Trokendi XR® (topiramate) – Expanded Indication

- On August 18, 2016, the FDA approved Supernus Pharmaceuticals' Trokendi XR (topiramate) extended-release capsules in patients ≥ 6 years of age as initial monotherapy for partial onset or primary generalized tonic-clonic seizures. Safety and effectiveness in patients who were converted to monotherapy from a previous regimen of other anticonvulsant drugs have not been established in controlled trials.
    - Previously, Trokendi XR was indicated as initial monotherapy in patients ≥ 10 years of age with partial onset or primary generalized tonic-clonic seizures and adjunctive therapy in patients ≥ 6 years of age with partial onset or primary generalized tonic-clonic seizures.
- Trokendi XR is also approved as adjunctive therapy in patients ≥ 6 years of age with partial onset seizures, primary generalized tonic-clonic seizures, and seizures associated with Lennox-Gastaut syndrome.
- The expanded indication is based on a pharmacokinetic study which demonstrated similarity of exposure-response in pediatric patients and adults when topiramate was given as initial monotherapy.
- The recommended dose of Trokendi XR as initial monotherapy in patients 6 -- 10 years of age for partial onset or primary generalized tonic-clonic seizures is 25 mg once daily at night for the first week. Based on tolerability, the dose is titrated over 5 -- 7 weeks. Total daily doses are weight-based.
    - Trokendi XR should be swallowed whole and intact. It should not be sprinkled on food, chewed or crushed.
    - Refer to the prescribing information for dosing recommendations for all other labeled indications.