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Batch No : Embossed
EXP : Embossed
Price : Embossed

CLONAZEPAM

tablets

Category

Sedative-hypnotic, Anticonvulsant, Antipanic agent.

Indications

It is used in Epilepsy (myoclonic, tonic-clonic, complex partial or absence seizure pattern) and Panic disorders.

Pharmacology/Pharmacokinetics

In general, Clonazepam acts as depressants of the central nervous system (CNS), producing all levels of CNS depression from mild sedation to hypnosis to coma, depending on dose.

Clonazepam is well absorbed from the gastrointestinal tract, usually within 1 to 2 hours, undergoes hepatic nitro-reduction to inactive metabolites also undergoes oxidative hydroxylation and CYP3A metabolism.

Pregnancy/ Breast feeding

FDA pregnancy category D. Clonazepam and/or its metabolites are assumed to be distributed into breast milk.

Using of this medicine has not been recommended during breast feeding and pregnancy.

Drug interactions and/or related problems

Concurrent use with medicaments that inhibit CYP3A isoenzymes; reduction in benzodiazepine dosage should be considered.

Drug interaction with the following should be considered:

Addictive medications especially CNS depressants with habituating potential, Alcohol or CNS depression-producing medications, Carbamazepine, Cimetidine or Contraceptives estrogen-containing, Diltiazem, Disulfiram, Erythromycin, Fluoxetine, Fluvoxamine, Grapefruit juice, Itraconazole, Ketoconazole, Nefazodone, Propoxyphene, Ranitidine, Verapamil, Clozapine, Hypotension-producing medications, Isoniazid, Levodopa, Rifampin, Zidovudine.

Medical considerations/Contraindications

Risk-benefit should be considered when the following medical problems exist

Acute Alcohol intoxication, with depressed vital signs Coma or Shock, Drug abuse or dependence or history of, Epilepsy or Seizures, angle-closure glaucoma, Hepatic function impairment, Hyperkinesia, Hypoalbuminemia, Mental depression, Myasthenia gravis, Organic brain disorders, Porphyria, Psychoses, Severe chronic obstructive pulmonary diseases, Renal function impairment, Sensitivity to benzodiazepines, Sleep apnea, Swallowing abnormality in children.

Side/Adverse Effects

Those indicating need for medical attention

Incidence less frequent:

Anterograde amnesia, anxiety, confusion, mental depression, tachycardia/palpitation, "Traveler's amnesia", which occurs in people taking benzodiazepines to avoid jet lag, Daytime anxiety.

Incidence rare:

Abnormal thinking, including delusions, depersonalization, disorientation, allergic reaction, behavior changes, including bizarre behavior, decreased inhibition, blood dyscrasias, including agranulocytosis, anemia, leukopenia, neutropenia, thrombocytopenia, extrapyramidal effects, dystonic, hepatic dysfunction, hypotension, muscle weakness, paradoxical reactions including agitation,

aggressive behavior, hallucinations, insomnia, excitement, irritability, or nervousness, phlebitis or venous thrombosis, seizures.

Those indicating need for medical attention only if they continue or are bothersome

Incidence more frequent:

Ataxia dizziness or lightheadedness drowsiness, including residual daytime drowsiness when used as a hypnotic, slurred speech.

Incidence less frequent or rare:

Abdominal or stomach cramps or pain, blurred vision or other changes in vision, changes in libido, constipation, diarrhea, dryness of mouth or increased thirst, euphoria, headache, increased bronchial secretions or excessive salivation, muscle spasm, nausea or vomiting, problems with urination, tremor, unusual tiredness or weakness.

Overdose

On the management of overdose or unintentional ingestion, contact a Poison Control Center.

Dosing

Usual adult dose

Anticonvulsant: initially up to 0.5 mg three times a day; the dosage may be increased in increments of 0.5 to 1 mg every three days until seizures are controlled or until side effects prevent any further increase.

Antipanic agent: initially 0.25 mg two times a day, the dosage being increased to 1 mg per day after three days in most patients. The dosage may be increased in increments of 0.125 to 0.25 mg two times a day every three days until panic disorder is controlled or until side effects prevent further dosage increases.

Usual adult prescribing limits

Anticonvulsant: 20 mg per day.

Antipanic agent: 4 mg per day.

Usual pediatric dose

Anticonvulsant: Infants and children younger than 10 years of age or less than 30 kg of body weight: Oral, initially 10 to 30 mcg not to exceed 50 mcg per kg of body weight per day in two or three divided doses, the dosage being increased by no more than 0.25 to 0.5 mg, every third day until a maintenance dose of 0.1 to 0.2 mg per kg of body weight per day is reached or until seizures are controlled or side effects prevent a further increase.

Antipanic agent: Safety and efficacy have not been established in children up to 18 years of age.

How supplied

1 and 2 mg tablets; 10 blisters of 10's in a folding box with the leaflet.

Storage

Store below 30 °C, protect from direct sunlight and moisture.



Manufactured by Marham Daru Co.
Tehran-IRAN

