Trokendi XR® (topiramate) – New indication

- On April 5, 2017 Supernus announced the FDA approval of Trokendi XR (topiramate) extended-release capsules, for the prophylaxis of migraine headache in adults and adolescents 12 years of age and older.
    - The usefulness of Trokendi XR in the acute treatment of migraine headache has not been studied.
- Trokendi XR is also indicated for the following:
    - Treatment of patients ≥ 6 years of age as initial monotherapy for partial onset or primary generalized tonic-clonic seizures.
    - Adjunctive therapy in patients ≥ 6 years of age with partial onset or primary generalized tonic-clonic seizures, and seizures associated with Lennox-Gastaut syndrome.
- The approval of Trokendi XR for the prophylaxis of migraine headache was based on clinical studies involving 937 adults and 103 adolescents randomized to immediate-release topiramate or placebo. Patients treated with immediate-release topiramate had greater reductions in migraine frequency from baseline vs. placebo.
- The most common adverse reactions (≥ 5% more frequent than placebo) with Trokendi XR at recommended dosing in adult and adolescent controlled migraine clinical trials were paresthesia, anorexia, decreased weight, difficulty with memory, taste perversion, upper respiratory tract infections, abdominal pain, diarrhea, hypoesthesia, and nausea.
- The recommended total daily dose of Trokendi XR as treatment for migraine prophylaxis is 100 mg orally once daily. Trokendi XR is initiated at 25 mg once daily for the first week, then increased weekly by 25 mg increments to the desired clinical outcome.
- Refer to the Trokendi XR drug label for the recommended doses in other indications.