ALPRAX

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

Abbreviated Prescribing information for ALPRAX [Alprazolam 0.25mg, 0.5mg and 1mg uncoated tablets] [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: It is of 1, 4 benzodiazepine class presumably exert their effects by binding at stereo specific receptors at several sites within the central nervous system (CNS) though exact mechanism unknown. Clinically, all benzodiazepines cause a dose-related central nervous system depressant activity varying from mild impairment of task performance to hypnosis. **INDICATION:** Indicated for the management of anxiety disorder, short-term relief of symptoms of anxiety, anxiety associated with depression and panic disorder, with or without agoraphobia. **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. Panic disorder: Initial-0.5 mg given three times daily Maximum-Doses up to 10 mg per day may be required to achieve a successful response . 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. **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**: Dependence and withdrawal reactions, including seizures; Status epilepticus while discontinuation of alprazolam; Interdose symptoms; Risk of withdrawal reactions with dose reduction; Impaired performance due to CNS depression; Risk of fetal harm if used during pregnancy; suicidal risk; Mania/Hypomania; Weak Uricosuric effect; Limit the dosage to smallest effective dose to preclude the development of ataxia or oversedation- a particular problem in elderly or debilitated patients. **DRUG INTERACTIONS**: It is having interaction with CNS active drugs and depressants, imipramine, desipramine, drugs that inhibit alprazolam metabolism via cytochrome P4503A, fluoxetine, propoxyphene, oral contraceptives, diltiazem, isoniazid, macrolide antibiotics such as erythromycin and clarithromycin, grapefruit juice, ergotamine, cyclosporine, amiodarone, nicardipine, and nifedipine drugs demonstrated to be inducers of CYP3A. **ADVERSE REACTIONS**: Sedation/drowsiness, light-headedness, numbed emotions, reduced alertness, confusion, fatigue, headache, dizziness, muscle weakness, ataxia, double or blurred vision, insomnia, nervousness/anxiety, tremor, change in weight, gastrointestinal disturbances, changes in libido, skin reactions, dystonia, anorexia, slurred speech, jaundice, musculoskeletal weakness, sexual dysfunction/changes in libido, menstrual irregularities, incontinence, urinary retention, abnormal liver function, hyperprolactinaemia, increased intraocular pressure, withdrawal symptoms, amnesia, depression, paradoxical and psychiatric reactions and dependence.

MARKETED BY:

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(Additional information is available on request)