

Package leaflet: Information for the patient

Alprazolam Grindeks 250 microgram tablets Alprazolam Grindeks 500 microgram tablets Alprazolam Grindeks 1 mg tablets

alprazolam

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

1. What Alprazolam Grindeks is and what it is used for

Alprazolam Grindeks is a sedative and belongs to the benzodiazepine group.

Alprazolam Grindeks is used in adults for treatment of anxiety symptoms which are severe, disabling or causing the patient great distress. This medicine is for short-term use only.

2. What you need to know before you take Alprazolam Grindeks

Do not take Alprazolam Grindeks

- if you are allergic to alprazolam, other benzodiazepines, or to any of the other ingredients of this medicine (listed in section 6),
- if you suffer from a disease called 'myasthenia gravis' where you have weak and tired muscles,
- if you have severe chest problems or breathing difficulties (e.g., chronic bronchitis or emphysema),
- if you have 'sleep apnoea' - this is a condition where your breathing becomes irregular, even stopping for short periods, while you are asleep,
- if you have severe liver problems.

Warnings and precautions

Talk to your doctor or pharmacist before taking Alprazolam Grindeks:

- if you abuse or have been abusing alcohol, drugs or medicines
- if you have been taking alprazolam for a long time as the effect may decrease
- if you have an impaired general condition
- if you have problems with your lungs, kidneys or liver
- if you are taking other medicines for mental illness.

Dependence

Use of Alprazolam Grindeks may lead to physical and mental dependence on the medicine. The risk of dependence is increased by dose and duration of treatment. Therefore, the duration of treatment must be as short as possible. Follow your doctor's dose recommendations (see section 3). You notice psychological dependence by not wanting to stop taking the medicine. Physical dependence means that withdrawal symptoms occur when the treatment with this medicine is stopped suddenly. The risk is also greater in patients who abuse or have been abusing alcohol or medicines (see also section 3. "If you stop taking Alprazolam Grindeks"). Medicine abuse is a known risk with Alprazolam Grindeks. If this medicine is abused, it may lead to overdose and death. Always follow your doctor's dose recommendations. This medicine may be sought after by people who abuse prescription medicines and should be stored out of the reach of other people.

Memory disturbance

During treatment with alprazolam your memory may be disturbed. This usually occurs several hours after the medicine has been taken. Please ask your doctor if you notice such a symptom. To reduce the risk, you should ensure that you are able to have a full night's sleep (7 to 8 hours) while taking this medicine.

Mental illness (psychosis)

If you suffer from psychosis, a severe mental illness which disturbs your behaviour, actions and self-control, then Alprazolam Grindeks is not appropriate.

Impact on mood

Use of alprazolam may increase the risk of episodes of hypomania (a milder form of mania) and mania (hyperactive mental state, excessive elation and energy) in patients with depression. Contact your doctor immediately if you develop signs of hypomania or mania.

Depression, thoughts of harming or killing yourself

The treatment with alprazolam may increase the risk to develop thoughts of harming or killing yourself if you have depression. Please ask your doctor before starting treatment with alprazolam. If treatment with alprazolam is necessary and if you are depressed or have previously had thoughts about harming or killing yourself your doctor will monitor you closely. If you develop thoughts of harming or killing yourself at any time, contact your doctor or go to a hospital **straight away**.

Elderly

Be especially careful when using alprazolam if you are elderly, because it may cause increased tiredness and/or muscle weakness that can increase the risk of falling.

Children and adolescents

Do not give this medicine to children and adolescents under the age of 18 years because the safety and efficacy have not been established.

Other medicines and Alprazolam Grindeks

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

The effect of the treatment may be affected if Alprazolam Grindeks is used together with other medicines to treat the listed conditions. Your doctor may need to adjust your dose.

- Mental problems (antipsychotic medicines including clozapine)
- sleep disorders (sleeping tablets)
- allergies or hay fever (some antihistamines)
- if you undergo major surgery (anaesthetics)
- severe pain (narcotic analgesics, e.g., dextropropoxyphene)
- therapy against drug addiction (substitutive treatment)

- problems such as anxiety or depression, including certain antidepressants containing fluoxetine, fluvoxamine, nefazodone or imipramine
- heart failure (digoxin)
- infections (antibiotics containing erythromycin, clarithromycin or telithromycin)
- fungal infections (itraconazole, fluconazole, ketoconazole, posaconazole, voriconazole)
- medicines to treat angina pectoris and high blood pressure, such as diltiazem
- HIV and AIDS (called HIV-protease inhibitors, such as ritonavir)
- heartburn and stomach ulcer, such as cimetidine or omeprazole
- asthma and bronchitis such as theophylline
- epilepsy, such as carbamazepine
- muscle relaxant medicines. When used together with alprazolam there may be an increase of the muscle relaxing effect and a risk of falling.

Concomitant use of Alprazolam Grindeks and opioids (strong painkillers, medicines for substitution therapy and some cough remedies) 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 Alprazolam Grindeks together with opioids, the dose and duration of concomitant treatment should be limited by your doctor.

Please tell your doctor about all opioid medicines that 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.

It is also possible that the treatment effect of alprazolam could be affected by concomitant treatment with any of the following medicines: the pill, rifampicin (for infections) or St. John's wort (herbal medicine).

Alprazolam Grindeks with alcohol

You should refrain from alcohol during treatment with Alprazolam Grindeks, as alcohol can alter and enhance the effect of Alprazolam Grindeks in unpredictable ways.

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

You must tell your doctor immediately if you are pregnant or plan to become pregnant. Observations in humans have shown that alprazolam may be harmful to the foetus (increased risk of malformation (cleft palate)). During pregnancy, alprazolam may only be used if the doctor has determined that the treatment benefits outweigh the risks to the unborn child and that the medicine is suitable for you.

If you use Alprazolam Grindeks up until the birth, inform your doctor because your newborn baby may develop withdrawal symptoms after the birth.

Breast-feeding

Alprazolam Grindeks should not be taken if you are breast-feeding. Alprazolam passes into breast milk. If your doctor has decided that you should receive this medicine, you will have to stop breast-feeding.

Driving and using machines

Even when used as directed, Alprazolam Grindeks may alter reaction skills to such an extent that the ability to drive or use machines is impaired. This risk is particularly high at the start of treatment, whenever the dose is increased, if you do not get enough sleep or if you also consume alcohol or take other substances that act on the central nervous system. You should therefore completely refrain from

driving, using machines or performing any other hazardous activities or at least during the first few days of treatment. The decision in each individual case is made by the treating doctor.

Alprazolam Grindeks contains lactose, sodium and sodium benzoate (E211)

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

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

Sodium benzoate: This medicine contains 0.12 mg sodium benzoate in each tablet.

3. How to take Alprazolam Grindeks

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

Unless otherwise prescribed by the doctor, the following dose guidelines apply

Initial dose: in general, the dose at the start of treatment is 0.25 to 0.5 mg alprazolam three times a day.

Maintenance dose: if clinically required your doctor may increase your dose up to 3 mg to 4 mg in small increments, divided into several individual doses.

Elderly and sensitive patients or debilitated patients

If you are an older and sensitive patient and you need a lower dose you will normally start on a dose of 0.25 mg twice to three times a day. This dose may be slowly increased if needed and if you do not get any side effects.

Patients with kidney or liver problems

If you have kidney or liver problems your doctor will adjust your dose.

Use in children and adolescents

Children and adolescents under 18 years of age should not take Alprazolam Grindeks.

Method of administration

Alprazolam Grindeks is for oral use. Take the tablets with some liquid (e.g., half a glass of water). The tablets have a score line and can be divided into equal doses.

Duration of treatment

The risk of dependency and abuse may increase with the dose and duration of treatment. The doctor will therefore prescribe the lowest effective dose and treatment duration possible, and frequently reassess the need for continued treatment.

The maximum duration of treatment should not be more than 2-4 weeks. Long-term treatment is not recommended. A decreased effect of the medicine may develop if used for more than a few weeks.

If you take more Alprazolam Grindeks than you should

If you have taken too much Alprazolam Grindeks, contact your doctor or local hospital immediately. Signs of (mild) overdose may be drowsiness, light-headedness, visual disturbances, slurred speech, drop in blood pressure, unsteady gait/movements and muscle weakness. In cases of severe intoxication, deep sleep and even unconsciousness, impaired breathing and circulatory collapse may occur. Intensive care monitoring is essential.

Assessment of the degree of intoxication should be made by the doctor, who will decide on the measures to treat it.

If you forget to take Alprazolam Grindeks

Do not take a double dose to make up for a forgotten dose. If you forget to take your dose skip the missed dose and continue to take Alprazolam Grindeks as prescribed by your doctor.

If you stop taking Alprazolam Grindeks

Always see your doctor before you stop taking Alprazolam Grindeks as the dose needs to be reduced gradually. If you stop taking the tablets or reduce the dose suddenly you can get 'rebound' effects which might cause you to become temporarily more anxious or restless or to have difficulty sleeping. Some people may also experience 'withdrawal' effects (see section 4. 'Dependence and withdrawal symptoms'). These symptoms will go away as your body re-adjusts. If you are worried, your doctor can tell you more about this. Your doctor will therefore reduce the dose gradually when the treatment is ended. Dose reduction is done according to individual needs, since gradual discontinuation depends on several factors (e.g., treatment duration and your daily dose). Ask your doctor about how to reduce your dose gradually.

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.

Reasons for seeing your doctor immediately

If you get any of these symptoms see your doctor straight away as treatment will need to be discontinued. Your doctor will then advise how treatment will be stopped.

- Treatment with alprazolam can cause serious behavioural or psychiatric effects - for example agitation, restlessness, aggressiveness, irritability, violent anger, false beliefs, nightmares and hallucinations or other inappropriate behaviour.
- Sudden wheeziness, difficulty in swallowing or breathing, swelling of eyelids, face or lips, rash or itching (especially affecting the whole body).

Reasons for seeing your doctor as soon as possible

Tell your doctor as soon as possible if you get the following symptoms as your dose or treatment might need to be changed:

- Memory loss (amnesia).
- Yellowing of the skin and whites of the eyes (jaundice).

Dependence and withdrawal symptoms

It is possible to become dependent on medicines like alprazolam while you are taking them which increases the likelihood of getting withdrawal symptoms when you stop treatment. Withdrawal symptoms are more common if you:

- stop treatment suddenly
- have been taking high doses
- have been taking this medicine for long time
- have a history of alcohol or drug abuse.

This can cause effects such as headaches, muscle pain, extreme anxiety, tension, restlessness, confusion, mood changes, difficulty sleeping and irritability.

In severe cases of withdrawal, you can also get the following symptoms: nausea (feeling sick), vomiting, sweating, stomach cramps, muscle cramps, a feeling of unreality or detachment, being unusually sensitive to sound, light or physical contact, numbness and tingling of the feet and hands,

hallucinations (seeing or hearing things which are not there while you are awake), tremor or epileptic fits. Please tell your doctor if any withdrawal symptoms get worse or do not go away.

Other side effects that may occur are:

Very common: may affect more than 1 in 10 people

- Depression
- Sleepiness and drowsiness
- Jerky, uncoordinated movements
- Inability to remember bits of information
- Slurred speech
- Dizziness, light-headedness
- Headaches
- Constipation
- Dry mouth
- Tiredness
- Irritability.

Common: may affect up to 1 in 10 people

- Loss of appetite
- Confusion and disorientation
- Changes in your sex drive (men and women)
- Nervousness or feeling anxious or agitated
- Insomnia (inability to sleep or disturbed sleep)
- Problems with balance, and unsteadiness (similar to feeling drunk) especially during the day
- Loss of alertness or concentration
- Inability to stay awake, feeling sluggish
- Shakiness or trembling
- Double or blurred vision
- Feeling sick
- Skin reactions
- Changes in your weight.

Uncommon: may affect up to 1 in 100 people

- Feeling elated or over-excited, which causes unusual behaviour
- Hallucination (seeing or hearing things that do not exist)
- Feeling agitated or angry
- Vomiting
- Muscle spasms or weakness
- Incontinence
- Cramping pain in the lower back and thighs, which may indicate menstrual disorder
- Drug addiction
- Drug withdrawal symptoms.

Not known: frequency cannot be estimated from the available data

- In women, irregular periods or production of too much prolactin (the hormone that stimulates milk production)
- Feeling hostile or aggressive
- Abnormal thoughts
- Twisting or jerking movements
- Being hyperactive
- Stomach upsets

- Problems with liver function (this shows up in blood tests), inflammation of the liver (hepatitis)
- Nervous system imbalance. Symptoms may include: fast heart beat and unstable blood pressure (feeling dizzy, light-headed or faint)
- Serious allergic reaction which causes swelling of the face or throat
- Swelling of the ankles, feet or fingers
- Skin reaction caused by sensitivity to sunlight
- Difficulty urinating or bladder control problems
- Increased pressure in the eyes, which can also affect your vision
- Drug abuse.

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:

HPRA Pharmacovigilance

Website: www.hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Alprazolam Grindeks

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.

Do not store above 25 °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. Contents of the pack and other information

What Alprazolam Grindeks contain

The active substance is alprazolam.

- Alprazolam Grindeks 250 microgram tablets
Each tablet contains 250 microgram alprazolam.
- Alprazolam Grindeks 500 microgram tablets:
Each tablet contains 500 microgram alprazolam.
- Alprazolam Grindeks 1 mg tablets:
Each tablet contains 1 mg alprazolam.

The other ingredients are lactose monohydrate; cellulose, microcrystalline (E460); maize starch, pregelatinised; docusate sodium; sodium benzoate (E211); magnesium stearate (E572); silica, colloidal anhydrous (E551), iron oxide red (E172) (*500 microgram tablets only*); indigo carmine lake (E132) (*1 mg tablets only*).

What Alprazolam Grindeks look like and contents of the pack

Alprazolam Grindeks 250 microgram is a white or almost white oval (10 mm x 5 mm) tablet with a score line on one side and debossed “0.25” on the other side.

Alprazolam Grindeks 500 microgram is a light pink to pink oval (10 mm x 5 mm) tablet with a score line on one side and debossed “0.5” on the other side.

Alprazolam Grindeks 1 mg is a light blue to blue oval (10 mm x 5 mm) tablet with a score line on one side and debossed “1” on the other side.

Alprazolam Grindeks are available in OPA/Alu/PVC//Alu blisters containing 10, 20, 30, 50, 60 or 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorization Holder and Manufacturer

AS GRINDEKS.

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

Germany	Alprazolam Grindeks 0,25 mg, 0,5 mg, 1 mg Tabletten
Austria	Alprazolam Grindeks 0,25 mg, 0,5 mg, 1 mg Tabletten
Belgium	Alprazolam Grindeks 0,25 mg, 0,5 mg, 1 mg comprimés
Bulgaria	Алпразолам Гриндекс 0,25 mg, 0,5 mg, 1 mg таблетки
	Alprazolam Grindeks 0,25 mg, 0,5 mg, 1 mg tablets
Croatia	Alprazolam Grindeks 0,25 mg, 0,5 mg, 1 mg tablete
Czech Republic	Alprazolam Grindeks
Denmark	Alprazolam Grindeks
Estonia	Ixhalanex
Finland	Alprazolam Grindeks 0,25 mg, 0,5 mg, 1 mg tabletit
France	ALPRAZOLAM GRINDEKS 0,25 mg comprimé sécable
	ALPRAZOLAM GRINDEKS 0,5 mg comprimé sécable
	ALPRAZOLAM GRINDEKS 1 mg comprimé sécable
Greece	Alprazolam Grindeks 0,25 mg, 0,5 mg, 1 mg δισκία
Hungary	Alprazolam Grindeks 0,25 mg, 0,5 mg, 1 mg tabletta
Ireland	Alprazolam Grindeks 250 microgram, 500 microgram, 1 mg tablets
Italy	Alprazolam Grindeks
Latvia	Ixhalanex 0,25 mg, 0,5 mg, 1 mg tabletes
Lithuania	Ixhalanex 0,25 mg, 0,5 mg, 1 mg tablečių
Luxembourg	Alprazolam Grindeks 0,25 mg, 0,5 mg, 1 mg Pëllen
The Netherlands	Alprazolam Grindeks 0,25 mg, 0,5 mg, 1 mg tabletten
Poland	Alprazolam Grindeks
Portugal	Alprazolam Grindeks 0,25 mg, 0,5 mg, 1 mg comprimidos
Romania	Alprazolam Grindeks 0,25 mg, 0,5 mg, 1 mg comprimate
Slovakia	Alprazolam Grindeks 0,25 mg, 0,5 mg, 1 mg tablety
Slovenia	Alprazolam Grindeks 0,25 mg, 0,5 mg, 1 mg tablete
Spain	Alprazolam Grindeks 0,25 mg, 0,5 mg, 1 mg comprimidos
Sweden	Alprazolam Grindeks 0,25 mg, 0,5 mg, 1 mg tabletter

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