

Patient Name: _____ Date: _____
 Doctor Name: _____ Emergency Phone Number: _____
 Pharmacy: _____ Number: _____

What is Tiagabine?

Tiagabine, also known as Gabitril, is a medicine that has been approved by the Food and Drug Administration to treat partial seizures in adults. This medicine should not be used by people with absence seizures or with an EEG abnormality called “spike wave”.

- Gabitril is not available in generic form in the United States.
- Sometimes seizure medicines are used for other conditions. The dose of tiagabine may vary depending on why the medicine is being given and if it is given alone or with other medicines. It is important to follow the exact directions given to you by your doctor.
- Always check the appearance of the tablets with the pharmacist when the prescription is filled to be certain you are given the right medication.

Important questions to ask your doctor:

- Why am I being given this medicine? _____
- What amount should I be taking? _____

What does the drug look like and how should I take it?

Gabitril Tablets

Available in four strengths:

2 mg (orange-peach, round)
Marked with “C” logo on one side and “402” on the other



2mg

4 mg (yellow, round)
Marked with “C” logo on one side and “404” on the other



4mg

12 mg (green, ovaloid)
Marked with “C” logo on one side and “412” on the other



12mg

16 mg (blue, ovaloid)
Marked with “C” logo on one side and “416” on the other



16mg

To take tablets:

- Swallow tablets whole with a full glass of water.
- Take with food to lessen stomach upset.
- Usually taken two to four times a day.
- Do not take antacids or medicines for diarrhea within 2 to 3 hours of taking tiagabine.

Frequently asked questions:

Is it best to take this medicine with food? This medicine can be taken with food or on an empty stomach. Taking it with food or milk may lessen stomach upset. Try to take it the same way each day, since taking this with food may change the time it takes to be absorbed.

What should I do if I miss a dose? If you miss or forget a dose take it as soon as possible. However, if you have missed a dose and it is within a few hours before your next dose, take only the next scheduled dose. Do not double up or take extra medicine, unless instructed to do so by your doctor.

How can I remember to take my medication?

- Take medicine at the same time each day.
- Take at the same time as some other routine, such as brushing teeth, after meals, or bedtime.
- Use a pillbox so you can check if you have taken a dose.
- Use an alarm to remind you of times to take a dose.
- Keep a written schedule or chart of when to take the medicine.
- Talk to your doctor or health care provider about problems remembering the medicine.

How long will it take for the medicine to work? It may take a number of weeks to find the right dose, and then more time may be needed to know how well the medicine works to control your seizures. How long this takes will be different for each person. It may depend on how often you have seizures, what other medicine you may be taking, and how your body responds to the drug.

Should I write down how the medicine is affecting me? It is important to write down how you feel while you are on the medicine. Also keep track of changes in how much medicine is prescribed, side effects, and changes in seizures. Take the information to all follow-up visits with your health care providers.

How should I store my medicine? Store the medicine at room temperature (25° C or 77° F), away from heat, moisture, and direct light. Keep all medicine out of reach of children. Don't keep in the bathroom, glove box of a car, or where children can easily find them, such as in purses, on low cabinets or on counter tops.

Will this medicine affect other medicines that I am taking? Make sure to tell all your health care providers the names of all medicines, herbal or dietary supplements, vitamins and over-the-counter medicines. Some of these medicines may interfere with how tiagabine works and lower or raise the amount in your system.

Some medicines that may interact with tiagabine include: other antiepileptic medicines, antacids or medicines for diarrhea. Please see AED Interaction Sheets for lists of medicines that may interact with tiagabine.
(<http://professionals.epilepsy.com/pdfs/epilepsy-tiagabine-912.pdf>)

What side effects may occur? Side effects may occur with any medicine. Some side effects will go away on their own or when the dose of medicine is changed. Others may be more serious and mean that your body is not tolerating the drug. Tell your doctor about all side effects that occur, but do not stop taking the medicine without advice from your doctor. Some side effects include the following:

Common: Chills, diarrhea, dizzy, drowsy, fever, headache, muscle aches or pain, nervous, sore throat, tremor, unusually tired or weak, vomiting, trouble with concentration.

Less Common: Stomach pain, flushing, vision problems, increased appetite, increased cough, mouth sores, muscle weakness, nausea or upset stomach, pain, trouble sleeping.

Potentially serious:

- **Behavior:** Agitation, hostility, memory problems, quick to react or over-react emotionally, generalized weakness, uncontrolled back and forth or rolling eye movements, walking unusually.
- **Change in urination:** Bloody or cloudy urine, burning or painful urination, difficulty urinating, frequent urge to urinate.
- **Rash:** Blue or purple spots on skin. Not all rashes are caused by the medicine, but all rashes should be reported to your doctor and checked out. Rashes that may be more serious usually begin in the first few weeks, but can happen at any time. Serious rashes may have the following symptoms and require immediate evaluation:
 - Blisters or sores in mouth, eyes, ears, nose, and genital area.
 - Swelling of eyelids or red eyes.
 - Red spots or patches on skin.
 - Fever or flu-like symptoms that don't go away.

- **Allergic reaction:** May be seen with symptoms such as hives or large red spots on the body, itching, difficulty breathing or closing of the throat.

When should I contact my doctor?

- Call a doctor right away if side effects become severe or cause problems in your ability to function, or if you have any of the following problems: staggering walk, confusion, rash, or an allergic reaction.
- Do not stop the medicine without talking to a doctor first.

Can this seizure medicine affect bone health? Some seizure medicines may cause thinning of the bones. While tiagabine is not known to cause bone problems, all people taking seizure medicine should take calcium and vitamin D supplements each day. Regular exercise and diet are also very important. People who have thinning of the bones may also need to take prescription medicines to treat this. Talk to your doctor about tests to check the health of your bones and what to do next.

Can I drink alcohol while on this medicine? People taking this medicine should not drink alcohol because tiagabine can increase the effects of alcohol.

May I drive while taking tiagabine? Use caution when driving, operating machinery, or performing other hazardous activities. Tiagabine may cause drowsiness, dizziness and other symptoms that may affect your safety. If you have these problems or are having seizures, avoid these activities and talk to your doctor.

Just for Women:

Is this medicine safe to take during pregnancy? Tiagabine has an FDA pregnancy category of “C” meaning that the benefits of taking the medicine may outweigh the risks of harming the baby. If you find or suspect that you are pregnant, continue use of this medicine and contact your doctor right away. Talk to your doctor about the potential benefits and risks before making any decisions about use of this medicine. Seizures can be harmful to the mother and the developing baby but these can be lessened with proper care.

Does this medicine affect birth control pills? This medicine is not known to affect hormonal contraceptives or birth control. Talk to your doctor if you start or stop hormonal birth control as it may have an effect on the amount of tiagabine in your body. Call your doctor if you have any signs of breakthrough bleeding or symptoms of pregnancy.

Will the medicine affect my menstrual cycle? This medicine is not known to affect the menstrual cycle. If your cycle becomes irregular, call your doctor.

Can I breast feed while taking this medicine? In general, women taking tiagabine can breastfeed while using this medicine. It is not known if tiagabine passes into breast milk or if there are any effects on the infant. According to the American Academy of Neurology, the benefits of breastfeeding for the infant and mother are believed to outweigh the risk for adverse effects. Talk to your doctor regarding all options.

Are there any specific vitamins I should be taking? Women who can possibly become pregnant should be taking at least 0.4 milligrams (mg) of folic acid or folate each day. Women taking some seizure medicines may need to take a higher dose of folic acid, up to 4 mg each day. Talk to your health care provider for specific instructions. Folic acid is also found in leafy dark green vegetables, fruits and juices, and lentils.

More questions?

For more detailed information about tiagabine and seizures, please visit www.epilepsy.com and click on Treatment >> Seizure Medicine (www.epilepsy.com/epilepsy/seizure_medicines.html).

On July 10, 2008, an advisory panel was convened by the Food and Drug Administration (FDA) to review data that the FDA had previously collected from drug studies showing an association between many of the antiepileptic drugs (AEDs) and suicidal ideation and behavior, which together are called suicidality. According to the FDA's Alert, among the patients with epilepsy in these drug studies, 1 out of 1000 people taking the placebo (inactive substance) showed suicidality compared to approximately 3.5 out of 1000 people who took an AED. The FDA advisory panel voted to accept the FDA's data at its meeting on July 10.

The FDA has provided the following information for patients, family members, and caregivers at www.fda.gov/cder/drug/InfoSheets/HCP/antiepilepticsHCP.htm:

- Taking antiepileptic medicines may increase the risk of having suicidal thoughts or actions;
- Do not make any changes to the medication regimen without first talking with the responsible healthcare professional;
- Pay close attention to any day-to-day changes in mood, behavior and actions. These changes can happen very quickly so it is important to be mindful of any sudden differences.
- Be aware of common warning signs that might be a signal for risk of suicide. Some of these are:
 - Talking or thinking about wanting to hurt yourself or end your life
 - Withdrawing from friends and family
 - Becoming depressed or having your depression get worse
 - Becoming preoccupied with death and dying
 - Giving away prized possessions

We again urge patients and families to contact their doctor before stopping an epilepsy medication because this may possibly lead to seizures and worsening of mood.