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AAP News

FDA Update, Pharmacology

FDA Update: Patients on perampanel should be monitored for behavior changes

by from the Food and Drug Administration Office of Pediatric Therapeutics, Division of Pediatric and Maternal Health and Division of Neurology Products

Health care professionals should evaluate the safety issues and risks associated with Fycompa (perampanel) before adding it to the treatment regimen of adolescents who have not responded adequately to other antiepileptic drugs typically used for partial onset (POS) or primary generalized tonic-clonic (PGTC) seizures.

Fycompa is a non-competitive alpha-amino-3-hydroxy-5-methylisoxazole-4-propionic acid (AMPA) glutamate receptor antagonist. It has been approved by the Food and Drug Administration for adjunctive treatment of POS and PGTC seizures in patients 12 years of age and older.

Fycompa labeling contains a boxed warning for serious psychiatric and behavioral reactions, including aggression, hostility, irritability, anger, delusions, and homicidal ideation and threats. These adverse reactions were seen in clinical trials in patients treated for POS or PGTC seizures. Patients require close monitoring for any change in behavior while taking Fycompa. Enzyme-inducing antiepileptic drugs, such as phenytoin, carbamazepine and oxcarbazepine, result in a marked reduction in Fycompa exposure.

Fycompa also is listed as a schedule III controlled substance, and abuse may lead to moderate or low physical dependence or high psychological dependence.

Fycompa's potential advantages are that it has a unique mechanism of action, it does not require routine monitoring of blood count or liver function tests, and the dosing schedule is once per day.

Resources

- Product labeling for Fycompa
- Perampanel Drug Enforcement Administration schedule III
- "AMPA Receptors as a Molecular Target in Epilepsy Therapy"