Keppra®/Keppra XR® (levetiracetam) – New warning

- On April 24, 2017, the FDA approved a new *Warning* to the Keppra/Keppra XR (levetiracetam) drug labels regarding anaphylaxis and angioedema.

- Keppra oral tablets, oral solution and injection are FDA-approved for adjunctive therapy in the treatment of: partial onset seizures in patients 1 month of age and older with epilepsy, myoclonic seizures in patients 12 years of age and older with juvenile myoclonic epilepsy, and primary generalized tonic-clonic seizures in patients 6 years of age and older with idiopathic generalized epilepsy.

    — Keppra injection is only approved as an alternative when oral administration is temporarily not feasible.

- Keppra XR is indicated for adjunctive therapy in the treatment of partial onset seizures in patients 12 years of age and older with epilepsy.

- Keppra/Keppra XR can cause anaphylaxis or angioedema after the first dose or at any time during treatment.

    — Signs and symptoms in cases reported in the postmarketing setting in patients treated with levetiracetam have included hypotension, hives, rash, respiratory distress, and swelling of the face, lip, mouth, eye, tongue, throat, and feet.
    — In some reported cases, reactions were life-threatening and required emergency treatment.

- If a patient develops signs or symptoms of anaphylaxis or angioedema, Keppra/Keppra XR should be discontinued and the patient should seek immediate medical attention.

- Keppra/Keppra XR should be discontinued permanently if a clear alternative etiology for the reaction cannot be established.