

Package leaflet: Information for the patient

Alprazolam Krka 250 microgram tablets Alprazolam Krka 500 microgram tablets Alprazolam Krka 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 Krka is and what it is used for
2. What you need to know before you take Alprazolam Krka
3. How to take Alprazolam Krka
4. Possible side effects
5. How to store Alprazolam Krka
6. Contents of the pack and other information

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

Alprazolam Krka contains the active substance alprazolam. It belongs to a group of medicines called benzodiazepines (anxiety-relieving medicines).

Alprazolam Krka is indicated for short-term symptomatic treatment of anxiety in adults.

Alprazolam Krka is only indicated when the disorder is severe, disabling or subjecting the individual to extreme distress.

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

Do not take Alprazolam Krka

- if you are allergic to alprazolam or similar benzodiazepine medicines, or to any of the other ingredients of this medicine (listed in section 6).
- if you suffer from a disease called myasthenia gravis (causing muscle weakness).
- if you have severe breathing difficulties (e.g. chronic bronchitis or emphysema).
- if you suffer from sleep apnoea (breathing becomes irregular, even stopping for short periods, while you are asleep).
- if you have severe liver impairment.
- in case of acute poisoning with alcohol or CNS depressants (e.g. sleeping pills or painkillers, medicines for the treatment of mental disorders, such as antipsychotics and antidepressants).

Warnings and precautions

Talk to your doctor or pharmacist before taking Alprazolam Krka if you:

- have ever felt so depressed that you have thought about taking your own life.
- have ever suffered any mental illness that required hospital treatment.

- have problems with your lungs, kidneys or liver.
- have abused drugs or alcohol in the past or find it difficult to stop taking medicines, drinking or taking drugs (see also section 4. "Possible side effects"). Your doctor may want to provide you special help when you need to stop taking these tablets.
- have been prescribed medicines for severe anxiety before, because your body can quickly become used to this type of medicine so that it no longer helps you.
- benzodiazepines and related products should be used with caution in elderly, due to the risk of sedation and / or musculoskeletal weakness that can promote falls, often with serious consequences in this population.
- experience excessively lively mood (mania).
- experience memory loss. This mostly occurs a few hours after taking the tablet. (See section 4 "Possible side effects").
- experience psychiatric and "paradoxical" reactions such as anxiety, irritability, attacks of rage, nightmares, increased insomnia, perceptions of things that do not exist (hallucinations), severe mental disorders in which control over one's own behaviour and actions is disturbed (psychosis), inappropriate behaviour and other behavioural disturbances. These paradoxical reactions occur more frequently in children and elderly patients. Tell your doctor if such symptoms occur as the treatment may possibly need to be stopped.
- notice that the effect of the tablets becomes less after a few weeks of use.
- are troubled by symptoms that indicate physical and psychological dependence on alprazolam. 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 (see the section "If you stop taking Alprazolam Krka"). The risk of dependence increases with higher dosages and a longer period of treatment. Therefore, the duration of treatment must be as short as possible.
- have a certain form of suddenly raised eyeball pressure (narrow-angle glaucoma) or if you are at risk of experience this.
- have movement or coordination disorders (spinal or cerebellar ataxia).

Children and adolescents

Alprazolam Krka should not be used in children and adolescents under the age of 18 years as safety and efficacy have not been established.

Other medicines and Alprazolam Krka

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines especially medicines listed below as the effect of Alprazolam Krka or the other medicine may change when they are taken at the same time:

- Any other medicines to treat anxiety or depression or to help you sleep (e.g. nefazodone, fluvoxamine, fluoxetine, sertraline, imipramine, desipramine).
- Some strong pain killers (e.g. morphine, codeine, propoxyphene).
- Antipsychotic medicines used to treat mental illnesses like schizophrenia (e.g. clozapine).
- St. John's wort, a herbal medicine used to treat depression.
- Medicines used to treat epilepsy (e.g. carbamazepine, phenytoin).
- Antihistamines for relief of allergies.
- Medicines for treating fungal infections (e.g. ketoconazole, itraconazole, posaconazole, voriconazole).
- Oral contraceptives.
- Certain antibiotics (e.g. erythromycin, clarithromycin, telithromycin).
- Cimetidine (for treating stomach ulcers).
- Diltiazem (used for angina and high blood pressure).
- Digoxin (used to treat various heart conditions).
- Ritonavir or other similar medicines used to treat HIV.
- Rifampicin, a medicine to treat tuberculosis.
- Muscle relaxants, such as pancuronium, atracurium. The muscle-relaxant effect may be greater, especially on beginning Alprazolam Krka treatment.

If you are going to have an operation during which will be given a general anaesthetic, tell your doctor or anaesthetist that you are taking Alprazolam Krka.

Concomitant use of Alprazolam Krka 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 Alprazolam Krka 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.

Alprazolam Krka with food and drink and alcohol

It is important not to drink any alcohol while you are taking Alprazolam Krka, as alcohol increases the effects of this medicine.

Pregnancy, breast-feeding and fertility

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

There are no adequate experiences from the use of alprazolam in pregnant women. You should not take Alprazolam Krka if you are pregnant or planning to become pregnant, unless your doctor considers it strictly indicated. Observations in humans have indicated that the substance alprazolam can be harmful to the unborn child. If you are pregnant or planning a pregnancy, consult your doctor about the possibility to stop the treatment. If you are taking Alprazolam Krka until birth, let your doctor know as your newborn might have some withdrawal symptoms when it is born.

Breast-feeding

Do not breast-feed while taking Alprazolam Krka, as this medicine may pass into breast milk.

Driving and using machines

Alprazolam Krka can cause side effects such as drowsiness, memory loss, muscle relaxation and decreased concentration. Therefore your ability to react may be affected, particularly if you have had insufficient sleep. These effects may be increased if you drink alcohol. Do not drive or operate machines during treatment with Alprazolam Krka.

Alprazolam Krka 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 Alprazolam Krka

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

Your doctor will determine the most suitable dose of Alprazolam Krka for you, based on the signs of illness and tolerance. If you experience severe side effects after the first dose, your dose should be reduced.

Treatment of anxiety

The recommended initial dose: take 0.25 – 0.5 mg three times daily.

The recommended dose: your doctor may increase your dose as needed, up to the maximum daily dose of 4 mg, taken in divided doses during the day.

Elderly

For elderly patient and those sensitive to the sedative effects of this medicine the initial dose is 0.25 mg two or three times daily.

The recommended dose: your doctor may increase your dose as needed.

Hepatic or renal impairment

The recommended initial dose: 0.25 mg two or three times daily.

The recommended dose: your doctor may increase your dose as needed.

Treatment duration

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 (see section 2 - Warnings and precautions).

The maximum duration of treatment should not be more than 2-4 weeks. Long-term treatment is not recommended.

Method of administration

You can take the tablets with or without food. Swallow the tablet with a small amount of liquid.

The score line is only there to help you break the tablet if you have difficulty swallowing it whole.

If you take more Alprazolam Krka than you should

If you take more tablets than prescribed by your doctor (or if someone else takes your tablets), seek medical attention or go to the nearest hospital. Take the package of this medicine with you.

The symptoms of overdose may include: dizziness, sleepiness, breathing problems, confusion, unconsciousness, muscle weakness, difficulties in coordinating body movements (ataxia).

If you forget to take Alprazolam Krka

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

If you stop taking Alprazolam Krka

Always ask your doctor before you stop taking Alprazolam Krka as the dose needs to be reduced gradually. If you stop taking the tablets or reduce the dose suddenly you can experience '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. Possible side effects). 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 the following side effects, see your doctor immediately as your treatment will need to be discontinued:

- Treatment with this medicine 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 Krka 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 of this medicine
- have been taking this medicine for a 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: 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 possible side effects that may occur are:

Very common: may affect more than 1 in 10 people

- Depression
- Sleepiness and drowsiness
- Jerky or uncoordinated movements (ataxia)
- Inability to remember bits of information
- Slurred speech (dysarthria)
- Dizziness, light-headedness
- Headache
- Constipation
- Dry mouth
- Tiredness
- Irritability

Common: may affect up to 1 in 10 people

- Decreased appetite
- Confusion
- Disorientation
- Changes in your sex drive (libido decreased, libido increased)
- Feeling nervous or anxious
- Insomnia (inability to sleep or disturbed sleep)
- Problems with balance, and unsteadiness (similar to feeling drunk) especially during the day
- Coordination abnormal
- Loss of alertness or concentration
- Inability to stay awake, feeling sluggish
- Shakiness or trembling
- Blurred vision
- Feeling sick
- Skin inflammation (dermatitis)
- Sexual dysfunction

- Changes in your weight

Uncommon: may affect up to 1 in 100 people

- Feeling elated or over-excited (mania)
- Hallucination (seeing or hearing things that do not exist)
- Feeling agitated or angry
- Memory loss (amnesia)
- Vomiting
- Muscle weakness
- Incontinence
- Menstrual irregularities

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)
- Hypomania
- Feeling hostile or aggressive
- Abnormal thoughts
- Being hyperactive
- Nervous system imbalance. Symptoms may include: fast heart beat and unstable blood pressure (feeling dizzy, light-headed or faint)
- Twisting or jerking movements (dystonia)
- Stomach upsets
- Inflammation of the liver (hepatitis)
- Problems with liver function (this shows up in blood tests)
- Yellowing of the skin and whites of the eyes (jaundice)
- Serious allergic reaction which causes swelling of the face or throat
- Skin reaction caused by sensitivity to sunlight
- Difficulty urinating or bladder control problems
- Swelling of the ankles, feet or fingers
- 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 Krka

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 packaging. The expiry date refers to the last day of that month.

Do not store above 25°C.

Store in the original package in order to protect from moisture.

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 Krka contains

- The active substance is alprazolam.
- Alprazolam Krka 250 microgram tablets
Each tablet contains 250 micrograms alprazolam.
The other ingredients of the 250 microgram tablets are lactose monohydrate, maize starch, crospovidone (type A), povidone K 25, magnesium stearate (E470b), polysorbate 80.
- Alprazolam Krka 500 microgram tablets
Each tablet contains 500 micrograms alprazolam.
The other ingredients of the 500 microgram tablets are lactose monohydrate, maize starch, crospovidone (type A), povidone K 25, carmines (E120), magnesium stearate (E470b), polysorbate 80.
- Alprazolam Krka 1 mg tablets
Each tablet contains 1 mg alprazolam.
The other ingredients of the 1 mg tablets are lactose monohydrate, maize starch, crospovidone (type A), povidone K 25, patent blue V (E131), magnesium stearate (E470b), polysorbate 80.
- See section 2: "Alprazolam Krka contains lactose".

What Alprazolam Krka looks like and contents of the pack

- 250 microgram tablets: white to almost white, round, biconvex tablets with bevelled edges. The tablet is scored on one side and engraved with mark 0.25 on the other, 7 mm in diameter. The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.
- 500 microgram tablets: pale pink, marbled, round, biconvex tablets with bevelled edges. The tablet is scored on one side and engraved with mark 0.5 on the other, 7 mm in diameter. The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.
- 1 mg tablets: pale greenish blue to pale blue, marbled, round, biconvex tablets with bevelled edges. The tablet is scored on one side and engraved with mark 1 on the other, 7 mm in diameter. The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

Alprazolam Krka is available in boxes of 10, 20, 30, 50, 100 tablets in blisters.

Alprazolam Krka is available in boxes of 10x1, 20x1, 30x1, 50x1, 100x1 tablets in perforated unit dose blisters.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia

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

France	Alprazolam HCS
Germany	Alprazolam TAD
Ireland	Alprazolam Krka
Slovenia	Aripsiq

This leaflet was last revised in