Pazolam
(Alprazolam)

AtralCipan

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QUALITATIVE AND QUANTITATIVE COMPOSITION OF ACTIVE SUBSTANCES

Pazolam, 0.25mg tablets
Per tablet: Alprazolam 0.25mg

Pazolam, 0.5mg tablets
Per tablet: Alprazolam 0.50mg

Pazolam, 1mg tablets
Per tablet: Alprazolam 1.00mg

PHARMACEUTICAL FORM AND PRESENTATION

Pazolam, tablets 0.25mg – each tablet contains 0.25mg of Alprazolam. Packs of 20 and 60 tablets.

Pazolam, tablets 0.5mg – each tablet contains 0.5mg of Alprazolam. Packs of 60 tablets.

Pazolam, tablets 1mg – each tablet contains 1mg of Alprazolam. Packs of 60 tablets.

Pharmaco-therapeutic group: Anxiolytics, sedatives and hypnotics.

MARKETING AUTHORIZATION HOLDER AND MANUFACTURER

LABORATÓRIOS ATRAL, S.A.
Rua da Estação, n.º 42 – Vala do Carregado
2600 – 726 Castanheira do Ribatejo - Portugal

DESCRIPTION

Pazolam is the Laboratórios Atral, S.A. brand name of a benzodiazepine generically known as Alprazolam, which is a triazolobenzodiazepine family member. Besides the anxiolytic, myorelaxant and anticonvulsant effect characteristic of benzodiazepines, **Pazolam** has also an antidepressive activity similar to tricyclic antidepressive, but with lower adverse effects.
Following oral administration, Alprazolam is well absorbed and the peak serum concentrations occur in two hours after administration. Alprazolam is 80% bound to plasma proteins. The mean elimination half-life of Alprazolam is 10 - 20 hours.
Alprazolam is highly metabolized in the liver. Metabolites are excreted primarily in the urine and their half-lives are the same, ranging from 12 to 15 hours.

THERAPEUTIC INDICATIONS

Pazolam is indicated in the treatment of anxiety disorders or anxiety associated with depression, in neurotic or reactive depression and in disorders associated with panic.

CONTRAINDICATIONS

Pazolam is contraindicated in patients with known sensitivity to benzodiazepines.

SPECIAL PRECAUTIONS FOR USE

Pazolam is not recommended in depressions with a psychotic component, with diagnostic of bipolar depression or in "endogenous" depression (hospitalised patients for severe depression).
Pazolam effects can be increased by alcohol intake, by barbiturics or by other substances with depressive action in the central nervous system.
Treatment with **Pazolam** should not be abruptly discontinued. A gradual dosage reduction is required under close supervision.
Pazolam should be carefully administered in patients with renal and hepatic impairment.
Alprazolam safety and efficacy have not been established in patients under 18 years old.
Pazolam contains lactose being unsuitable for people with lactase insufficiency, galactosemia or glucose/galactose malabsorption syndrome.

UNDESIRABLE EFFECTS

Although **Pazolam** is generally well tolerated, some adverse effects were observed, generally in the beginning of therapy. These effects may disappear during the treatment or with dosage reduction.
The more frequent undesirable effects are somnolence and giddiness. Blurred vision, motor discoordination, chronic headache, gastrointestinal effects and neurovegetative alterations occur occasionally. Some paradoxical reactions have been described, with agitation, concentration problems, confusion and hallucinations.

INTERACTIONS WITH OTHER MEDICINAL PRODUCTS

The benzodiazepines, including Alprazolam, produce additive central nervous system depressant effects when co-administered with other psychotropic medications, anticonvulsants, antihistaminics, ethanol and other drugs which themselves produce central nervous system depression.
Co-administration of Cimetidine with Alprazolam can delay the **Pazolam** clearance.

EFFECTS ON PREGNANT WOMEN, LACTATING INFANTS, CHILDREN, ELDERLY AND PATIENTS WITH SPECIAL PATHOLOGIES

Pazolam should be avoided during pregnancy and lactation.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

Pazolam has effects on the central nervous system and may provoke, at the beginning of therapy, dizziness and somnolence that affect the ability to drive and use machines.

LISTS OF EXCIPIENTS

Pazolam tablets contain lactose.

USUAL POSOLOGY AND METHOD OF ADMINISTRATION

Pazolam optimal dosage should be individualized according to the intensity of the symptoms and the needs of the patient. It is recommended that the dosage be limited to the smallest effective dose to avoid the development of ataxia or oversedation.
Generally, treatment should begin with a dose of 0.25 to 0.5mg given three times daily. The dose may be increased if necessary.
When the posology is increased, the highest dose should be administered at bedtime.

The elderly patients need, normally, minor doses, while patients that are using psychotropic drugs or with chronic alcoholism habits, need usually higher doses.

THE RECOMMENDED DOSAGE RELATED TO THE PATHOLOGY IS:

Anxiety: initial dose is 0.25 to 0.5mg, three times daily; the average dosage is 0.5mg to 4mg per day, in divided doses. In elderly or debilitated patients, the usual initial dose is 0.25mg, two or three times daily; the average dosage is 0.5 to 0.75mg, in divided doses, which can be increased, as long as well tolerated.
Depression: initial dose is 0.5mg three times daily; the average dosage is 1.5mg to 4.5mg daily in divided doses.
Panic: initial dose is 0.5 to 1mg daily, at bedtime; the average dosage should be adapted to the patients response; it shouldn't be increased more than 1mg every three or four days.

ACTION IN CASE OF OVERDOSE AND/OR INTOXICATION

In case of overdose it is recommended vomiting induction and gastric lavage. Flumazenil administration could be useful for **Pazolam** overdosage treatment.

If you notice any undesirable effects not mentioned in this leaflet, please inform your doctor or pharmacist.
Please verify the shelf life stated on the label.

SPECIAL PRECAUTIONS FOR STORAGE

Store below 25°C, in a dry place protected from light.

Keep out of the reach and sight of children

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