ALPRAX 0.25, ALPRAX 0.5, ALPRAX 1

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

Abbreviated Prescribing information for ALPRAX 0.25, ALPRAX 0.5, ALPRAX 1 [Alprazolam Tablets I.P]
[Please refer the complete prescribing information available at www.torrentpharma.com]

WARNING: RISKS FROM CONCOMITANT USE WITH OPIOIDS; ABUSE, MISUSE, AND ADDICTION; and DEPENDENCE AND WITHDRAWAL REACTIONS

- **Concomitant use of benzodiazepines and opioids may result in profound sedation, respiratory depression, coma, and death. Reserve concomitant prescribing for use in patients for whom alternative treatment options are inadequate. Limit dosages and durations to the minimum required. Follow patients for signs and symptoms of respiratory depression and sedation.**
- **The use of benzodiazepines, including alprazolam, exposes users to risks of abuse, misuse, and addiction, which can lead to overdose or death. Before prescribing alprazolam and throughout treatment, assess each patient's risk for abuse, misuse, and addiction.**
- **Abrupt discontinuation or rapid dosage reduction of alprazolam after continued use may precipitate acute withdrawal reactions, which can be life-threatening. To reduce the risk of withdrawal reactions, use a gradual taper to discontinue alprazolam or reduce the dosage.**

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 (GABAA) receptors in the brain and enhances GABA-mediated synaptic inhibition**.**

INDICATIONS: Alprazolam Tablets are indicated in the treatment of anxiety associated with depression.

DOSAGE AND ADMINISTRATION: The recommended starting oral dosage of alprazolam tablets for the acute treatment of patients with GAD is 0.25 mg to 0.5 mg administered three times daily. The maximum recommended dosage is 4 mg daily (in divided doses). To reduce the risk of withdrawal reactions, use a gradual taper to discontinue alprazolam tablets or reduce the dosage. If a patient develops withdrawal reactions, consider pausing the taper or increasing the dosage to the previous tapered dosage level. In geriatric patients, the recommended starting oral dosage of alprazolam tablets is 0.25 mg, given 2 or 3 times daily. This may be gradually increased if needed and tolerated. In patients with hepatic impairment, the recommended starting oral dosage of alprazolam tablets is 0.25 mg, given 2 or 3 times daily. This may be gradually increased if needed and tolerated.

CONTRAINDICATION: Alprazolam is contraindicated in patients with known hypersensitivity to alprazolam or other benzodiazepines. Also, in patients taking strong cytochrome P450 3A (CYP3A) inhibitors (e.g., ketoconazole, itraconazole), except ritonavir.

WARNINGS & PRECAUTIONS: The use of benzodiazepines, including alprazolam, exposes users to the risks of abuse, misuse, and addiction, which can lead to overdose or death. Before prescribing alprazolam and throughout treatment, assess each patient's risk for abuse, misuse, and addiction (e.g., using a standardized screening tool). Use of alprazolam, particularly in patients at elevated risk, necessitates counselling about the risks and proper use of alprazolam along with monitoring for signs and symptoms of abuse, misuse, and addiction. Benzodiazepines may worsen depression. Episodes of hypomania and mania have been reported in association with the use of alprazolam in patients with depression. 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. Monitor neonates exposed to alprazolam during pregnancy or labor. There have been reports of death in patients with severe pulmonary disease shortly after the initiation of treatment with alprazolam. Closely monitor patients with impaired respiratory

function.

DRUG INTERACTIONS: The concomitant use of benzodiazepines and opioids increases the risk of respiratory depression. The benzodiazepines, including alprazolam, produce additive CNS depressant effects when co-administered with other CNS depressants. Concomitant use of alprazolam with CYP3A inhibitors has a profound effect on the clearance of alprazolam, resulting in increased concentrations of alprazolam and increased risk of adverse reactions. Concomitant use of CYP3A inducers can increase alprazolam metabolism and therefore can decease plasma levels of alprazolam. Short term administration of ritonavir increased alprazolam exposure due to CYP3A4 inhibition. Increased digoxin concentrations have been reported when alprazolam was given, especially in geriatric patients.

ADVERSE REACTIONS: Drowsiness, light-headedness, dizziness, akathisia, dry mouth, increase salivation, hypotension, dermatitis/allergy, dystonia, irritability, concentration difficulties, anorexia, transient amnesia or memory impairment, loss of coordination, fatigue, seizures, sedation, slurred speech, musculoskeletal weakness, pruritus, diplopia, dysarthria, changes in libido, incontinence, urinary retention, tiredness, impaired coordination, cognitive disorder, decreased libido, confusional state, increased libido, disinhibition, talkativeness, derealization, constipation, rash, increased appetite, decreased appetite, weight gain, weight loss, micturition difficulties, menstrual disorders, sexual dysfunction, incontinence, hallucinations, depersonalization, taste alterations, diplopia, elevated bilirubin, elevated hepatic enzymes, jaundice, abnormal involuntary movement, headache, muscular twitching, muscle tone disorders, anxiety, depression, nausea/vomiting, diarrhea, decreased salivation, decreased appetite, sweating, tachycardia, blurred vision, agitation, rage, aggressive or hostile behavior, hyperprolactinemia, edema peripheral, hypomania, mania, gynecomastia, galactorrhea, photosensitivity reaction, angioedema, and Steven Johnson Syndrome.

MARKETED BY:

Torrent Pharmaceuticals Limited.

IN/ALPRAX 0.25 mg, 0.5 mg, 1 mg/DEC-2025/01/ABPI

(Additional information is available on request)