News

Perampanel approved for epilepsy

Eisai Company Ltd. on October 23 announced the approval of perampanel oral tablets as adjunct therapy for epilepsy.

According to the drug's FDA-approved labeling, perampanel is indicated for the treatment of partial seizures in patients with epilepsy who are at least 12 years of age.

Perampanel will be marketed as Fycompa and will be available after the Drug Enforcement Administration assigns the drug to a schedule, according to Eisai.

Perampanel's labeling describes the drug as a noncompetitive antagonist of the α-amino-3-hydroxy-5-methyl-4-isoxazolepropionic acid glutamate receptor on postsynaptic neurons. Eisai stated that perampanel is the first FDA-approved drug that targets these receptors, but the drug's mechanism of action against symptoms of epilepsy is not fully understood.

In pooled data from three placebo-controlled clinical trials examining maintenance therapy with different dosages of perampanel along with other antiepileptic drugs (AEDs), about 29–35% of patients treated with the drug had a 50% or greater reduction in seizure frequency. Approximately a quarter of patients reported a worsening of seizure frequency during maintenance therapy, according to the drug's labeling.

The labeling includes a boxed warning about serious neuropsychiatric adverse events that have been reported during treatment with perampanel; these include "aggression, hostility, irritability, anger, and homicidal ideation," according to the labeling.

Additional neuropsychiatric adverse events mentioned in the warnings and precautions section of the labeling include suicidal thoughts and behavior, dizziness, gait disturbance, somnolence, and fatigue.

Neuropsychiatric adverse events are also the main focus of a medication guide that is part of the labeling for perampanel.

The recommended starting dosage of perampanel for patients who are not concurrently treated with hepatic-enzyme-inducing AEDs is 2 mg taken once daily at bedtime.

Patients concurrently treated with enzyme-inducing AEDs should initiate perampanel therapy at 4 mg once daily and be closely monitored for a response to the drug. Cessation of enzyme-inducing AED therapy may necessitate adjustments to the dosage of perampanel.

The recommended maintenance dosage of perampanel is 8–12 mg taken once daily. Dose escalations should be performed slowly and cautiously as described in the labeling.

Special precautions and reduced dosages are recommended for patients with mild or moderate liver disease or moderate kidney disease. Perampanel is not recommended for patients with severe liver or kidney disease or patients undergoing hemodialysis.

Perampanel will be available as 2-, 4-, 6-, 8-, 10-, and 12-mg tablets packaged in bottles of 30 or 60 tablets each. The bottles should be stored at controlled room temperature.

—Kate Traynor

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New drugs and dosage forms

Ocriplasmin intravitreal injection (Jetrea, ThromboGenics): The proteolytic enzyme is indicated for the treatment of symptomatic vitreomacular adhesion.

Omacetaxine mepesuccinate for injection (Synribo, Teva Pharmaceutical): The protein synthesis inhibitor is indicated for the treatment of adults with chronic- or accelerated-phase chronic myelogenous leukemia who have an intolerance to or whose disease is resistant to two or more tyrosine kinase inhibitors.

Tobramycin inhalation solution (Bethkis, Cornerstone Therapeutics): The antibiotic solution, for use with a nebulizer, is indicated for the management of patients with cystic fibrosis and *Pseudomonas aeruginosa* infection.

Meningitis outbreak challenges hospital pharmacies

Pharmacists involved in the care of patients with fungal meningitis say both clinical and administrative issues are important in the response to the outbreak.

Before the infections were linked to tainted injectable medications made by the New England Compounding Center (NECC) of Framingham, Massachusetts, no one knew what was making the patients sick.

"Initially, just trying to figure out what was wrong with these patients—that was really the hard time [for us]," said Mark Sullivan, director of pharmacy