Abridged Prescribing Information:

Active Ingredient: ZAPIZ tablet contains clonazepam 0.25 mg / 0.50 mg / 1 mg / 2 mg

Indication: In the treatment of petitmal and its variant, akinetic and myoclonic seizures. Treatment of of panic disorder. **Dosage & Administration**: **(1) Seizure Disorders: Adults: Initial dose:** 1.5mg/day in 3 divided portions; increments of 0.5-1mg every 3 days until adequate seizure control or side effects appear**; maximum adult dose:** 20mg/day; maintenance dosage: individualized for each patient depending upon response. **Pediatric Patients:** Initial dosage (up to 10yrs/30Kg): 0.01-0.03 mg/kg/day but not to exceed 0.05 mg/kg/day given in 2 or 3 divided doses; dosage should be increased by no more than 0.25 to 0.5 mg every 3rd day until a daily maintenance dose of 0.1 to 0.2 mg/kg or seizures are controlled or side effects preclude further increase. Whenever possible, the daily dose should be divided into 3 equal doses. **Panic Disorder: Adults:** The initial dose is 0.25 mg bid. An increase to the target dose for most patients of 1 mg/day may be made after 3 days. Some individual patients may benefit from doses of up to a maximum of 4 mg/day, and in them the dose may be increased in increments of 0.125 to 0.25 mg bid every 3 days until panic disorder is controlled or until side effects make further increases undesired. To reduce the inconvenience of somnolence, administration of one dose at bedtime may be desirable. Treatment should be discontinued gradually, with a decrease of 0.125 mg bid every 3 days, until the drug is completely withdrawn. **Contraindication:** Clonazepam should not be used in patients with a history of sensitivity to benzodiazepines, nor in patients with clinical or biochemical evidence of significant liver disease. It may be used in patients with open angle glaucoma who are receiving appropriate therapy, but is contraindicated in acute narrow angle glaucoma. **Warnings & Precautions:** May impair cognitive and motor performance – patients to be cautioned against driving, operating machinery, or other activities requiring full mental alertness and intact reflexes. Worsening of seizure may occur when used in patients in whom several types coexist – esp. generalized tonic-clonic seizures may be precipitated. Gradual withdrawal after long-term use is essential to avoid status epilepticus. May cause excess salivation. **Pregnancy:** Benzodiazepines, including clonazepam, are known to have teratogenic potential. Use of clonazepam during the 1st trimester must be avoided. Use of clonazepam during known pregnancy should be considered only when the clinical situation warrants the risk to the fetus. Patients must notify their physician if they become pregnant or intend to become pregnant during therapy with clonazepam. **Specific Population: Renal impairment:** clonazepam metabolites may accumulate, dosage modification may be needed. **Hepatic impairment:** dosage modification may be needed. **Adverse Reactions:** Prominent side effects are: (1) in Seizure disorder patients: drowsiness (50% patients), ataxia (30% patients) – these may diminish with time; behavioral problems; and (2) in panic disorder patients: somnolence, depression, dizziness, nervousness, ataxia, and reduced intellectual ability. **Overdose:** Symptoms of clonazepam overdosage include somnolence, confusion, coma and diminished reflexes. Overdose Management: Treatment includes monitoring of respiration, pulse and blood pressure, general supportive measures and immediate gastric lavage. Intravenous fluids should be administered and an adequate airway maintained. Hypotension may be combated by the use of levarterenol or metaraminol. Dialysis is of no known value. Flumazenil, is indicated for the complete or partial reversal of the sedative effects of benzodiazepines.

(For details, please refer full prescribing information)

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