

Alprax®

Alprazolam

Description: Alprazolam (Alprax®) is a triazolo analog of the 1,4-benzodiazepine class of central nervous system-active compounds. It is an anxiolytic with hypnotic & anticonvulsive properties.

Mode of action: Alprazolam (Alprax®) produced its effects via interacting with the GABA- benzodiazepine receptor complex.

Pharmacokinetics: Alprazolam (Alprax®) is readily absorbed. Peak plasma concentrations occurring 1 to 2 hours following administration. The half-life range is 6 to 20 hours following single dose administration. With multiple doses, given 3 times daily, steady state is reached within 7 days. Alprazolam (Alprax®) and its metabolites are excreted primarily in the urine. Active metabolites appear to have half-life similar to alprazolam but are present at only low levels in the plasma. Alprazolam (Alprax®) is 80% protein bound.

Composition

Alprax® 0.25 mg Tablet: Each tablet contains Alprazolam BP 0.25 mg.

Alprax® 0.5 mg Tablet: Each tablet contains Alprazolam BP 0.5 mg.

Alprax® XR 1 mg Tablet: Each extended release tablet contains Alprazolam BP 1 mg.

Alprax® XR 2 mg Tablet: Each extended release tablet contains Alprazolam BP 2 mg.

Indications

- Management of anxiety disorder (Generalized Anxiety Disorder) or short-term relief of symptoms of excessive anxiety
- Panic disorder with or without agoraphobia
- Anxiety associated with depression

Dosage & administration: *Adult:* Treatment should be initiated with a dose of 0.25 to 0.5 mg 3 times daily (for elderly or debilitated 0.25 mg 2 to 3 times daily), increased if necessary to a total of 3 or 4 mg daily.

Alprax® XR 1 mg/2 mg tablet once daily. *Child:* Not recommended.

Contraindications

Hypersensitivity to alprazolam or other benzodiazepines. Alprazolam is also contraindicated in pregnancy, in infants and in patients with myasthenia gravis and acute narrow angle glaucoma.

Side effects: Drowsiness and light headedness the next day; confusion and ataxia (especially in the elderly); amnesia; dependence; paradoxical increase in aggression; muscle weakness. Occasionally: headache, vertigo, hypotension, salivation changes, gastro-intestinal disturbances, visual disturbances, dysarthria, tremor, changes in libido, incontinence, urinary retention. Blood disorders and jaundice reported; skin reactions.

Precautions: Respiratory disease, muscle weakness, history of drug or alcohol abuse, marked personality disorder, pregnancy, breast-feeding. Reduce dose in elderly and debilitated, and in hepatic impairment (avoid if severe), renal impairment. Avoid prolonged use (and abrupt withdrawal thereafter).

Use in pregnancy & lactation: Not recommended

Drug interactions: Alprazolam, produce additive CNS depressant effects when coadministered with other psychotropic medications, anticonvulsants, antihistaminics, ethanol and other drugs. Drugs that inhibit alprazolam metabolism are: Fluoxetine, Propoxyphene, oral contraceptives. Carbamazepine can increase alprazolam metabolism and therefore can decrease plasma levels of alprazolam.

Overdose: Vomiting may be induced if the patient is fully awake. Vital signs should be monitored and general supportive measures should be employed as indicated. Gastric lavage should be instituted as soon as possible. I.V. fluids may be administered and an adequate airway should be maintained.

Storage: Store in a cool dry place, protected from light.

Packaging

Alprax® 0.25 mg Tablet: Each carton contains 10X5 tablets in blister pack.

Alprax® 0.5 mg Tablet: Each carton contains 10X5 tablets in blister pack.

Alprax® XR 1 mg Tablet: Each carton contains 10X3 tablets in blister pack.

Alprax® XR 2 mg Tablet: Each carton contains 10X3 tablets in blister pack.

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