

TRIKA

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

Abbreviated Prescribing information for TRIKA [Alprazolam Tablets I.P.]

[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: The exact mechanism of action of alprazolam is unknown. Benzodiazepines bind to gamma aminobutyric acid (GABA) receptors in the brain and enhance GABA mediated synaptic inhibition; such actions may be responsible for the efficacy of alprazolam in anxiety disorder and panic disorder.

INDICATIONS: TRIKA is an Anxiolytic agent- Indicated in the treatment of anxiety associated with depression.

DOSAGE AND ADMINISTRATION: 250 micrograms (0.25 mg) to 500 micrograms (0.5 mg) three times daily, increasing if required to a total of 3 mg daily. *Elderly*- 250 micrograms (0.25 mg) two to three times daily to be gradually increased if needed and tolerated. Trika is for oral use. Treatment should be as short as possible. It is recommended that the patient be reassessed at the end of no longer than 4 weeks of treatment and the need for continued treatment established, especially in case the patient is symptom free. Treatment should always be tapered off gradually. During discontinuation of alprazolam treatment, the dosage should be reduced slowly.

CONTRAINDICATION: Hypersensitivity to benzodiazepines, alprazolam, or to any of the excipients. Benzodiazepines are also contraindicated in patients with myasthenia gravis, severe respiratory insufficiency, sleep apnoea syndrome and severe hepatic insufficiency.

WARNINGS & PRECAUTIONS: Caution is recommended when treating patients with impaired renal function or mild to moderate hepatic insufficiency. In patients presenting with major depression or anxiety associated with depression benzodiazepines and benzodiazepine-like agents should not be prescribed alone to treat depression as they may precipitate or increase the risk of suicide. Safety and efficacy of alprazolam have not been established in children and adolescents below the age of 18 years; therefore, use of alprazolam is not recommended. Benzodiazepines and related products should be used with caution in elderly, due to the risk of sedation and / or musculoskeletal weakness that can promote falls. Benzodiazepines should be used with extreme caution in patients with a history of alcohol or drug abuse). Once physical dependence has developed; abrupt termination of treatment will be accompanied by withdrawal symptoms. Benzodiazepines may induce anterograde amnesia. Some loss of efficacy to the hypnotic effects of benzodiazepines may develop after repeated use for a few weeks. Benzodiazepines are not recommended for the primary treatment of psychotic illness. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.

DRUG INTERACTIONS: The concomitant use of sedative medicines such as benzodiazepines or related drugs such as TRIKA with opioids increases the risk of sedation, respiratory depression, coma and death because of additive central nervous system (CNS) depressant effect. The co-administration of alprazolam with ketoconazole, itraconazole, or other azoletype antifungals is not recommended. Caution is recommended when alprazolam is co-administered with fluoxetine, propoxyphene, oral contraceptives, sertraline, diltiazem, or macrolide antibiotics such as erythromycin, clarithromycin and troleandomycin. Increased digoxin concentrations have been reported when alprazolam was given, especially in elderly (>65 years of age).

ADVERSE REACTIONS: Hyperprolactinaemia, decreased appetite, depression, confusional state,

disorientation, libido decreased, anxiety, insomnia, nervousness, libido increased, mania , hallucination, anger, agitation, hypomania, aggression, hostility, thinking abnormal, psychomotor hyperactivity, sedation, somnolence, ataxia, memory impairment, dysarthria, dizziness, headache, balance disorder, coordination abnormal, disturbance in attention, hypersomnia, lethargy, tremor, amnesia, autonomic nervous system imbalance, dystonia, vision blurred, constipation, dry mouth, nausea, hepatitis, hepatic function abnormal, jaundice, dermatitis, angioedema, photosensitivity reaction, muscular weakness, incontinence, urinary retention, sexual dysfunction, menstruation irregular, fatigue, irritability, oedema peripheral, weight increased, weight decreased, intraocular pressure increased, abdominal and muscle cramps, vomiting, sweating, tremor, anterograde amnesia, depression, restlessness, agitation, irritability, aggressiveness, delusion, rages, nightmares, hallucinations, psychoses, inappropriate behaviour, irritability, hostility and intrusive thoughts, dependence and convulsions.

MARKETED BY:



Torrent Pharmaceuticals Limited.

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(Additional information is available on request)