

PACKAGE LEAFLET: Information for the patient

ALZOLAX

Tablets – 0.25 mg, 0.5 mg

(Alprazolam)

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects becomes worse or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Alzolax is and what it is used for
2. Before you take Alzolax
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1. WHAT ALZOLAX IS AND WHAT IT IS USED FOR

Alzolax contains alprazolam which belongs to a group of medicines called benzodiazepines.

It is indicated in:

- short-term treatment of anxiety disorders;
- treatment of panic attacks.

2. BEFORE YOU TAKE ALZOLAX

Do not take Alzolax:

- if you are hypersensitive (allergic) to alprazolam, benzodiazepines or to any of the excipients of the drug;
- in chronic psychosis;
- in obsessional or phobic states;
- if you have respiratory depression;
- if you suffer from acute pulmonary insufficiency;
- in hyperkinesis;
- in severe hepatic impairment;
- if you suffer from myasthenia gravis;
- as single treatment to treat depression (or anxiety associated with depression);
- if you suffer from sleep apnoea syndrome.

Take special care with Alzolax

Ask your doctor before taking Alzolax:

- if you suffer from impaired renal, hepatic or pulmonary function;
- if you have been prescribed medicines for severe anxiety before;
- if you have ever suffered any mental illness that required hospital treatment;
- if you have abused with alcohol or drugs in the past and find it difficult to stop;
- if you are an elderly patient or debilitated patient;
- if you suffer or have ever suffered from depression or if you have thought about taking your own life;
- if you suffer from muscle weakness;
- if you suffer from glaucoma.

Long-term treatment with Alzolax should be avoided.

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

Paradoxical effects like hostile behaviors accentuation and aggressivity may appear during the use of benzodiazepines. In these cases treatment should be discontinued.

Taking other medicines

Other concomitant drug treatment may affect or be affected by Alzolax.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Remember to tell your doctor about the treatment with Alzolax if you are prescribed another drug during treatment.

It is especially important that your doctor be aware if you are already being treated with:

- dextropropoxyphene or other strong analgesics;
- carbamazepine, phenobarbital, phenytoin (drugs used for epilepsy treatment);
- itraconazole, ketoconazole, azole antifungals (drugs used for fungal infections treatment);
- fluoxetine, nefazodone, fluvoxamine (drugs used to treat depression);
- oral contraceptives;
- diltiazem (drug used for angina pectoris and high blood pressure treatment);
- erythromycin, clarithromycin (macrolide antibiotics);
- ritonavir or other similar drugs used for HIV treatment;
- digoxin (cardiac glycoside);
- cimetidine (for treating stomach ulcers);
- antihistamines (drugs for allergies);
- antipsychotics (drugs used to treat mental illnesses, like schizophrenia);
- sodium oxybate;
- general anaesthetics.

Taking Alzolax with food or drinks

Avoid drinking alcohol while taking Alzolax.

Pregnancy

If you are pregnant, think that may be pregnant or you are planning to become pregnant, ask your doctor or pharmacist for advice before taking Alzolax.

Do not use benzodiazepines during pregnancy.

Breastfeeding

Alprazolam is excreted in breast milk so it should not be used during breastfeeding.

Driving and using machines

Driving and using machines is not recommended during alprazolam therapy since sedation, amnesia, impaired concentration and impaired muscle function may adversely affect these abilities.

Important information about some of the excipients of Alzolax

Alzolax tablets contain lactose. If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE ALZOLAX

Take this medication exactly as it was prescribed for you. Do not take the medication in higher doses, or for longer than recommended by your doctor. Do not stop taking this medication without first talking to your doctor. If you stop taking Alzolax suddenly, your condition may become worse.

The recommended doses are prescribed below:

Adults: the usual dose in *short-term treatment of anxiety disorders* is 0.25 mg – 0.5 mg three times daily, increased where necessary to a total daily dose of 3 mg.

The optimum dosage should be based upon the severity of the symptoms and individual patient response.

Elderly and debilitated patients: the recommended initial dose is 0.25 mg two or three times daily.

Patients with impaired hepatic or renal function: if treatment is necessary, start with lower initial doses or reduce the dose. Alprazolam should be avoided in severe hepatic impairment.

Paediatric population: safety and efficacy of alprazolam have not been established in children and adolescents below the age of 18 years, therefore use of alprazolam in this age group is not recommended.

In the treatment of panic attacks more than 4 mg daily may be used.

Treatment should always be tapered off gradually. During discontinuation of alprazolam treatment, the dosage should be reduced slowly.

If you take more Alzolax than you should

If you take more Alzolax than you should, or if the children have taken this medicine by accident, please contact your doctor, the hospital, or call the emergency to get an opinion of the risk and advice on the actions to be taken.

Symptoms of overdose may include: drowsiness, confusion, feeling cold, slurred speech, ataxia, drop in blood pressure, difficulty in breathing and rarely coma.

In case of overdose with oral benzodiazepines, vomiting should be induced (within the first hour).

If you forget to take Alzolax

If you forget 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 the forgotten dose.

If you stop taking Alzolax

Do not stop taking Alzolax suddenly, because your condition may become worse as the dose needs to be reduced gradually.

If you have any further questions on the use of this medicinal product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Alzolax can cause side effects, although not everybody gets them.

Possible side effects listed below according to frequencies are defined as:

- *Very common side effects ($\geq 1/10$)*

Depression, sedation, somnolence, ataxia, memory impairment, dysarthria, dizziness, headache, constipation, dry mouth, fatigue, irritability.

- *Common side effects ($\geq 1/100$ to $< 1/10$)*

Decreased appetite, confusional state, disorientation, decreased libido, anxiety, insomnia, nervousness, increased libido, balance disorder, abnormal coordination, attention disturbances, hypersomnia, lethargy, tremor, blurred vision, nausea, dermatitis, sexual dysfunction, weight decrease, weight increase.

- *Uncommon side effects (≥ 1/1000 to < 1/100)*

Mania, hallucinations, anger, agitation, amnesia, muscular weakness, incontinence, menstrual disorders.

- *Side effects with unknown frequency*

Hyperprolactinaemia, hypomania, aggression, hostility, abnormal thinking, psychomotor hyperactivity, autonomic nervous system imbalance, dystonia, hepatitis, abnormal hepatic function, jaundice, gastrointestinal disorders, angioedema, photosensitivity reaction, urinary retention, peripheral oedema, elevation of intraocular pressure.

Dependence and withdrawal symptoms

It is possible to become dependent on medicines like Alzolax while you are taking them which increases the likelihood of getting withdrawal symptoms when you stop treatment. These symptoms include: anxiety, mood changes, insomnia and irritability.

If any of the side effects gets serious, or if you notice side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE ALZOLAX

Keep out of the reach and sight of children!

Do not use Alzolax after the expiry date which is stated on the package!

Do not store above 25°C!

Store in the original package in order to protect from light and humidity!

6. FURTHER INFORMATION

What Alzolax tablets contain

The active substance is alprazolam.

1 tablet contains 0.25 mg or 0.5 mg alprazolam.

Excipients of 0.25 mg tablets:

Lactose, microcrystalline cellulose, sodium starch glycolate, sodium docusate, sodium benzoate, magnesium stearate.

Excipients of 0.5 mg tablets:

Lactose, microcrystalline cellulose, sodium starch glycolate, sodium docusate, sodium benzoate, magnesium stearate, iron oxide red.

Content of the pack

Box with 30 tablets.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. "Skënder Vila",

Tirana, Albania.

Tel.: +355 4 23 89 602

This leaflet was last revised in October 2023.