

fact sheet

GABITRIL® (tiagabine hydrochloride) Tablets

What is GABITRIL?

GABITRIL® (tiagabine hydrochloride) is indicated as adjunctive therapy in adults and children 12 years and older in the treatment of partial seizures.

How does GABITRIL work?

While the precise way by which GABITRIL works is unknown, GABITRIL is believed to affect the level of gamma aminobutyric acid or GABA in the brain by selectively blocking its reuptake (a selective GABA reuptake inhibitor or SGRI). GABA is the principle inhibitory neurotransmitter of the central nervous system. Dysfunction in the GABA system is thought to play a role in a variety of disorders, including epilepsy and other seizure disorders.

How was the effectiveness of GABITRIL demonstrated?

In three multicenter, double-blind, placebo-controlled, parallel-group clinical trials and two placebo-controlled crossover studies, GABITRIL significantly reduced the seizure frequency in patients with epilepsy who took GABITRIL as add-on therapy.

What is important to know about the safety of GABITRIL?

Postmarketing reports have shown that GABITRIL use has been associated with new onset seizures and status epilepticus in patients without epilepsy. Safety and effectiveness of GABITRIL have not been established for any indication other than as adjunctive therapy for partial seizures.

Antiepileptic drugs (AEDs), including GABITRIL, increase the risk of suicidal thoughts or behavior in patients taking these drugs for any indication. Patients treated with any 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.

GABITRIL should be withdrawn gradually to minimize the potential of increased seizure frequency, unless safety concerns require a more rapid withdrawal. In clinical trials, the most common adverse events for GABITRIL in combination with other anticonvulsants were dizziness/lightheadedness, asthenia/lack of energy, somnolence, nausea, nervousness/irritability, tremor, abdominal pain, and thinking abnormal/difficulty with concentration or attention.

Please see Full Prescribing Information for GABITRIL.

In what form is GABITRIL supplied?

GABITRIL is available in tablet form in four dosage strengths: 2 mg, 4 mg, 12 mg, and 16 mg.

Where is GABITRIL available?

Cephalon, Inc. (Nasdaq: CEPH), Frazer, PA, an international biopharmaceutical company, currently markets GABITRIL in the United States and Europe.