Supernus – Recall of Trokendi XR® (topiramate)

- On December 7, 2016, Supernus announced a consumer-level recall of one packaged lot of Trokendi XR (topiramate) 200 mg extended-release capsules because the lot has improperly placed tamper evident seals that do not meet specification for child-resistance, as required by the Poison Prevention Packaging Act, posing a risk of poisoning if swallowed by children.
    - There is no issue with the internal blister card or drug product. The product is safe for use when used as directed.
- The recalled lot was initially shipped on November 9, 2016 and manufactured by Catalent Pharma Solutions on behalf of Supernus.

Product Description	NDC #	Lot # (expiration date)
Trokendi XR (topiramate) extended-release 200 mg capsules, 30 count blister card	17772-104-15	476916 (6/11/2019)

- Trokendi XR is indicated in patients 6 years of age and older as initial monotherapy for partial onset or primary generalized tonic-clonic seizure, and as adjunctive therapy in patients 6 years of age and older with partial onset seizures, primary generalized tonic-clonic seizures, and seizures associated with Lennox-Gastaut syndrome.
- Healthcare providers, distributers and wholesalers should immediately check inventory, quarantine, and discontinue distribution of the recalled product.
- For any questions regarding this recall, contact Supernus at **1-866-398-0833**.

Action Plan

- Clinical Services will conduct mailings to member(s) that may be affected by the Trokendi XR recall, and to providers who prescribed for the drug recently.
- Information regarding Trokendi XR will be posted on the optumrx.com portals.