

Package leaflet: Information for the patient

Alprazolam 0.25 mg Tablets

Alprazolam 0.5 mg Tablets

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

1. What Alprazolam is and what it is used for

Alprazolam is a tranquilliser containing the active substance alprazolam. Alprazolam belongs to one of a group of medicines called benzodiazepines. Benzodiazepines affect chemical activity in the brain to promote sleep and to reduce anxiety and worry.

Alprazolam is used to **treat anxiety** that is severe, disabling or causing the sufferer great distress. Alprazolam tablets should only be used for short-term treatment of anxiety. The overall duration of treatment should not be more than 12 weeks including a period where the dose is gradually reduced (this is called dose 'tapering').

2. What you need to know before you take Alprazolam

Do not take Alprazolam if you

- are allergic to alprazolam or any of the other ingredients of this medicine (listed in section 6), or previously had an allergic reaction to another benzodiazepine
- suffer from myasthenia gravis (severe muscle weakness)
- have a severe lung disease e.g. bronchitis, emphysema
- have "sleep apnoea", where breathing temporarily stops during sleep
- have a severe liver disease.

Warnings and precautions

Talk to your doctor or pharmacist before taking Alprazolam

- if you have ever suffered any mental illness that requires hospital treatment
- if you are under 18 years old
- if you have problems with your lungs, kidneys or liver
- if you have abused drugs or alcohol in the past or find it difficult to stop taking medicines, drinking or taking drugs. Your doctor may want to give you special help when you need to stop taking these tablets.
- if you notice that the effect of the tablets becomes less after a few weeks of use

- if you 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”).

The risk of dependence increases with higher doses and a longer period of treatment. Therefore, the duration of treatment must be as short as possible.

- if you experience memory loss.
This mostly occurs a few hours after taking the tablet. See section 4 “Possible side effects”.
- if you 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 conflicting 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.

- if you suffer from chronic tightness of the chest you should be aware that Alprazolam can aggravate this
- if you suffer from severe depression
Alprazolam can sometimes cause an excessively lively mood (mania) or an increase in suicidal tendencies.
- if you suffer from psychosis - a severe mental illness which disturbs your behaviour, actions and self-control, then Alprazolam is not appropriate.
- if you have a certain form of suddenly raised eyeball pressure (narrow-angle glaucoma) or if you are at risk of experiencing this.

Please tell your doctor if any of the above apply or have previously applied to you.

Children and adolescents

Alprazolam is not recommended for children and adolescents under the age of 18 years.

Other medicines and Alprazolam

Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines, including medicines obtained without a prescription especially medicines listed below, as the effect of Alprazolam may be stronger when taken at the same time:

Medicines that increase Alprazolam’s sedative effect:

- sleep-inducing and tranquillising medicines
- medicines used to treat severe mental disorder like schizophrenia (antipsychotics)
- medicines used to treat severe depression
- any other medicines to treat anxiety or depression
- medicines used to treat epilepsy
- medicines that are used for anaesthesia
- certain medicines used to treat allergies, so called sedative antihistamines.

Concomitant use of Alprazolam 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 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.

These painkillers can also increase the euphoria and dependence risk.

Medicines that increase Alprazolam's effect as a result of suppression of the breakdown of alprazolam in the liver:

- nefazodone, fluvoxamine, fluoxetine, sertraline, medicines used to treat severe depression
- cimetidine, a medicine used to treat gastric disorders
- certain medicines used to treat AIDS (known as HIV protease inhibitors, e.g. ritonavir, saquinavir, indinavir)
- dextropropoxyphene, a medicine used to treat pain
- the oral contraceptive pill
- diltiazem, a medicine used to treat high blood pressure and heart disorders
- macrolide antibiotics such as erythromycin, medicines used to treat infections
- certain medicines used to treat fungal infections, such as ketoconazole and itraconazole.

Medicines that decrease Alprazolam's effect due to the increased alprazolam breakdown in the liver:

- carbamazepine or phenytoin, medicines used to treat epilepsy and other conditions
- St John's wort, a herbal medicine used to treat depression
- rifampicin, a medicine to treat tuberculosis.

Medicines whose effects may be increased by Alprazolam:

- digoxin, a medicine used to treat heart failure and heart rhythm disturbances
The risk of digoxin poisoning is particularly increased in elderly patients and, where doses exceeding 1 mg Alprazolam are taken daily.
- muscle relaxants, such as pancuronium, atracurium
The muscle-relaxant effect may be greater, especially on beginning Alprazolam treatment.
- imipramine and desipramine, certain medicines used to treat severe depression
- clozapine, a medicine used to treat severe mental disorder (psychosis)
The risk of respiratory and/or cardiac arrest may be higher.

Alprazolam with alcohol

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

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

There are no adequate experiences from the use of Alprazolam in pregnant women. Do not take Alprazolam 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 until birth, let your doctor know as your newborn might have some withdrawal symptoms when it is born.

Breast-feeding

There is a risk of an effect on the baby. Therefore you should not breast-feed during Alprazolam treatment.

Driving and using machines

Alprazolam 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.

Alprazolam contains lactose and sodium benzoate.

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

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'. This medicine contains 0.12 mg sodium benzoate in each tablet. Sodium benzoate may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).

3. How to take Alprazolam

Always take Alprazolam exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Adults

- Starting dose: 0.25 - 0.5 mg three times daily.
- If the effect is insufficient the dose may be increased by your doctor to a maximum of 3 mg per day (= 24 hours), divided into several doses.

Elderly, debilitated patients and patients with disturbed kidney function or mild liver dysfunction

- Starting dose: 0.25 mg two to three times per day (= 24 hours).
- If the effect is insufficient the dose may be increased by your doctor to a maximum of 0.75 mg per day (= 24 hours), divided into several doses.

There is a reduced clearance of the medicine and an increased sensitivity to the medicine in elderly patients.

Alprazolam must not be taken by patients with severely reduced liver function. See chapter 2 "What you need to know before you take Alprazolam."

Use in children and adolescents

Alprazolam is not recommended for children and adolescents under the age of 18 years.

If you feel that Alprazolam is too strong or not strong enough, ask your doctor or pharmacist for advice.

Method of administration

Alprazolam is intended for oral use. The tablets should be taken at the same time every day with a glass of water. The tablet can be taken independently of mealtimes and can be divided into equal doses.

Duration of treatment

Treatment with Alprazolam should be as short as possible. This means that you will not normally be given Alprazolam for more than 8 to 12 weeks, including the tapering-off period. In some cases your doctor may decide to extend the duration of treatment. Treatment with Alprazolam should not be for more than 12 weeks without review of your condition by your doctor. This is because use of benzodiazepines may lead to the development of physical and psychic dependence upon these products. The risk of dependence increases with the dose and duration of treatment; but it is also greater in patients with a history of alcohol or drug abuse. Talk to your doctor if you are worried about this.

If you take more Alprazolam than you should

Please contact your doctor or pharmacist immediately if this occurs. Overdose symptoms can include:

- drowsiness
- confusion and
- lethargy.

In a severe overdose the symptoms can be coordination problems, for example:

- drunken gait
- reduced muscle tone
- lowered blood pressure
- suppressed breathing
- in rare cases coma
- fatal in very rare cases.

If you forget to take Alprazolam

If you have forgotten to take a dose, you can still take it unless it is almost time for your next dose. In this case follow the normal dosing schedule.

Do not take a double dose of Alprazolam to make up for the forgotten dose.

If you stop taking Alprazolam

If you suddenly stop taking Alprazolam, directly after stopping treatment or several days later withdrawal symptoms may occur, such as mood changes, insomnia and restlessness. This risk will increase if your dose is reduced too quickly or, if you suddenly stop the treatment.

Suddenly stopping this medicine is therefore not recommended. Your doctor will gradually reduce the dose. This should be done by reducing the dose every three days, by a maximum of 0.5 mg. It may be necessary in some cases to reduce the dose more slowly.

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.

Some of the following symptoms occur particularly at the beginning of treatment and usually disappear after continuation of treatment:

Very common, may affect up to 1 to 10 people:

- sedation
- drowsiness.

Common, may affect up to 1 to 10 people:

- double or blurred vision
- nausea (feeling sick)
- constipation
- feeling of weakness
- irritability
- confusion
- depression. A pre-existing unnoticed depression may become apparent during the use of Alprazolam.
- loss of appetite
- jerky, uncoordinated movements
- memory impairment
- slurred speech
- dizziness
- loss of alertness or concentration
- headaches
- light-headedness
- irritability.

Uncommon, may affect up to 1 to 100 people:

- in women, irregular periods or production of too much prolactin (the hormone that stimulates milk production)
- change in your weight
- increased pressure in the eyes, which can also affect your vision
- hallucinations (seeing or hearing things which are not there while you are awake)
- outbursts of rage, aggressive or hostile behaviour
- nervousness or feeling anxious
- restlessness
- insomnia (inability to sleep or disturbed sleep)

- changes in your sex drive (men and women)
- thinking abnormal
- loss of memory
- feeling stimulated
- muscle spasms or muscle weakness
- shakiness or trembling
- difficulty urinating or bladder control problems
- hepatitis
- gastrointestinal disturbances such as diarrhoea and vomiting
- skin reactions
- hypomania, mania.

Rare, may affect up to 1 to 1000 people:

- memory loss of events that happened a few hours after you took your tablets
This may be accompanied by inappropriate behaviour particularly in higher doses. See also the section “Warnings and precautions”.
- psychiatric and “paradoxical” reactions (symptoms are listed in section “Warnings and precautions”).
The inappropriate behaviour and other behavioural disturbances occur particularly in children and elderly people.

Not known, frequency cannot be estimated from the available data:

- feeling lifeless
- tiredness
- coordination problems, such as feeling drunk, swelling of the ankles, feet or fingers
- manifestation of autonomic nervous system (dysautonomia)
- stimulation of appetite and weight gain
- swallowing difficulties
- lowered blood pressure
- dry mouth, increase in salivation, blocked nose and accelerated heartbeat
- inability to retain urine and/or faeces
- dependence (See section “Take special care with Alprazolam”)
- anorexia
- concentration disturbances.

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, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Alprazolam

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 blister and carton after ‘EXP’. The expiry date refers to the last day of that month.

Do not store above 25°C.

Keep the blister in the outer carton in order to protect from light.

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 contains

The active substance is alprazolam.

Each tablet contains 0.25 mg of alprazolam.

Each tablet contains 0.5 mg of alprazolam.

Each tablets contains 1 mg of alprazolam.

The other ingredients are sodium docusate, sodium benzoate, pregelatinised potato starch, microcrystalline cellulose, lactose, magnesium stearate, colloidal anhydrous silica, erythrosine aluminium lake (E127) (only for 0.5 mg), indigo carmine aluminium lake (E132) (only for 1 mg).

What Alprazolam looks like and contents of the pack

0.25 mg tablets:

White, oblong tablet with a score line and debossed "APZM 0.25".

The tablet can be divided into equal halves.

0.5 mg tablets:

Pink, oblong tablet with a score line and debossed "APZM 0.5".

The tablet can be divided into equal halves.

1 mg tablets:

Light blue, oblong tablet with a score line and debossed "APZM 1".

The tablet can be divided into equal halves.

The tablets are packed in in aluminium/PVC blisters which are inserted in a carton.

Pack sizes:

10, 20, 30, 40, 50, 60 or 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturers

Marketing Authorisation Holder

Rowex Ltd., Bantry, Co. Cork, Ireland.

Manufacturers

Dragenopharm Apotheker Püschl GmbH, Göllstr. 1, D-84529 Tittmoning, Germany.

Salutas Pharma GmbH, Otto-von-Guericke-Allee 1, 39179 Barleben, Germany.

Lek Pharmaceuticals d.d., Verovškova 57, 1526 Ljubljana, Slovenia.

Lek Pharmaceuticals d.d., Trimlini 2D, 9220 Lendava, Slovenia.

This medicinal product is authorised in the Member States of the EEA under the following names:

Netherlands	ALPRAZOLAM HEXAL 0,25 MG, TABLETTEN ALPRAZOLAM HEXAL 0,5 MG, TABLETTEN ALPRAZOLAM HEXAL 1,0 MG, TABLETTEN
Ireland	Alprazolam 0.25 mg Tablets Alprazolam 0.5 mg Tablets Alprazolam 1 mg Tablets

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