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Tiagabine

pronounced as (ty ag' a been)

Why is this medication prescribed?

Tiagabine is used in combination with other medications to treat partial seizures (a type of epilepsy). Tiagabine is in a class of medications called anticonvulsants. It is not known exactly how tiagabine works, but it increases the amount of natural chemicals in the brain that prevent seizure activity.

How should this medicine be used?

Tiagabine comes as a tablet to take by mouth. It usually is taken with food two to four times a day. However, for the first week of treatment you will only take tiagabine once a day. Your doctor will slowly increase your dose (not more often than once each week) until you reach the dose of tiagabine you are to take regularly. To help you remember to take tiagabine, take it around the same time(s) every day. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take tiagabine exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.

Continue to take tiagabine even if you feel well. Do not stop taking tiagabine without talking to your doctor, even if you experience side effects such as unusual changes in behavior or mood. Abruptly stopping this medication can cause seizures. Your doctor will probably decrease your dose gradually.

Your doctor or pharmacist will give you the manufacturer's patient information sheet (Medication Guide) when you begin treatment with tiagabine and each time you refill your prescription. Read the information carefully and ask your doctor or pharmacist if you have any questions. You can also visit the Food and Drug Administration (FDA) website (http://www.fda.gov/Drugs [http://www.fda.gov/Drugs]) or the manufacturer's website to obtain the Medication Guide.

Other uses for this medicine

Tiagabine should not be prescribed for other uses. Ask your doctor or pharmacist for more information.

What special precautions should I follow?

Before taking tiagabine,

• tell your doctor and pharmacist if you are allergic to tiagabine or any other medications.

- tell your doctor and pharmacist what other prescription and nonprescription medications, vitamins, and nutritional supplements you are taking or plan to take. Be sure to mention any of the following: amiodarone (Cordarone, Pacerone);anticonvulsants such as carbamazepine (Tegretol), ethosuximide (Zarontin), gabapentin (Neurontin), lamotrigine (Lamictal), phenobarbital (Luminal, Solfoton), phenytoin (Dilantin, Phenytek), primidone (Mysoline), and valproic acid (Depakene, Depakote); anticholinesterases such as neostigmine (Prostigmin), physostigmine (Antilirium), and pyridostigmine (Mestinon, Regonol); antidepressants; antifungals such as fluconazole (Diflucan), itraconazole (Sporanox), and ketoconazole (Nizoral); chloroquine sulfate (Aralen); clarithromycin (Biaxin, in Prevpac); contrast dyes used during radiology procedures (CAT scans, X-rays); cyclosporine (Neoral, Sandimmune); dexamethasone (Decadron, Dexpak); diazepam (Valium); dicloxacillin; diltiazem (Cardizem, Dilacor, Tiazac, others); erythromycin (E.E.S., E-Mycin, Erythrocin); furosemide (Lasix); griseofulvin (Fulvicin-U/F, Grifulvin V, Gris-PEG); isoniazid (INH, Laniazid, Nydrazid); imipenemcilastatin (Primaxin); lovastatin (Altocor, Mevacor, in Advicor); medications to treat HIV infection including delavirdine (Rescriptor), efavirenz (Sustiva), nevirapine (Viramune), and ritonavir (Norvir, in Kaletra): medications that may make you drowsy such as cough, cold, and allergy products. medications for anxiety, muscle relaxants, pain medications, sedatives, sleeping pills, or tranquilizers; medications for mental illness; methocarbamol (Robaxin); mycophenolate mofetil (CellCept); penicillins; phenylbutazone (no longer available in the US);propranolol (Inderal, Inderide); quinidine (Quinidex); quinolones such as cinoxacin (Cinobac) (no longer available in the US), ciprofloxacin (Cipro), enoxacin (Penetrex) (no longer available in the US), gatifloxacin (Tequin), levofloxacin (Levaguin), lomefloxacin (Maxeguin), nalidixic acid (NegGram) (no longer available in the US), norfloxacin (Noroxin), ofloxacin (Floxin), sparfloxacin (Zagam) and trovafloxacin/alatrofloxacin combination (Trovan) (no longer available in the US); rifabutin (Mycobutin); rifampin (Rifadin, Rifamate, Rimactane, others); stimulants such as caffeine-containing products and decongestants; tacrolimus (Prograf); triazolam (Halcion); troleandomycin (TAO); verapamil (Calan, Covera, Isoptin, Verelan); warfarin (Coumadin); or zafirlukast (Accolate).
- tell your doctor what herbal products you are taking, especially St. John's wort.
- tell your doctor if you have or have ever had a severe rash caused by taking a medication; status epilepticus (seizures following one another without a break); or eye or liver disease.
- tell your doctor if you are pregnant, plan to become pregnant, or are breast-feeding. If you become pregnant while taking tiagabine, call your doctor immediately.
- if you are having surgery, including dental surgery, tell the doctor or dentist that you are taking tiagabine.
- you should know that tiagabine may make you drowsy and may affect your ability to think clearly. Do not drive a car or operate machinery until you know how this drug will affect you.
- remember that alcohol may add to the drowsiness caused by this medication. Ask your doctor about the safe use of alcoholic beverages while you are taking tiagabine.
- you should know that seizures, including status epilepticus, have occurred in people without epilepsy
 who take tiagabine. These seizures usually occurred soon after beginning treatment with tiagabine or
 near the time of a dose increase, but also have also occurred at other times during treatment.
- you should know that your mental health may change in unexpected ways and you may become suicidal (thinking about harming or killing yourself or planning or trying to do so) while you are taking tiagabine for the treatment of epilepsy, mental illness, or other conditions. A small number of adults and children 5 years of age and older (about 1 in 500 people) who took anticonvulsants such as tiagabine to treat various conditions during clinical studies became suicidal during their treatment. Some of these people developed suicidal thoughts and behavior as early as one week after they started taking the medication. There is a risk that you may experience changes in your mental health if you take an anticonvulsant medication such as tiagabine, but there may also be a risk that you will experience changes in your mental health if your condition is not treated. You and your doctor will

decide whether the risks of taking an anticonvulsant medication are greater than the risks of not taking the medication. You, your family, or your caregiver should call your doctor right away if you experience any of the following symptoms: panic attacks; agitation or restlessness; new or worsening irritability, anxiety, or depression; acting on dangerous impulses; difficulty falling or staying asleep; aggressive, angry, or violent behavior; mania (frenzied, abnormally excited mood); talking or thinking about wanting to hurt yourself or end your life; withdrawing from friends and family; preoccupation with death and dying; giving away prized possessions; or any other unusual changes in behavior or mood. Be sure that your family or caregiver knows which symptoms may be serious so they can call the doctor if you are unable to seek treatment on your own.

What special dietary instructions should I follow?

Talk to your doctor about drinking grapefruit juice while taking this medication.

What should I do if I forget a dose?

Take the missed dose as soon as you remember it. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one. If you have missed more than one dose, call your doctor for instructions about re-starting your medication.

What side effects can this medication cause?

Tiagabine may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:

- · dizziness or lightheadedness
- drowsiness
- · lack of energy or weakness
- wobbliness, unsteadiness, or incoordination causing difficulty walking
- depression
- hostility or anger
- irritability
- confusion
- difficulty concentrating or paying attention
- abnormal thinking
- · speech or language problems
- · increased appetite
- nausea
- stomach pain
- nervousness
- difficulty falling asleep or staying asleep

- itching
- bruising
- painful or frequent urination

Some side effects can be serious. The following symptoms are uncommon, but if you experience any of them, call your doctor immediately:

- rash
- sores on the inside of your mouth, nose, eyes or throat
- flu-like symptoms
- · changes in vision
- severe weakness
- shaking hands you cannot control
- · numbness, pain, burning, or tingling in the hands or feet
- seizures, including status epilepticus

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online (http://www.fda.gov/Safety/MedWatch [http://www.fda.gov/Safety/MedWatch]) or by phone (1-800-332-1088).

What should I know about storage and disposal of this medication?

Keep this medication in the container it came in, tightly closed, and out of reach of children. Store it at room temperature and away from excess heat and moisture (not in the bathroom).

It is important to keep all medication out of sight and reach of children as many containers (such as weekly pill minders and those for eye drops, creams, patches, and inhalers) are not child-resistant and young children can open them easily. To protect young children from poisoning, always lock safety caps and immediately place the medication in a safe location – one that is up and away and out of their sight and reach. http://www.upandaway.org [http://www.upandaway.org]

Unneeded medications should be disposed of in special ways to ensure that pets, children, and other people cannot consume them. However, you should not flush this medication down the toilet. Instead, the best way to dispose of your medication is through a medicine take-back program. Talk to your pharmacist or contact your local garbage/recycling department to learn about take-back programs in your community. See the FDA's Safe Disposal of Medicines website (http://goo.gl/c4Rm4p [http://goo.gl/c4Rm4p]) for more information if you do not have access to a take-back program.

In case of emergency/overdose

In case of overdose, call the poison control helpline at 1-800-222-1222. Information is also available online at https://www.poisonhelp.org/help [https://www.poisonhelp.org/help] . If the victim has collapsed, had a seizure, has trouble breathing, or can't be awakened, immediately call emergency services at 911.

Symptoms of overdose may include:

- tiredness
- weakness
- · wobbliness, unsteadiness, or incoordination causing difficulty walking
- · shaking hands you cannot control
- confusion
- · speech or language problems
- · agitation
- · anger or hostility
- depression
- vomiting
- · loss of consciousness
- abnormal, uncontrollable muscle contractions
- temporary inability to move (paralysis)
- · seizures, including status epilepticus

What other information should I know?

Keep all appointments with your doctor and the laboratory.

Do not let anyone else take your medication. Ask your pharmacist any questions you have about refilling your prescription.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

Brand names

Gabitril ®

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