Generic Name:
Cenobamate
Trade Name:
Xcopri
Company:
SK Life Science
Notes:

FDA approved cenobamate tablets to treat partial-onset seizures in adults.

Cenobamate's safety and efficacy to treat partial-onset seizures were established in two randomized, double-blind, placebo-controlled studies that enrolled 655 adults. Participants had partial-onset seizures with or without secondary generalization for an average of approximately 24 years and median seizure frequency of 8.5 seizures per 28 days during an 8-week baseline period. Doses of 100 mg, 200 mg, and 400 mg daily of cenobamate reduced the percentage of seizures per 28 days compared with the placebo group.

The recommended maintenance dose of cenobamate, following a titration period, is 200 mg daily; however, some patients may need an additional titration to 400 mg daily, the maximum recommended dose, based on their clinical response and tolerability.

Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS), also known as multiorgan hypersensitivity, has been reported among patients taking cenobamate. In the clinical trials, some patients experienced DRESS, and one patient died, when cenobamate was titrated rapidly (weekly or faster titration). No cases of cenobamate were reported in an open-label safety study of 1,339 patients with epilepsy when cenobamate was started at 12.5 mg per day and adjusted every 2 weeks; however, this finding does not show that the risk of DRESS is prevented by a slower titration.

A higher percentage of patients who took cenobamate also had a shortening of the QT interval of greater than 20 ms compared with placebo. The drug should not be used in patients with hypersensitivity to cenobamate or any of the inactive ingredients or Familial Short QT syndrome. QT shortening can be associated with ventricular fibrillation.

Antiepileptic drugs (AEDs), including cenobamate, increase the risk of suicidal thoughts or behavior in patients taking these drugs for any indication. Patients taking an AED for any indication should be monitored for the emergence or worsening of depression, suicidal thoughts or behavior, and/or any unusual changes in mood or behavior. Cenobamate may cause neurological adverse reactions, including sleepiness and fatigue, dizziness, trouble with walking and coordination, trouble with thinking, and visual changes. Patients should also be advised not to drive or operate machinery until the effect of the drug is known.

Common adverse effects are sleepiness, dizziness, fatigue, double vision, and headaches.

Medication Monitor Categories:
New Drug Approvals