

## Alprazolam Tablets I.P.

**For the use of a Registered Medical Practitioner or a Hospital or a Laboratory Only**

Abbreviated Prescribing information for Alprazolam Tablets I.P. [Alprazolam 0.25 mg Tablets I.P.]

[Please refer the complete prescribing information available at [www.torrentpharma.com](http://www.torrentpharma.com)]

### PHARMACOLOGICAL PROPERTIES

**MECHANISM OF ACTION:** Alprazolam is a 1,4 benzodiazepine. Alprazolam exerts its effect for the acute treatment of generalized anxiety disorder through binding to the benzodiazepine site of gamma-aminobutyric acid-A (GABA) receptors in the brain and enhances GABA-mediated synaptic inhibition.

**INDICATIONS:** Alprazolam Tablets are indicated for the management of anxiety disorder or the short-term relief of symptoms of anxiety. Anxiety associated with depression is responsive to Alprazolam.

**DOSAGE AND ADMINISTRATION:** Individualize the dosage for maximum beneficial effect. Dosage should be increased cautiously in patients who require doses greater than 4 mg/day. *Anxiety:* Initial-0.25 mg to 0.5 mg given three times daily. Maximum-4 mg per day given in divided doses. Use the lowest possible effective dose. Periodically reassess the need for continued treatment. Discontinuation of treatment or dose reduction should be gradual and under close physician supervision. *Dosing in elderly:* the starting dose is 0.25 mg, given two or three times daily. *Severe hepatic impairment:* the starting dose is 0.25 mg, given two or three times daily. Alprazolam tablets should be reduced to half of the recommended dosage when a patient is started on ritonavir and alprazolam tablets together, or when ritonavir administered to a patient treated with alprazolam tablets. The tablet should be swallowed whole with water.

**CONTRAINDICATION:** In patients with known sensitivity to this drug or other benzodiazepines and in patients with acute narrow angle glaucoma as alprazolam can exacerbate narrow angle closure. Contraindicated with potent CYP3A inhibitors (e.g., ketoconazole and itraconazole) can increase the serum concentration of alprazolam.

**WARNINGS & PRECAUTIONS:** Concomitant use of benzodiazepines, including alprazolam, and opioids may result in profound sedation, respiratory depression, coma, and death. Use of alprazolam, particularly in patients at elevated risk, necessitates counseling about the risks and proper use of alprazolam along with monitoring for signs and symptoms of abuse, misuse, and addiction. To reduce the risk of withdrawal reactions, use a gradual taper to discontinue alprazolam or reduce the dosage. Alprazolam is contraindicated in patients receiving strong inhibitors of CYP3A. Use of alprazolam late in pregnancy can result in sedation (respiratory depression, lethargy, hypotonia) and/or withdrawal symptoms (hyperreflexia, irritability, restlessness, tremors, inconsolable crying, and feeding difficulties) in the neonate. Closely monitor patients with impaired respiratory function. If signs and symptoms of respiratory depression, hypoventilation, or apnea occur, discontinue alprazolam.

**DRUG INTERACTIONS:** The concomitant use of benzodiazepines and opioids increases the risk of respiratory depression. The concomitant use of benzodiazepines and opioids increases the risk of respiratory depression. Concomitant use of alprazolam with strong CYP3A inhibitors results in increased concentrations of alprazolam and increased risk of adverse reactions. Concomitant use of alprazolam with CYP3A inhibitors may increase the concentrations of alprazolam, resulting in increased risk of adverse reactions of alprazolam. Concomitant use of CYP3A inducers can increase alprazolam metabolism and therefore can decrease plasma levels of alprazolam. Short term administration of ritonavir increased alprazolam exposure due to CYP3A4 inhibition. Following long term treatment of ritonavir (>10 to 14 days), CYP3A4 induction offsets this inhibition. Alprazolam exposure was not meaningfully affected in the presence of ritonavir. Increased digoxin concentrations have been reported when alprazolam was given, especially in geriatric patients (>65 years of age).

**ADVERSE REACTIONS:** Sedation/drowsiness, light-headedness, confusion, fatigue, headache, dizziness, muscle weakness, double or blurred vision, insomnia, irritability, changes in libido, dermatitis/allergy, muscular twitching, muscle tone disorders, sexual dysfunction, menstrual irregularities, incontinence, urinary retention, hepatitis, hepatic failure, liver enzyme elevations, hypomania, mania, gynecomastia, galactorrhea, photosensitivity reaction, angioedema, Stevens-Johnson Syndrome, hyperprolactinaemia, akathisia, dry mouth, increased salivation, hypotension, impaired coordination, memory impairment, cognitive disorder, dysarthria,

disinhibition, talkativeness, derealization, constipation, rash, increased appetite, decreased appetite, weight gain, weight loss, micturition difficulties, nausea/vomiting, diarrhea, decreased salivation, sweating, tachycardia, edema peripheral, abdominal pain, amnesia, anorexia, anxiety, aggression, ataxia, depression, disinhibition, disorientation, euphoria, indigestion, irritability, muscle pain, slurred speech, tremors, vertigo, delirium, paranoia, suicidal ideation and behavior, seizures, coma, breathing difficulty, death, catatonia and convulsions.

**MARKETED BY:**



Torrent Pharmaceuticals Limited.

**IN/ALPRAZOLAM 0.25 mg/SEP 2025/01/ABPI**

(Additional information is available on request)