

**Patient leaflet in accordance with the
Pharmacists' Regulations (Preparations) - 1986**

This medicine is dispensed with a doctor's prescription only

Diazepam Grindeks 5 mg Tablets

Composition

Each tablet contains:

Diazepam 5 mg

For information about inactive ingredients in this medicine see section 2 under "Important information about some of this medicine's ingredients", and section 6 "Additional information".

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

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

Introduction

This medicine belongs to the group of benzodiazepines, which has special properties requiring extreme caution when medicines belonging to this group are used.

- Close medical follow-up is very important when taking this medicine.
- When you take this medicine, be sure to contact your doctor after 2-4 weeks, as the treatment is only intended for short periods of time.
- Prolonged use of this medicine may cause it to be less effective.
- Prolonged use may cause a serious effect of dependence, which will make it difficult for the patient to stop taking the medicine.
- Uncontrolled treatment discontinuation is accompanied by withdrawal symptoms such as tension, nervousness, confusion, tremor, insomnia, abdominal pain, nausea, vomiting, sweating, spasms.
- Sometimes, prolonged use of this medicine may cause changes in behavioural patterns and intrusive thoughts.
- Particularly in the elderly, it is recommended to be careful when walking, as the medicine impairs alertness and sometimes coordination of body movements, and therefore, there is a concern of slips and falls.

Taking this medicine with opioids, other central nervous system depressants (including drugs) or alcohol may cause a sense of deep drowsiness, difficulty breathing (respiratory depression), coma and death.

1. What is this medicine intended for?

Diazepam Grindeks 5 mg is indicated for treatment of tension, anxiety, agitation due to acute alcohol withdrawal, and as adjunct treatment for relief of skeletal muscle spasm and convulsive disorders.

This medicine is usually not intended for children.

This medicine should be used for as short a time as possible, and for no more than four weeks. If used for a long period without a break, there is a risk of developing dependence or problems upon treatment discontinuation.

When taking this medicine, there is a risk of dependence (a need to take the medicine). The risk increases with the dose and treatment duration. The risk is greater if you have

a history of alcohol or drug abuse.

Therapeutic group: Benzodiazepines.

This medicine belongs to the group of benzodiazepines, which act by altering brain activity related to emotion.

2. Before using this medicine

Do not use this medicine if:

- You are **sensitive (allergic)** to the active ingredient or other benzodiazepine medicine, or to any of the other ingredients in this medicine (see section 6 "Additional information").
- You have **severe** or long-term **liver problems**.
- You have **severe breathing problems**.
- You suffer from **sleep apnoea** (difficulty breathing while asleep).
- You suffer from **myasthenia gravis** (a condition causing muscles to weaken and tire easily).
- You suffer from **mental illness**, such as phobia or obsessive thoughts.
- You suffer from depression (with or without anxiety) or hyperactivity (Do not use Diazepam Grindeks 5 mg as monotherapy for treatment of depression or anxiety accompanied by depression).
- You have **porphyria** (an inherited condition causing skin blisters, abdominal pain and brain or nervous system disorders).
- You suffer from **hyperkinesia** (a state of hyperactivity, restlessness).
- You are **pregnant** or **planning a pregnancy** (see section "Pregnancy and breastfeeding" below).
- Children below the age of 6 months.

Special warnings about using this medicine

Before using Diazepam Grindeks 5 mg, tell your doctor if:

- You have someone close to you who has recently died
- You have lung problems
- You have liver problems
- You have a personality disorder
- You have a history of alcoholism or drug abuse
- You have **heart and lung problems** or **severe kidney failure**
- You have **low blood levels** of a protein called albumin
- You have a poor blood supply to the brain (**arteriosclerosis**)
- You are **elderly** (There is a risk of confusion or disorders of movement coordination, which may cause injuries or falls)
- You **smoke**

Important information that you should know when taking Diazepam Grindeks 5 mg

- **Dependence** - When taking this medicine, there is a risk of dependence (a need to keep taking the medicine), which increases with the dose and treatment duration. The risk is greater in patients with a history of alcohol or drug abuse or in patients suffering from a personality disorder.
- **Withdrawal** - Treatment with the medicine should be stopped gradually. **Withdrawal symptoms** appear with Diazepam Grindeks 5 mg even when normal doses are given for short periods of time. See section 3 under "Stopping use of Diazepam Grindeks 5 mg and withdrawal effects".

- **Tolerance** - If after a few weeks you notice that the medicine is not working as well as it did when starting treatment, you should consult your doctor.
- **Behavioural effects** - may occur while taking Diazepam Grindeks 5 mg (see section 4 – "**Side effects**").
- To reduce the risk of amnesia (**loss of memory**), you should ensure that you have an uninterrupted sleep of at least 7 hours.
- Tell your doctor or dentist that you are taking Diazepam Grindeks 5 mg if you need a treatment or surgery requiring use of anaesthetics.

Interactions with other medicines

Concomitant use of Diazepam Grindeks 5 mg and opioids (strong painkillers, medicines assisting in drug withdrawal and certain cough medicines) increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life threatening. Therefore, concomitant use of these medicines should only be considered when other treatment options are not possible. However, if your doctor prescribes Diazepam Grindeks 5 mg together with opioids, the dose and treatment duration should be limited by your doctor. Tell your doctor about all the opioid medicines you are taking, and follow your doctor's dose recommendation closely. It can be helpful to inform friends or relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms.

Avoid using Diazepam Grindeks 5 mg in combination with:

- **sodium oxybate** (used to prevent cataplexy attacks (attacks of muscle weakness that appear suddenly and last for a short time) in patients with narcolepsy (a sleep disorder that may cause extreme sleepiness, sudden uncontrollable urge to fall asleep during the day and cataplexy)).
- **zidovudine** (a medicine assisting in treatment of HIV/AIDS virus)

If you are taking or have recently taken other medicines, including non-prescription medicines and dietary supplements, tell your doctor or pharmacist.

Especially if you are taking:

- **Combining the following medicines with Diazepam Grindeks 5 mg may cause sleepiness:**
Antidepressants e.g. amitriptyline, fluvoxamine, fluoxetine, **antipsychotics** e.g. chlorpromazine, haloperidol (to treat mental problems e.g. zotepine), **antihistamines** with a sedative effect (for allergies), e.g. chlorpheniramine, promethazine, **general anaesthetics**, **hypnotics** e.g. temazepam, zopiclone (help to fall asleep), **alpha blockers** or **moxonidine** (to lower high blood pressure), **muscle relaxants** (e.g. baclofen, tizanidine), **anxiolytics/sedatives** e.g. lorazepam, buspirone.
- Certain **strong painkillers** (e.g. codeine or medicines containing dextropropoxyphene hydrochloride and paracetamol) may enhance the sense of general wellbeing when taken in combination with Diazepam Grindeks 5 mg, which can increase your desire to continue using these medicines (dependence) or make you very sleepy.
- **Combining the following medicines with Diazepam Grindeks 5 mg may cause sleepiness and cause Diazepam Grindeks 5 mg to be removed from the body more slowly than usual: lofexidine** (helps to relieve withdrawal symptoms in patients discontinuing opioids or heroin), **nabilone** (to treat nausea and vomiting), **disulfiram** (to treat alcohol addiction), baclofen and tizanidine (to relieve muscle spasms).
- **Medicines for epilepsy** e.g. phenobarbital, phenytoin, carbamazepine or sodium valproate (Diazepam Grindeks 5 mg may affect the blood levels of these medicines).

- **Combining the following medicines with Diazepam Grindeks 5 mg may cause Diazepam Grindeks 5 mg to be removed from the body more slowly than usual: cimetidine, omeprazole or esomeprazole** (medicines for treatment of gastric ulcer), **oestrogen-containing contraceptives, erythromycin** (an antibiotic), **antifungals** (e.g. fluconazole, itraconazole, ketoconazole or voriconazole), **isoniazid** (to treat tuberculosis).
- **Combining the following medicines with Diazepam Grindeks 5 mg may cause Diazepam Grindeks 5 mg to be removed from the body more quickly than usual: rifampicin**, to treat infections (an antibiotic), **theophylline** (to treat asthma).
- **Amprenavir or ritonavir** (antivirals), as these can make you feel sleepy for a longer period or cause difficulty breathing.
- **Medicines to lower high blood pressure** (e.g. hydralazine, minoxidil, sodium nitroprusside), **diuretics, nitrates** (for heart conditions), **ACE inhibitors** (used to treat high blood pressure, e.g. perindopril, captopril), **alpha blockers** (used to treat high blood pressure, e.g. alfuzosin, prazosin), **angiotensin II receptor antagonists** (used to treat high blood pressure, e.g. valsartan), **calcium channel blockers** (used to treat high blood pressure, e.g. amlodipine), **adrenergic neuron blockers** (used to treat high blood pressure, e.g. reserpine), **beta blockers** (used to treat high blood pressure, e.g. bisoprolol), as these medicines could lower the blood pressure too much.
- **Levodopa** (used to treat Parkinson's disease). Diazepam Grindeks 5 mg may reduce the effect of levodopa.
- **Antacids** (reduce stomach acid) may slow down the absorption of Diazepam Grindeks 5 mg into the body.
- **Cisapride** (used to treat gastric reflux).

Using this medicine and alcohol consumption

Do not drink alcohol during treatment with Diazepam Grindeks 5 mg. Alcohol may increase the sedative effect of Diazepam Grindeks 5 mg.

Using this medicine and food

Grapefruit juice may increase the amount of Diazepam Grindeks 5 mg in your blood. If you are elderly, suffer from liver cirrhosis or from any of the conditions listed in section 2 above, drinking grapefruit juice may increase the sedative effect of Diazepam Grindeks 5 mg, and you should talk about it with your doctor or pharmacist. Drinks containing caffeine may reduce the effect of the medicine.

Pregnancy and breastfeeding

Do not use Diazepam Grindeks 5 mg if you are pregnant, plan to become pregnant, might be pregnant or are breastfeeding. If your doctor decided that you should use this medicine towards the end of pregnancy (or during labour), your baby may have a low body temperature, low muscle tone, difficulty in breathing or feeding. In addition, if you use this medicine regularly during the end of pregnancy, your baby may develop withdrawal symptoms.

If you are pregnant or breastfeeding, think you may be pregnant or plan to become pregnant, ask your doctor for advice before taking this or any other medicine.

Driving and using machines

Using Diazepam Grindeks 5 mg may make you confused, forgetful, sleepy, unstable or have poor coordination, along with other side effects that can affect your everyday activities (see section 4 "Side effects"). These effects may be increased if you have not had enough sleep. Do not drive or operate dangerous machines if you are affected by the medicine in this manner.

This medicine may affect your ability to drive as it may make you feel sleepy or dizzy. Do not drive while using this medicine until you know how it affects you. Consult your doctor or pharmacist if you are not confident in your ability to drive carefully while using this medicine.

Important information about some of this medicine's ingredients

Diazepam Grindeks 5 mg tablets contain lactose. If you have been told by your doctor that you have intolerance to certain sugars, consult your doctor before taking this medicine.

3. How to use this medicine?

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.

Only your doctor will determine your dose and how you should take this medicine.

Do not exceed the recommended dose.

This medicine is usually not intended for children.

Elderly or frail

If you are elderly or frail, you may be more sensitive to the effects of Diazepam Grindeks 5 mg, such as confusion, and your doctor will prescribe lower doses for you. The dose should not exceed half of the adult dose.

Impaired kidney or liver function

If you have liver or kidney problems, you will probably receive lower doses.

Manner of use

Swallow the medicine with water.

You may split the Diazepam Grindeks 5 mg tablet on the score line.

There is no information about crushing and chewing.

If you have accidentally taken a higher dose

If you (or someone else) swallow many tablets at the same time, or if you think that a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you. Signs of an overdose include clumsiness and loss of coordination, sleepiness or deep sleep, speech problems, irregular or slow heartbeat, difficulty in controlling movements, uncontrolled eye movements, muscle weakness or excitement, low blood pressure. An extreme overdose may cause coma (a state of unconsciousness and irresponsiveness), reflex problems and breathing difficulties.

If you forget to take the medicine

If you forget to take a dose, take it as soon as you remember, unless it is nearly time to take the next dose. Do not take a double dose to make up for the forgotten dose.

Adhere to the treatment as recommended by your doctor.

Stopping use of Diazepam Grindeks 5 mg and withdrawal effects

Do not stop using this medicine suddenly; keep taking it until your doctor tells you how to reduce the dose gradually. If you stop taking the medicine suddenly, you may experience the following side effects:

- Headaches, muscle pain, tension.
- Severe anxiety, confusion, restlessness, depression, nervousness, sweating, rapid and/or irregular heartbeat, muscle spasms, shaking, loss of appetite, nausea or vomiting, abdominal pain, diarrhoea, agitation.

- **In severe cases** of withdrawal symptoms, you may experience a sensation of things that do not exist, a feeling of detachment from reality, numbness and tingling in the hands and feet, sounds seeming to be louder than usual and which can sometimes be painful if the sounds are indeed loud, sensitivity to light or touch, hallucinations and seizures.
- If you have been taking a high dose, you may occasionally experience confusion or unusual behaviour. Patients at risk of seizures may be more susceptible to experiencing seizures upon withdrawal.

Treatment should be stopped gradually, otherwise the symptoms for which you have taken the medicine may return more intensely than previously (rebound insomnia and anxiety). The risk of this happening is greater when the medicine is discontinued suddenly. You may also experience mood changes, anxiety, restlessness and changes in sleep patterns. Even if you stop taking the medicine gradually, you may experience anxiety, depression, restlessness and difficulty sleeping. You may also experience diarrhoea and sweating. If you experience these effects, consult your doctor.

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

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

As with any medicine, using Diazepam Grindeks 5 mg may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Stop using the medicine and contact your doctor immediately or go to the emergency room if you experience any of the following effects:

- An allergic reaction (swelling of the lips, face or neck leading to severe difficulty breathing; skin rash or skin allergy (hives))

This is a serious but rare side effect. You may need urgent medical treatment or hospitalisation.

Tell your doctor immediately if:

- You suffer from behavioural changes such as restlessness, irritability, agitation, aggressiveness, hallucinations, rage, nightmares, seeing or sensing things that are not there, psychiatric disorders and inappropriate behaviour, as your treatment may be stopped by your doctor.

Tell your doctor if you notice any of the following side effects or any other effect that does not appear here:

- Sleepiness, falling asleep, tiredness, slurred speech, dizziness, unsteadiness or clumsiness, loss of coordination (you may notice these even after a single dose and this may continue on the following day)
- Confusion (particularly in the elderly), memory loss (which may occur several hours after taking Diazepam Grindeks 5 mg. If possible, in order to reduce the risk, allow seven to eight hours of uninterrupted sleep after taking the medicine), difficulty concentrating, excitement, numbed emotions, reduced alertness, depression associated with suicidal tendencies, headache, spinning sensation, difficulty sleeping, anxiety
- Blood disorders (you may develop throat sores, nosebleeds or infections), changes in sex drive (libido), low blood pressure
- Muscle spasms/shaking or weakness, difficulty in controlling movements, breathing difficulties

- Urinary incontinence or problems with urinating
- You feel that you are abusing or developing dependence on the medicine
- Visual disturbances, blurred or double vision
- Nausea, vomiting, stomach problems, dry mouth, diarrhoea, constipation, secretion of too much or too little saliva
- Skin reactions

Rarely, jaundice (characterized by yellowing of the skin or the whites of the eyes) may occur, and very rarely, high blood levels of liver enzymes may occur.

Withdrawal symptoms are known to occur (see section 3 under "Stopping use of Diazepam Grindeks 5 mg and withdrawal effects").

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

Reporting side effects

You can report side effects to the Ministry of Health by following the "Reporting Side Effects of Drug Treatment" link on the Ministry of Health home page (www.health.gov.il), which opens an online form for reporting side effects, or you can also use this link: <https://sideeffects.health.gov.il>

5. How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this and all other medicines in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by your doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.
- **Store the medicine below 25°C, in the original package to protect from light.**
- Do not dispose of medicines via wastewater or household waste. Ask the pharmacist how to dispose of medicines you no longer use. These measures will help protect the environment.

6. Additional information

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

Cellulose, microcrystalline, starch, hydroxypropyl, lactose monohydrate, talc, magnesium stearate, silicon dioxide.

What the medicine looks like and the contents of the pack

White, round flat tablet with bevelled edges and a score line on one side.

A pack contains 20 or 30 tablets packed in blisters.

Not all pack sizes may be marketed.

Registration holder's name and address:

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

Manufacturer's name and address:

JSC Grindeks, 53 Krustpils street, Riga, LV-1057, Latvia

The leaflet was revised in June 2024.

Registration number of the medicine in the Ministry of Health National Drug Registry: 173-32-36670-99

For further information about the medicinal product and for updated patient leaflets in Hebrew, Arabic and English, please scan the code



<https://israeldrugs.health.gov.il/#!/medDetails/173%2032%2036670%2099>

For a printed copy of the patient information leaflet in English, please contact the registration holder by email humane-info@medi-market.co.il or by phone 09-8844451.