



Medication Guide

Tiagabine Hydrochloride (tye-AG-a-been hye-droe-KLOR-ide) Tablets

Read this Medication Guide before you start taking tiagabine hydrochloride tablets and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or treatment.

What is the most important information I should know about tiagabine hydrochloride tablets?

Do not stop taking tiagabine hydrochloride tablets without first talking to your healthcare provider.

Stopping tiagabine hydrochloride tablets suddenly can cause serious problems.

Tiagabine hydrochloride tablets can cause serious side effects, including:

1. Tiagabine hydrochloride tablets may cause seizures in people who do not have epilepsy. If you do not have a seizure disorder and you take tiagabine hydrochloride tablets, you may have a seizure or seizures that do not stop (status epilepticus). **Call your healthcare provider right away if you have a seizure and you are not taking tiagabine hydrochloride tablets for epilepsy.**
2. **Like other antiepileptic drugs, tiagabine hydrochloride tablets may cause suicidal thoughts or actions in a very small number of people, about 1 in 500. Call a healthcare provider right away if you have any of these symptoms, especially if they are new, worse, or worry you:**
 - thoughts about suicide or dying
 - new or worse irritability
 - attempts to commit suicide
 - acting aggressive, being angry, or violent
 - new or worse depression
 - new or worse anxiety
 - acting on dangerous impulses
 - feeling agitated or restless
 - an extreme increase in activity and talking (mania)
 - panic attacks
 - trouble sleeping (insomnia)
 - other unusual changes in behavior or mood

Suicidal thoughts or actions can be caused by things other than medicines. If you have suicidal thoughts or actions, your healthcare provider may check for other causes.

How can I watch for early symptoms of suicidal thoughts and actions?

- Pay attention to any changes, especially sudden changes, in mood, behaviors, thoughts, or feelings.
- Keep all follow-up visits with your healthcare provider as scheduled.
- Call your healthcare provider between visits as needed, especially if you are worried about symptoms.

Do not stop tiagabine hydrochloride tablets without first talking to a healthcare provider.

- Stopping tiagabine hydrochloride tablets suddenly can cause serious problems. If you have epilepsy and stop a seizure medicine suddenly, you may have more frequent seizures or seizures that will not stop (status epilepticus).

What are tiagabine hydrochloride tablets?

Tiagabine hydrochloride tablets are a prescription medicine used with other medicines to treat partial seizures in adults and children age 12 and older.

Who should not take tiagabine hydrochloride tablets?

Do not take tiagabine hydrochloride tablets if you are allergic to tiagabine hydrochloride or any of the other ingredients in tiagabine hydrochloride tablets. See the end of this Medication Guide for a complete list of ingredients in tiagabine hydrochloride tablets.

What should I tell my healthcare provider before taking tiagabine hydrochloride tablets?

Before taking tiagabine hydrochloride tablets, tell your healthcare provider if you:

- have or have had depression, mood problems, or suicidal thoughts or behavior
- have liver problems
- have a history of seizures that do not stop (status epilepticus)
- have any other medical conditions
- are pregnant or plan to become pregnant. It is not known if tiagabine hydrochloride tablets can harm your unborn baby. Tell your healthcare provider right away if you become pregnant while taking tiagabine hydrochloride tablets. You and your healthcare provider will decide if you should take tiagabine hydrochloride tablets while you are pregnant.
 - If you become pregnant while taking tiagabine hydrochloride tablets, talk to your healthcare provider about registering with the North American Antiepileptic Drug (NAAED) Pregnancy Registry. The purpose of this registry is to collect information about the safety of antiepileptic medicines during pregnancy. You can enroll in this registry by calling 1-888-233-2334.
- are breastfeeding or plan to breastfeed. It is not known if tiagabine passes into breast milk or if it can harm your baby. Talk to your healthcare provider about the best way to feed your baby if you take tiagabine hydrochloride tablets.

Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Taking tiagabine hydrochloride tablets with certain other medicines can cause side effects or affect how well they work. Do not start or stop other medicines without talking to your healthcare provider.

Know the medicines you take. Keep a list of them and show it to your healthcare provider and pharmacist when you get a new medicine. Always tell your healthcare provider if there are any changes in any other medicines that you take.

How should I take tiagabine hydrochloride tablets?

- Take tiagabine hydrochloride tablets exactly as your healthcare provider tells you.
- Your healthcare provider may change your dose.
- Tiagabine hydrochloride tablets should be taken with food.
- Do not stop taking tiagabine hydrochloride tablets without talking to your healthcare provider. Stopping tiagabine hydrochloride tablets suddenly can increase your chances of having a seizure or cause seizures that will not stop.
- If you miss a dose of tiagabine hydrochloride tablets, do not take 2 doses of tiagabine hydrochloride tablets at the same time. Contact your healthcare provider if you miss more than one dose.

If you take too many tiagabine hydrochloride tablets, call your healthcare provider or local Poison Control Center right away.

What should I avoid while taking tiagabine hydrochloride tablets?

- Do not drink alcohol or take other medicines that make you sleepy or dizzy while taking tiagabine hydrochloride tablets without first talking to your healthcare provider. Taking tiagabine hydrochloride tablets with alcohol or drugs that cause sleepiness or dizziness may make your sleepiness or dizziness worse.
- Do not drive, operate heavy machinery, or do other dangerous activities until you know how tiagabine hydrochloride tablets affect you. Tiagabine hydrochloride tablets can slow your thinking and motor skills.

What are possible side effects of tiagabine hydrochloride tablets?

See “What is the most important information I should know about tiagabine hydrochloride tablets?”

Tiagabine hydrochloride tablets may cause other serious side effects including:

- seizures that can happen more often or become worse
- trouble concentrating, problems with speech and language, feeling confused, feeling sleepy and tired, and problems thinking
- weakness all over your body
- eye and vision problems
- serious rash

Call your healthcare provider right away if you have any of the serious side effects listed above.

The most common side effects of tiagabine hydrochloride tablets include:

- dizziness
- lack of energy
- drowsiness
- nausea
- nervousness
- tremor
- stomach pain
- abnormal thinking
- difficulty with concentration or attention

These are not all the possible side effects of tiagabine hydrochloride tablets. For more information, ask your healthcare provider or pharmacist. Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store tiagabine hydrochloride tablets?

- Store tiagabine hydrochloride tablets at 20° to 25°C (68° to 77°F); excursions permitted between 15° and 30°C (59° and 86°F).
- Keep tiagabine hydrochloride tablets out of light
- Keep tiagabine hydrochloride tablets dry

Keep tiagabine hydrochloride tablets and all medicines out of the reach of children.

General Information about Tiagabine Hydrochloride Tablets

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use tiagabine hydrochloride tablets for a condition for which it was not prescribed. Do not give tiagabine hydrochloride tablets to other people, even if they have the same symptoms that you have. It may harm them.

This Medication Guide summarizes the most important information about tiagabine hydrochloride tablets. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about tiagabine hydrochloride tablets that is written for health professionals.

For more information, call 1-800-818-4555.

What are the ingredients in tiagabine hydrochloride tablets?

Active Ingredient: tiagabine hydrochloride, USP

Inactive Ingredients: Hydrogenated vegetable oil, anhydrous lactose, butylated hydroxyanisole, pregelatinized maize starch, colloidal silicon dioxide, talc, crospovidone, titanium dioxide, hypromellose, polyethylene glycol.

In addition, individual tablets contain:

- 2 mg tablets: FD&C Yellow No. 6 and polysorbate 80.
- 4 mg tablets: Lactose monohydrate and D&C Yellow No. 10.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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