Topirva® XR

Topiramate

Presentation
Topirva® XR 25: Each extended release capsule contains Topiramate USP 25 mg.
Topirva® XR 50: Each extended release capsule contains Topiramate USP 50 mg.
Topirva® XR 100: Each extended release capsule contains Topiramate USP 100 mg.

Description
The precise mechanisms by which Topiramate exerts its anticonvulsant and migraine prophylaxis effects are unknown. Electrophysiological and biochemical evidence suggests that Topiramate, at pharmacologically relevant concentrations, blocks voltage-dependent sodium channels, augments the activity of the neurotransmitter Gamma Amino Butyrate at some subtypes of the GABA-A receptor, antagonizes the AMPA / kainate subtype of the glutamate receptor, and inhibits the carbonic anhydrase enzyme, particularly isoenzymes II and IV.

Indications and Uses
Monotherapy Epilepsy: Topiramate XR is indicated as initial monotherapy for the treatment of partial-onset or primary generalized tonic-clonic seizures in patients 6 years of age and older.
Adjunctive Therapy Epilepsy: Topiramate XR is indicated as adjunctive therapy for the treatment of partial onset seizures, primary generalized tonic-clonic seizures and seizures associated with Lennox-Gastaut syndrome in patients 6 years of age and older.
Migraine: Topiramate XR is indicated for the preventive treatment of migraine in patients 12 years of age and older.

Dosage and Administration
Monotherapy Epilepsy
Pediatrics (6-9 Years): The initial dose is 25 mg/day nightly for the first week. Based upon tolerability, the dosage can be increased to 50 mg/day in the second week. Dosage can be increased by 25 mg to 50 mg/day each subsequent week as tolerated. Maintenance Dosing: Up to 11 kg: 150-250 mg/day; 12-22 kg: 200-300 mg/day; 23-31 kg: 200-350 mg/day; 32-38 kg: 250-350 mg/day; Greater than 38 kg: 250-400 kg/day
Adults & Pediatrics (≥ 10 Years): Week 1: 50 mg once daily; Week 2: 100 mg once daily; Week 3: 150 mg once daily; Week 4: 200 mg once daily; Week 5: 300 mg once daily; Week 6: 400 mg once daily

Adjunctive Therapy Epilepsy
Pediatrics (6-16 Years): Begin titration at 25 mg once daily (1-3 mg/kg/day) given nightly for the first week. Subsequently, increase the dosage at 1- or 2-week intervals by increments of 1-3 mg/kg/day to achieve optimal clinical response. The recommended total daily dose is approximately 5-9 mg/kg once daily.
Adults (≥ 17 Years): Initiate therapy at 25-50 mg once daily followed by titration to an effective dose in increments of 25-50 mg every week. The recommended total daily dose is 200-400 mg orally once daily. The total daily dose should not exceed 400 mg/day.

Preventive Treatment of Migraine (≥ 12 Years)
Week 1: 25 mg once daily; Week 2: 50 mg once daily; Week 3: 75 mg once daily; Week 4: 100 mg once daily

Side-effects
The most common side-effects of Topiramate XR are paresthesia, anorexia, weight loss, fatigue, dizziness, somnolence, nervousness, psychomotor slowing, abnormal vision, fever, nausea, abdominal pain, diarrhea etc.

Precautions
Monitor patients for acute myopia and secondary angle closure glaucoma, Visual field defects, Oligohydrosis and hyperthermia, Metabolic acidosis, Hyperammonemia/Encephalopathy, Kidney stones etc.

Contraindications
With recent alcohol use (i.e., within 6 hours prior to and 6 hours after Topiramate XR use)

Drug Interactions
Topiramate XR should be used with caution in combination with antiepileptic drugs (i.e. Phenobarbital, Phenytoin, Carbamazepine, Primidone, Valproate, Lamotrigine), Other carbonic anhydrase inhibitors, CNS depressants, Oral contraceptives, Hydrochlorothiazide (HCTZ), Pioglitazone, Lithium, Amitriptyline etc.

Pregnancy and Lactation
Pregnancy: Topiramate XR can cause fetal harm when administered to a pregnant woman and it should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.
Lactation: Topiramate XR is excreted in human milk. The known benefits of breastfeeding should be weighed against the unknown risks of infant exposure to Topiramate.

Use in Special Population
Pediatric use: Safety and effectiveness of Topiramate XR has not been established in pediatrics below 6 in epilepsy and 12 in migraine.
Geriatric use: Start at the low end of the dosing range.
Renal impairment: A dosage adjustment is recommended in patients with moderate to severe renal impairment.

Overdose
In the event of overdose, Topiramate XR should be discontinued and general supportive treatment given until clinical toxicity has been diminished or resolved.

Storage
Do not store above 30 ^{0}C. Keep away from light and out of the reach of children.

Commercial Pack
Topirva® XR 25: Each box contains 7 blister strips of 8 capsules.
Topirva® XR 50: Each box contains 3 blister strips of 10 capsules.
Topirva® XR 100: Each box contains 3 blister strips of 10 capsules.

Manufactured by
Incepta Pharmaceuticals Ltd
Savar, Dhaka, Bangladesh