Abridged Prescribing Information:

Active Ingredient: TOPAZ 25 / 50 / 100 /200 tablets contain topiramate 25 mg / 50 mg / 100 /200 mg.

Indication: (i) Epilepsy: (a) As initial monotherapy in patients 10 years of age and older with partial onset or primary generalized tonic-clonic seizures. (b) As adjunctive therapy for adults and pediatric patients ages 2-16 years with partial onset seizures, or primary generalized tonic-clonic seizures, and in patients 2 years of age and older with seizures associated with Lennox-Gastaut syndrome. (ii) For prophylaxis of migraine headache in adults & adolescents. **Dosage & Administration:** (i) Epilepsy (a) Monotherapy Use: The recommended dose in adults and children 10 years of age and older is 400 mg/day in two divided doses. (b) Adjunctive Therapy Use: The recommended total daily dose in adults with partial seizures is 200-400 mg/day in two divided doses, and 400 mg/day in two divided doses. For pediatrics (age 2-16 years): 5 to 9 mg/kg/day in two divided doses. (ii) Migraine: The recommended total daily dose is 100 mg/day administered in two divided doses. **Contraindications:** Known hypersensitivity to product components. **Warnings & Precautions:** Metabolic Acidosis, Acute Myopia and Secondary Angle Closure Glaucoma, Oligohidrosis and Hyperthermia. Topiramate should be withdrawn gradually to minimize the potential of increased seizure frequency. Concomitant administration of topiramate and valproic acid has been associated with hyperammonemia with or without encephalopathy. Increased risk for renal stone formation. **Pregnancy & Lactation:** Pregnancy Category C. Potential benefit to the mother should be weighed against the potential risk to the infant when considering recommendations regarding nursing. **Interaction:** Addition of topiramate to phenytoin may result in an increased plasma concentration of phenytoin. Phenytoin and carbamazepine decrease the plasma concentration of topiramate. TOPAZ should be used with extreme caution if used in combination with alcohol and other CNS depressants. Efficacy of oral contraceptives may be compromised by topiramate. Patients taking oral contraceptives should be asked to report any change in their bleeding patterns. Topiramate C_{max} increased by 27% and AUC increased by 29% when Hydrochlorothiazide added to topiramate. Oral plasma clearance of topiramate appears to be reduced when administered with metformin. Concomitant use of topiramate, a weak carbonic anhydrase inhibitor, with other carbonic anhydrase inhibitors (e.g., acetazolamide) may increases the risk of renal stone formation, and should therefore be avoided. **Adverse Reactions:** Adults: paresthesia, weight decrease, somnolence, anorexia, dizziness, and difficulty with memory. Pediatrics: weight decrease, upper respiratory tract infection, paresthesia, anorexia, diarrhea, and mood problems. **Overdose:** Signs and symptoms included convulsions, drowsiness, speech disturbance, blurred vision, diplopia, mentation impaired, lethargy, abnormal coordination, stupor, hypotension, abdominal pain, agitation, dizziness and depression. Treatment should be appropriately supportive. Hemodialysis is an effective means of removing topiramate from the body. *(For details, please refer full prescribing information)*

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