 mg

For information about inactive and allergenic ingredients in the preparation: see section 2 "Important information about some of the ingredients of the medicine" and section 6 "Further information".

Read this leaflet carefully in its entirety before using the medicine.

This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed to treat you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

This medicine is not intended for children and adolescents under 18 years of age.

1. WHAT IS THE MEDICINE INTENDED FOR?

Zopiclone Grindeks 7.5 mg is intended for short term treatment of sleep problems in adults. Do not use for long-term. Treatment should be as short as possible, because the risk of dependence increases with the duration of treatment. You should consult with a doctor.

Therapeutic group: Hypnotic and sedative from the cyclopyrrolone group.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- you are sensitive (allergic) to zopiclone or to any of the additional ingredients contained in the medicine (see section 6). Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of the lips, face, throat or tongue.
- you suffer from a problem that causes severe muscle weakness (myasthenia gravis).
- you suffer from a problem in lung function (respiratory failure).
- you suffer from a problem in which you stop breathing for short periods at night (sleep apnoea).
- you suffer from severe liver problems.
- you are under the age of 18. The safety and efficacy of Zopiclone Grindeks 7.5 mg in children and adolescents aged less than 18 years have not been established.
- you have ever experienced sleepwalking or any other unusual behavior (such as driving, eating, making a phone call or having sex, etc.) while you are not fully awake after taking Zopiclone.

Do not take this medicine if any of the above conditions applies to you. If you are not sure, talk to your doctor or pharmacist before taking Zopiclone Grindeks 7.5 mg.

Special warnings regarding use of the medicine:

Before treatment with Zopiclone Grindeks 7.5 mg, tell your doctor if:

- you suffer from any liver problems (see also in section “Do not use the medicine if”). The doctor may need to give you a lower dose of Zopiclone Grindeks 7.5 mg.
- you suffer from any kidney problems. The doctor may need to give you a lower dose of Zopiclone Grindeks 7.5 mg.
- you suffer from mild breathing problems. The doctor will decide if you should receive Zopiclone Grindeks 7.5 mg (also see in section “Do not use the medicine if”).
- you have had a mental disorder (including depression and personality disorder) or you have abused or have been dependent on alcohol or drugs.
- you have recently used Zopiclone Grindeks 7.5 mg or other similar medicines for more than 4 weeks.

Risk of abuse and dependence:

Use of Zopiclone Grindeks 7.5 mg 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 Zopiclone Grindeks 7.5 mg is used for longer than 4 weeks, and in patients with a history of mental disorders and/or alcohol, illicit substance or drug abuse.

The medicine is not intended for the treatment of depression.

Zopiclone Grindeks 7.5 mg and mental health:

Some people being treated with Zopiclone Grindeks 7.5 mg may 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.

Zopiclone Grindeks 7.5 mg and unusual behaviour:

Zopiclone Grindeks 7.5 mg may cause sleepwalking or other unusual behavior (such as driving, eating, making a phone call, or having sex, etc.) while you are not 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 Zopiclone Grindeks 7.5 mg. If you experience any of the above effects, stop the treatment with Zopiclone Grindeks 7.5 mg immediately and contact your doctor or healthcare provider.

Before taking Zopiclone Grindeks 7.5 mg, 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 - “Side effects”).

If you are not sure if any of the above conditions applies to you, talk to your doctor or pharmacist before taking Zopiclone Grindeks 7.5 mg.

Children and adolescents:

This medicine is not intended for children and adolescents under 18 years of age.

Tests and follow up:

Zopiclone Grindeks 7.5 mg can change the liver enzyme levels shown up in blood tests. This may indicate 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 Zopiclone Grindeks 7.5 mg.

Drug interactions:

If you are taking, have recently taken, or might take other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. This is because Zopiclone Grindeks 7.5 mg may affect the way some other medicines work. Also, some medicines may affect the way Zopiclone Grindeks 7.5 mg works. Especially if you are taking:

Zopiclone Grindeks 7.5 mg may increase the effect of the following medicines:

- Medicines for treatment of mental diseases (antipsychotics)
- Medicines for treatment of depression
- Medicines for treatment of epilepsy (anticonvulsants)
- Medicines used in surgeries (anesthetics)
- Medicines to calm or reduce anxiety or medicines for sleep problems (hypnotics)
- Medicines for treatment of hay fever, rashes or other allergies, that can make you sleepy (sedative antihistamines) such as chlorphenamine or promethazine
- Some medicines to relieve moderate to severe pain (narcotic analgesics) such as codeine, methadone, morphine, oxycodone, pethidine or tramadol

The following medicines can increase the chance of getting side effects when taken with Zopiclone Grindeks 7.5 mg. To make this less likely, your doctor may decide to lower the dosage of Zopiclone Grindeks 7.5 mg that you are taking:

- Some antibiotics, such as clarithromycin or erythromycin
- Some medicines for the treatment of fungal infections, such as ketoconazole and itraconazole
- Ritonavir (a protease inhibitor) - for treating HIV infection
- Concomitant use of Zopiclone Grindeks 7.5 mg and opioids increases the risk of drowsiness, breathing difficulties, coma and death. Zopiclone Grindeks 7.5 mg 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 Zopiclone Grindeks 7.5 mg work less well:

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

Use of the medicine and alcohol consumption:

Do not drink alcohol while using Zopiclone Grindeks 7.5 mg. Alcohol can increase the effect of Zopiclone Grindeks 7.5 mg and make you sleep very deeply, so that you will not breathe properly or will have difficulty waking up.

Pregnancy and breast-feeding:

Pregnancy

Use of Zopiclone Grindeks 7.5 mg is not recommended during pregnancy. Before taking the medicine, consult your doctor if you are pregnant, think you might be

pregnant, or are planning to have a baby.

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 Zopiclone Grindeks 7.5 mg during the second and/or third trimester of pregnancy.

If Zopiclone Grindeks 7.5 mg 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 the late stages of 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 Zopiclone Grindeks 7.5 mg if you are breast-feeding or are 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, consult the doctor or pharmacist before taking any medicine. Consult a doctor or pharmacist before taking any medicine if you are pregnant or breast-feeding.

Driving and operating machinery:

Like other medicines used for sleep problems, Zopiclone Grindeks 7.5 mg can cause slowing of normal brain function (central nervous system depression). The risk of psychomotor impairment, including driving ability, is increased if:

- you perform activities that require alertness within 12 hours of taking Zopiclone Grindeks 7.5 mg
- you take a higher dose than the recommended dose of Zopiclone Grindeks 7.5 mg
- you take Zopiclone Grindeks 7.5 mg while taking another central nervous system depressant, or another medicine that increases levels of Zopiclone Grindeks 7.5 mg in your blood, or while drinking alcohol

Do not engage in hazardous activities requiring complete alertness, such as driving or operating machinery, after taking Zopiclone Grindeks 7.5 mg, and in particular during the 12 hours after taking the medicine.

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

Important information about some of the ingredients of the medicine:

Zopiclone Grindeks 7.5 mg contains:

- **Sodium:** This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say it is essentially “sodium-free”.

3. HOW SHOULD YOU USE THE MEDICINE?

The treatment should be as short as possible and should not exceed 4 weeks including the period of tapering off.

Always use the preparation according to the doctor’s instructions.

Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.

The dosage and treatment regimen will be determined by the doctor only.

Adults:

The usual dosage is one Zopiclone Grindeks 7.5 mg tablet (7.5 mg) just before bedtime.

Elderly:

The usual starting dosage is half a tablet (3.75 mg) just before bedtime. The doctor may decide to increase your dose if needed.

Children and adolescents:

Zopiclone Grindeks 7.5 mg is not intended for use in children and adolescents under 18 years of age. The efficacy and safety of Zopiclone Grindeks 7.5 mg in children and adolescents aged less than 18 years have not yet been established.

Patients with liver, respiratory or kidney problems:

The usual starting dose is half a tablet (3.75 mg) just before bedtime.

Do not exceed the recommended dosage.**Duration of treatment:**

The usual duration of treatment is two days to 3 weeks.

Method of administration:

- Swallow the medicine with water.
- There is no information regarding crushing/chewing the tablets.
- The tablet can be halved if a lower dose of 3.75 mg is required.
- Take the required dose of Zopiclone Grindeks 7.5 mg in a single intake, and do not take an additional dose during the same night.
- Take the preparation when you are in bed, just before bedtime and make sure that you will be able to sleep 7-8 hours without interruption.

If you took a higher dosage or if a child has accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you.

Taking too much of Zopiclone Grindeks 7.5 mg is very dangerous. You may suffer from the following effects:

- Feeling drowsy, confused, sleeping deeply and even the possibility of falling into coma
- Floppy muscles (hypotonia)
- Feeling dizzy, lightheaded or faint. These effects are due to low blood pressure
- Falling over or losing balance (ataxia)
- Shallow breathing or difficulty breathing (respiratory depression)

If you forget to take the medicine:

Zopiclone Grindeks 7.5 mg must only be taken at bedtime.

If you forgot to take the medicine at bedtime, do not take the medicine at any other time. Otherwise, you may feel drowsy, dizzy and confused during the day. **Never take** two doses at once to make up for a forgotten dose!

If you stop taking the medicine:

Keep taking Zopiclone Grindeks 7.5 mg until your doctor tells you to stop. Do not stop taking Zopiclone Grindeks 7.5 mg suddenly, but tell your doctor if you want to stop. Your doctor will need to lower your dosage and stop the treatment gradually over a period of time.

If you stop the treatment with Zopiclone Grindeks 7.5 mg suddenly, your sleep problems may come back and you may suffer from a "withdrawal effect".

If this happens, you may suffer from some of the effects listed below.

Refer to a doctor immediately if you suffer from any of the following effects:

- Feeling anxious, shaky, irritable, agitated, confused or you have panic attacks
- Sweating
- Headache
- Faster 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
- Poor reality perception
- Numbness and tingling in the hands and feet
- Aching muscles
- Stomach problems

In rare cases, fits (seizures) may also occur.

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Zopiclone Grindeks 7.5 mg may cause side effects in some users. Do not be alarmed by the list of side effects. You may not suffer from any of them.

Discontinue use and refer to a doctor or hospital immediately if:

- you suffer from an **allergic reaction** to Zopiclone Grindeks 7.5 mg. The signs may include: a rash, swallowing or breathing problems, swelling of the lips, face, throat or tongue.

Refer to the doctor as soon as possible if you have any of the following side effects:

Rare side effects, effects that occur in 1-10 in 10,000 users:

- Memory impairment since taking Zopiclone Grindeks 7.5 mg (amnesia). You can reduce the chance of this effect by making sure that you have 7-8 hours of continuous and uninterrupted sleep after taking Zopiclone Grindeks 7.5 mg.
- Seeing or hearing things that are not real (hallucinations)
- Falling, especially in the elderly

Side effects of unknown frequency (effects whose frequency has not yet been determined):

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

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

Common side effects, effects that occur in 1-10 in 100 users:

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

Uncommon side effects, effects that occur in 1-10 in 1,000 users:

- Feeling sick (nausea) or being sick (vomiting)
- Feeling dizzy or sleepy
- Headache

- Nightmares
- Feeling physically or mentally tired
- Agitation

Rare side effects, effects that occur in 1-10 in 10,000 users:

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

Side effects of unknown frequency (effects whose frequency has not yet been determined):

- 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 Zopiclone Grindeks 7.5 mg
- Slower breathing (respiratory depression)
- Unusual skin sensations such as numbness, tingling, pricking, burning or creeping on the skin (paresthesia)
- Mental problems such as poor memory
- Difficulty paying attention
- Disrupted speech
- Zopiclone Grindeks 7.5 mg may cause sleepwalking or other unusual behavior (such as driving, eating, making a phone call, or having sex etc.) while you are not fully awake.
- Delirium (a sudden and severe change in mental state that can cause a combination of confusion, disorientation and/or attention deficit)

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: <https://sideeffects.health.gov.il>

5. HOW SHOULD THE MEDICINE BE STORED?

Avoid poisoning! This medicine, and any other medicine, should be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor.

Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.

Storage conditions: Store at a temperature that does not exceed 30°C.

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. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:

Calcium hydrogen phosphate (E341 (ii)), maize starch, cellulose, microcrystalline (E460), sodium starch glycolate (type A), hypromellose (type 2910) (E464), macrogol poly (vinyl alcohol) grafted copolymer (E1209); talc (E553b); titanium dioxide (E171); magnesium stearate (E572), glycerol monocaprylocaprate (type 1) (E471); poly (vinyl alcohol) (E1203).

What the medicine looks like and the contents of the package:

Zopiclone Grindeks 7.5 mg tablets are round, white, film-coated tablets, convex on one side and dimple with break-line on other with plain surfaces.

Package size: 20, 30 tablets in a blister pack. Not all package sizes may be marketed.

This leaflet does not contain all the information about the preparation. If you have any questions or are uncertain about anything, please refer to the doctor.

License Holder and Importer name and address:

A.L.Medi-Market Ltd., 3 Hakatif street, Emek Hefer Industrial Park, 3877701, Israel.

Manufacturer name and address: JSC Grindeks, 53 Krustpils street, Riga, LV-1057, Latvia

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