

ALPRAX PLUS

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

Abbreviated Prescribing information for Alprax Plus [Alprazolam 0.5 mg (Sustained release) and Sertraline Hydrochloride 25 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: For depression associated with anxiety and insomnia: once Daily after lunch.

CONTRAINDICATION: It is contraindicated in patients with known hypersensitivity to alprazolam or other benzodiazepines, sertraline or any of the inactive ingredients of tablet. Alprazolam: In patients with acute narrow angle glaucoma. It is also contraindicated with ketoconazole and itraconazole.

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

WARNINGS & PRECAUTIONS: While prescribing Alprax Plus, 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 plus may interact with the use with other CNS depressants, drugs that inhibit alprazolam metabolism via cytochrome P450 3A, increase concentration of Alprax plus.

Fluoxetine may increase levels of Alprax Plus. 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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(Additional information is available on request)