

ALPRAX FORTE

For the Use of a Registered Medical Practitioner or a Hospital or a Laboratory Only.

Abbreviated Prescribing information for ALPRAX FORTE [Alprazolam 0.5 mg (Sustained release) and Sertraline Hydrochloride 50 mg Tablets] [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: Alprazolam: CNS agents of the 1, 4 benzodiazepine class, Sertraline: It is a selective serotonin reuptake inhibitor (SSRI). Act through inhibition of CNS neuronal uptake of serotonin (5HT).

INDICATION: For the treatment of panic disorders with or without agoraphobia

DOSAGE AND ADMINISTRATION: As directed by the physician

CONTRAINDICATION: Hypersensitivity to any of the components of product; Narrow angle glaucoma; Use with ketoconazole and itraconazole; Monoamine oxidase inhibitors use within 14 days of stoppage of treatment of sertraline; Pimozide.

Sertraline: Concomitant use of monoamine oxidase inhibitors (MAOIs) and pimozide with ALPRAX FORTE are contraindicated.

WARNINGS & PRECAUTIONS: While prescribing Aprax FORTE , care should be taken for dependence and withdrawal reactions, including seizures, status epilepticus and its treatment, CNS depression and impaired performance, mania, uricosuric effect, suicidal thoughts, serotonin syndrome, angle-closure glaucoma, other serotonergic drugs e.g. tryptophan and 5-HT agonists, Use in children and adolescents under 18 years of age, abnormal bleeding/haemorrhage, hyponatraemia.

DRUG INTERACTION: ALPRAX FORTE may interact with the use with other CNS depressants, drugs that inhibit alprazolam metabolism via cytochrome P450 3A, increase concentration of ALPRAX FORTE.

Fluvoxamine may increases levels of ALPRAX FORTE. Special precautions should be taken while concomitant administration of Sertraline with Lithium, phenytoin, triptans, Warfarin.

ADVERSE REACTIONS: Drowsiness, fatigue, change in weight, nausea, vomiting, halitosis, depression, paranoia, schizophrenia and mania, allergic dermatitis, peripheral neuritis, hepatic cell damage, optic neuritis, polyneuritis, peripheral neuropathy, dystonia, anorexia, slurred speech, jaundice, musculoskeletal weakness, sexual dysfunction/changes in libido, menstrual irregularities, incontinence, urinary retention and hyperprolactinaemia. Pharyngitis, upper respiratory tract infection, rhinitis, increased appetite, insomnia, depersonalization, nightmare, anxiety, agitation, nervousness, dizziness, somnolence and headache.

MARKETED BY:

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IN /ALPRAX FORTE 0.5mg and 50 mg /SEP-19/01/AbPI

(Additional information is available on request)