ALPRAX SR

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

Abbreviated Prescribing information for ALPRAX SR [Alprazolam 0.5 mg, 1mg and 1.5mg sustained release 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: Short term symptomatic treatment of anxiety including anxious patients with symptoms of depression.

DOSAGE AND ADMINISTRATION: Alprax SR Tablets may be administered once daily, preferably in the morning. The tablets should be taken intact; they should not be chewed, crushed, or broken. The suggested total daily dose ranges between 3 to 6 mg/day.

CONTRAINDICATION: Hypersensitivity to any of the components of product; Narrow angle glaucoma; Use with ketoconazole and itraconazole.

WARNINGS & PRECAUTIONS: Drug overdose, clinical worsening and suicidal risk; Status epilepticus while discontinuation of alprazolam; Dependence and withdrawal reactions, Risk of fetal harm if used during pregnancy; Interdose symptoms; Impaired performance due to CNS depression activity; Mania/Hypomania; Drugs metabolized via CYP3A; Weak Uricosuric effect; underline screening for bipolar disorder; Serotonin syndrome; Angle-Closure Glaucoma, Seizure; Abnormal bleeding; Drugs affecting QTc prolongation; Hyponatremia.

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, Dependency.

MARKETED BY:

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(Additional information is available on request)