

# **Alprox** Tablets

## **0.25 mg, 0.5 mg, 1.0 mg**

### **Active ingredient**

Each tablet contains: 0.25, 0.5, or 1.0 mg of alprazolam.

### **Excipients**

Lactose, maize starch, gelatin, magnesium stearate.

### **Therapeutic indications**

Treatment of anxiety, anxiety associated with depression, depression, panic disorder.

### **Contraindications**

Hypersensitivity to alprazolam or to other benzodiazepines, acute narrow angle glaucoma and open angle glaucoma if not in adequate treatment, myasthenia gravis, severe respiratory insufficiency, sleep apnoea syndrome and severe hepatic insufficiency.

### **Precautions for use**

Use Alprox tablets according to your physician's prescription only. Do not use alcohol concurrently with Alprox.

The use of Alprox, as with other benzodiazepines, may lead to the development of dependence. Once physical dependence has developed, abrupt termination of treatment will be accompanied by withdrawal symptoms.

### **Interactions**

Concurrent use of alcohol or central nervous depressant drugs potentiate the effects of alprazolam.

Concomitant administration of therapeutic doses of cimetidine (a drug for gastrointestinal ulcer) extends the elimination of alprazolam.

There are also drugs which may have influence on the efficacy or elimination of Alprox or vice versa. Thus, it is important that you discuss with your physician if you are taking any other medicinal products with Alprox.

### **Special warnings**

A withdrawal syndrome has been reported with alprazolam. The withdrawal symptoms are very much like the anxiety symptoms and thus careful attention needs to be given to differentiate these symptoms.

Use of Alprox is not recommended during pregnancy or breast-feeding. If you suspect that you are pregnant, discuss the use of this product with your physician.

Alprox is not recommended for children.

This medical product may affect your ability to operate machinery or drive a vehicle. It may also lower your ability to accomplish tasks which require concentration.

### **Dosage and administration**

Alprox tablets are for oral use only.

Alprox tablets are not recommended for children.

In panic disorders, the dosage should be individualized, starting at 0.25 to 0.5 mg three times daily. The dose may be titrated upwards (no greater than 1 mg every 3-4 days). For most patients the sufficient dose is 4-6 mg per day for a duration of 4-12 weeks.

In depression and anxiety: 0.5 mg three times daily. The dosage is increased, if required, to a total of 4 mg daily.

### **Adults**

In anxiety disorders, the dosage should be individualized, starting at 0.25 to 0.5 mg three times daily. Initial doses may be given at bedtime to minimize daytime lethargy. Discontinuation of the medication should be done with great care. The dose must be decreased gradually and slowly.

### **Elderly**

The starting dose is 0.25 mg two times daily. The dose is titrated upwards according to the needs of the patient to the recommended maximum of 4 mg/day in divided doses.

### **Overdosage and intoxication**

In case of overdosage and intoxication, contact the nearest doctor or hospital immediately. As with other benzodiazepines, the toxicity of alprazolam is very low. Manifestations of alprazolam overdosage include somnolence, confusion, impaired coordination, diminished reflexes and coma.

There is no specific antidote for alprazolam. As in all cases of drug overdosage, the patient should be monitored, and general supportive measures should be employed, along with immediate gastric lavage.

### **Undesirable effects**

Alprazolam-induced side effects are usually mild or moderate. The side-effects appear usually in the beginning of the treatment and disappear when medication is continued. The most frequent side-effects of alprazolam are drowsiness, sedation, lightheadedness, dry mouth, numbed emotions, reduced alertness, confusion, fatigue, headache, dizziness, muscle weakness, ataxia and double vision.

Anterograde amnesia may occur using therapeutic dosages, the risks increasing at higher dosages. This may be associated with inappropriate behaviour.

Reactions like restlessness, agitation, irritability, aggressiveness, delusions, rages, nightmares, hallucinations, psychosis, inappropriate behaviour or other adverse behavioural effects are known to occur when using benzodiazepines or benzodiazepine-like drugs.

Both physical and psychic dependence to this product may develop.

### **Storage conditions**

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

Do not refrigerate.

### **Do not use after expiry date.**

### **Presentation**

Tablets 0.25, 0.5, and 1 mg: Blister packs of 30's.

Not all strengths may be marketed.

### **Keep medicament out of reach of children.**

Manufactured by

**ALGORITHM S.A.L.** Zouk Mosbeh, Lebanon.