

Tiagabine Hcl Cas No. : 145821-59-6

Tiagabine is used with other medications to treat certain epileptic seizure disorders (e.g., partial seizures) which have not been controlled by other medications. Seizures occur because of problems with communication between nerves.

Active Pharmaceuticals Ingredients Manufacturers

Taj Pharmaceuticals Ltd.

Tiagabine Hcl

CAS No. : 145821-59-6



Identifiers

Molecular Formula C₂₀H₂₅NO₂S₂.HCl

Molecular Weight 412.01

CAS Registry Number 145821-59-6

Pharmacokinetic data

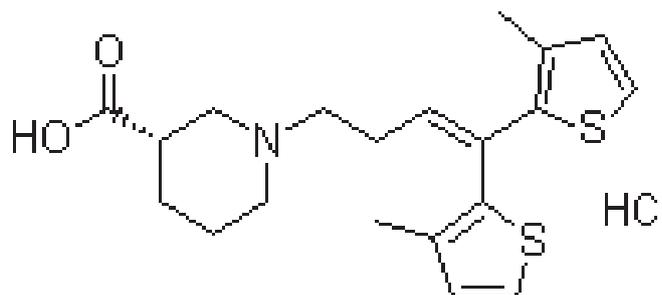
Bioavailability 90%

Protein binding 96%

Metabolism Hepatic (CYP450 system)

Half life 7-9 hours

Excretion Fecal and renal



DOSAGE

The dose of tiagabine hydrochloride that your healthcare provider recommends will vary, depending on a number of factors, including:

- * Other medications you may be taking
- * Other medical conditions you may have.

As is always the case, do not adjust your tiagabine dose unless your healthcare provider specifically instructs you to do so. Tiagabine is approved to be used along with other seizure medications to treat partial seizures in adults and adolescents age 12 and older. Your tiagabine dose will depend on which other seizure medications you are taking. Some medications cause the body to metabolize tiagabine more quickly (causing it to be removed from the body more quickly), while others do not. Most of the studies on tiagabine were in people taking seizure medications that increase the metabolism of tiagabine, so little is known about how exactly to dose tiagabine in people taking seizure medications that do not affect it.

For people taking any of the above medications, tiagabine is usually started (and increased) as follows:

- * Week 1 -- Tiagabine 4 mg once daily
- * Week 2 -- Tiagabine 4 mg twice daily
- * Week 3 -- Tiagabine 4 mg three times daily
- * Week 4 -- Tiagabine 4 mg four times daily (or tiagabine 8 mg twice daily)
- * Week 5 -- Tiagabine 20 to 24 mg total per day (taken as two to four smaller doses per day)
- * Week 6 -- Tiagabine 24 to 32 mg total per day (taken as two to four smaller doses per day).

SIDE EFFECTS

If you experience any of the following serious side effects, stop taking tiagabine and seek emergency medical attention or contact your doctor immediately:

- an allergic reaction (difficulty breathing; closing of the throat; swelling of the lips, tongue, or face; or hives);
- increasing frequency or worsening of seizures;
- irregular back-and-forth movements of the eyes (nystagmus);
- weakness; or
- rash.

Other, less serious side effects may be more likely to occur. Continue to take tiagabine and talk to your doctor if you experience



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Bruising or bleeding Temozolomide can reduce the production of platelets (which help the blood to clot). Let your dizziness, poor coordination, or drowsiness;

- nausea and vomiting;
- agitation or nervousness; or
- tremor.

Side effects other than those listed here may also occur. Talk to your doctor about any side effect that seems unusual or that is especially bothersome.

PRECAUTIONS

Warnings and precautions to be aware of prior to taking tiagabine include the following:

- * The medication is approved only to treat partial seizures in people with epilepsy. If you do not have seizures or epilepsy, taking tiagabine can actually increase your risk of having seizures. If you are taking tiagabine "off-label" for an unapproved use (such as for treating anxiety or bipolar disorder), tell your healthcare provider right away if you have a seizure.
- * As with all seizure medications, tiagabine should not be stopped suddenly
- * The medication can cause concentration problems, speech problems, drowsiness, and problems with coordination. Be sure to tell your healthcare provider if you develop any of these tiagabine side effects. Also, make sure that you know how tiagabine affects you before driving or operating any machinery.
- * It is possible that tiagabine may increase the risk of status epilepticus (a dangerous seizure that lasts a very long time, often more than 30 minutes). If you have a seizure that lasts longer than usual or is different in any way from your usual seizures, seek immediate medical attention.
- * About 1 percent of people taking tiagabine report experiencing extreme weakness. This usually goes away once the medication is stopped.
- * In dogs, tiagabine binds to tissues in the eye, suggesting that it may cause eye problems. It is not known if this is also true for humans. Tell your healthcare provider if you notice any eye or vision problems that are possibly due to tiagabine.
- * The liver helps remove tiagabine from your body. If you have liver disease, your healthcare provider may suggest a lower tiagabine dosage.
- * The recommended dose depends on which other seizure medications you are taking. Make sure your healthcare provider knows about all the medications you are taking, and be sure to tell your healthcare provider if you stop or start any medication, especially seizure medications.
- * In rare cases, tiagabine has been reported to cause dangerous skin rashes (which can lead to loss of large sections of skin). While most rashes due to the drug are not dangerous, be sure to tell your healthcare provider if you notice any unexplained rash while you are taking it.
- * Tiagabine can interact with other medications
- * Tiagabine is considered a pregnancy Category C medication. This means that it may not be safe for pregnant women. Talk to your healthcare provider about the risks and benefits of taking the drug while pregnant (see Gabitril and Pregnancy).



* It is not known if tiagabine passes through breast milk. Therefore, if you are breastfeeding or plan to start, discuss this with your healthcare provider prior to taking the drug

* Early evidence suggests that seizure medications, including tiagabine, may increase the risk of suicidal thoughts or behaviors

DRUG DESCRIPTION

The exact way that tiagabine works is unknown. However, it is believed that it alters chemical impulses in the brain that cause seizures.



Tiagabine is used to control seizures.

Tiagabine may also be used for purposes other than those listed in this medication guide.

Tiagabine hydrochloride (®) is a prescription medication used to treat a specific type of epileptic seizure. Seizures are divided into two major categories: partial seizures (sometimes called focal seizures) and generalized seizures. Partial seizures occur in just one part of the brain, while generalized seizures affect both sides of the brain. Tiagabine is approved to be used with other seizure medications to control partial seizures in people with epilepsy.

tiagabine HCl is an antiepilepsy drug available as 2 mg, 4 mg, 12 mg, and 16 mg tablets for oral administration. Its chemical name is (-)-(R)-1-[4,4-Bis(3-methyl-2-thienyl)-3-butenyl]nipecotic acid hydrochloride, its molecular formula is C₂₀H₂₅NO₂S₂ HCl, and its molecular weight is 412.0. Tiagabine HCl is a white to off-white, odorless, crystalline powder. It is insoluble in heptane, sparingly soluble in water, and soluble in aqueous base.

Note /Government Notification: These chemicals are designated as those that are used in the manufacture of the controlled substances and are important to the manufacture of the substances. For any (Control Substance) products Import and Export *** subjected to your country government laws /control substance ACT.

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The Controlled Substances Act (CSA) was enacted into law by the Congress of the United States as Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970.[1] The CSA is the federal U.S. drug policy under which the manufacture, importation, possession, use and distribution of certain substances is regulated. The Act also served as the national implementing legislation for the Single Convention on Narcotic Drugs

This document plus the full buyer/ prescribing information, prepared for health professionals can be found at:

<http://www.tajapi.com>

or by contacting the sponsor, Taj Pharmaceuticals Limited., at:
91 022 30601000.

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