

Medication Guide

GABITRIL[®] (găb-ĭ-trĭl)

(tiagabine hydrochloride)

Tablets

Read this Medication Guide before you start taking GABITRIL 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 GABITRIL?

Do not stop taking GABITRIL without first talking to your healthcare provider.

Stopping GABITRIL suddenly can cause serious problems.

GABITRIL can cause serious side effects, including:

1. GABITRIL may cause seizures in people who do not have epilepsy. If you do not have a seizure disorder and you take GABITRIL, 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 GABITRIL for epilepsy.

2. Like other antiepileptic drugs, GABITRIL 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:

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| • thoughts about suicide or dying | • new or worse irritability |
| • attempts to commit suicide | • acting aggressive, being angry, or violent |
| • new or worse depression | • acting on dangerous impulses |
| • new or worse anxiety | • an extreme increase in activity and talking (mania) |
| • feeling agitated or restless | • other unusual changes in behavior or mood |
| • panic attacks | |
| • trouble sleeping (insomnia) | |

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 GABITRIL without first talking to a healthcare provider.

- Stopping GABITRIL 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 is GABITRIL?

GABITRIL is a prescription medicine used with other medicines to treat partial seizures in adults and children age 12 and older.

Who should not take GABITRIL?

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

What should I tell my healthcare provider before taking GABITRIL?**Before taking GABITRIL, 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 GABITRIL can harm your unborn baby. Tell your healthcare provider right away if you become pregnant while taking GABITRIL. You and your healthcare provider will decide if you should take GABITRIL while you are pregnant.
 - If you become pregnant while taking GABITRIL, 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 GABITRIL 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 GABITRIL.

Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Taking GABITRIL 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 GABITRIL?

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

If you take too much GABITRIL, call your healthcare provider or local Poison Control Center right away.

What should I avoid while taking GABITRIL?

- Do not drink alcohol or take other medicines that make you sleepy or dizzy while taking GABITRIL without first talking to your healthcare provider. Taking GABITRIL 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 GABITRIL affects you. GABITRIL can slow your thinking and motor skills.

What are possible side effects of GABITRIL?

See “What is the most important information I should know about GABITRIL?”

GABITRIL 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 GABITRIL 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 GABITRIL. 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 GABITRIL?

- Store GABITRIL between 68°F to 77°F (20°C to 25°C)
- Keep GABITRIL out of light
- Keep GABITRIL dry

Keep GABITRIL and all medicines out of the reach of children.

General Information about GABITRIL

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use GABITRIL for a condition for which it was not prescribed. Do not give GABITRIL 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 GABITRIL. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about GABITRIL that is written for health professionals.

For more information, go to www.GABITRIL.com or call 1-800-896-5855.

What are the ingredients in GABITRIL?

Active Ingredient: tiagabine hydrochloride

Inactive Ingredients: ascorbic acid, colloidal silicon dioxide, crospovidone, hydrogenated vegetable oil wax, hydroxypropyl cellulose, hypromellose, lactose, magnesium stearate, microcrystalline cellulose, pregelatinized starch, stearic acid and titanium dioxide.

In addition:

- the 2 mg tablets contain FD&C Yellow No. 6
- the 4 mg tablets contain D&C Yellow No. 10
- the 12 mg tablets contain D&C Yellow No. 10 and FD&C Blue No. 1
- the 16 mg tablets contain FD&C Blue No. 2

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

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