

MEDICATION GUIDE

Vigabatrin (vye ga' ba trin) Tablets

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

Vigabatrin tablets can cause serious side effects, including:

- **Permanent vision loss**
- **Magnetic resonance imaging (MRI) changes in babies with infantile spasms (IS)**
- **Risk of suicidal thoughts or actions**

1. Permanent vision loss:

Vigabatrin tablets can damage the vision of anyone who takes it. Some people can have severe loss particularly to their ability to see to the side when they look straight ahead (peripheral vision). With severe vision loss, you may only be able to see things straight in front of you (sometimes called “tunnel vision”). You may also have blurry vision. If this happens, it will not get better.

- **Vision loss and use of vigabatrin tablets in adults and children 2 years and older:** Because of the risk of vision loss, vigabatrin tablets are used to treat complex partial seizures (CPS) only in people who do not respond well enough to several other medicines.

Tell your healthcare provider right away if you (or your child):

- o might not be seeing as well as before starting vigabatrin tablets.
- o start to trip, bump into things, or are more clumsy than usual.
- o are surprised by people or things coming in front of you that seem to come out of nowhere.
- These changes can mean that you (or your child) have damage to your vision.
- It is recommended that your healthcare provider test your (or your child's) vision (including peripheral vision) and visual acuity (ability to read an eye chart) before you (or your child) start vigabatrin tablets or within 4 weeks after starting vigabatrin tablets, and at least every 3 months after that until vigabatrin tablets are stopped. It is also recommended that you (or your child) have a vision test about 3 to 6 months after vigabatrin tablets are stopped. Your vision loss may get worse after you stop taking vigabatrin tablets.
- Some people are not able to complete testing of vision. Your healthcare provider will determine if you (or your child) can be tested. If you (or your child) cannot complete vision testing, your healthcare provider may continue prescribing vigabatrin tablets, but your healthcare provider will not be able to watch for any vision loss you (or your child) may get.
- Even if your vision (or your child's vision) seems fine, it is important that you (or your child) get these regular vision tests because vision damage can happen before you (or your child) notice any changes.
- These vision tests cannot prevent the vision damage that can happen with vigabatrin tablets, but they do allow the healthcare provider to decide if you (or your child) should stop vigabatrin tablets if your vision has gotten worse.
- Vision testing may not detect vision loss before it is severe.
- If you do not have these vision tests regularly, your healthcare provider may stop prescribing vigabatrin tablets.
- If you drive and your vision is damaged by vigabatrin tablets, driving might be more dangerous, or you may not be able to drive safely at all. Talk about this with your healthcare provider.
- **Vision loss in babies:** Because of the risk of vision loss, vigabatrin tablets are used in babies 1 month to 2 years of age with infantile spasms (IS) only when you and your healthcare provider decide that the possible benefits of vigabatrin tablets are more important than the risks.
 - o Parents or caregivers are not likely to recognize the symptoms of vision loss in babies until it is severe. Healthcare providers may not find vision loss in babies until it is severe.
 - o It is difficult to test vision in babies, but, to the extent possible, all babies should have their vision tested before starting vigabatrin tablets or within 4 weeks after starting vigabatrin tablets, and every 3 months after that until vigabatrin tablets are stopped. Your baby should also have a vision test about 3 to 6 months after vigabatrin tablets are stopped.
 - o Your baby may not be able to be tested. Your healthcare provider will determine if your baby can be tested. If your baby cannot be tested, your healthcare provider may continue prescribing vigabatrin tablets, but your healthcare provider will not be able to watch for any vision loss.

Tell your healthcare provider right away if you think that your baby is:

- o not seeing as well as before taking vigabatrin tablets.
- o acting differently than normal.
- Even if your baby's vision seems fine, it is important to get regular vision tests because damage can happen before your baby acts differently. Even these regular vision exams may not show the damage to your baby's vision before it is severe and permanent.

All people who take vigabatrin tablets:

- You are at risk for permanent vision loss with any amount of vigabatrin tablets.
- Your risk of vision loss may be higher the more vigabatrin tablets you take daily and the longer you take it.
- It is not possible for your healthcare provider to know when vision loss will happen. It could happen soon after starting vigabatrin tablets or any time during treatment. It may even happen after treatment has stopped.

- Because vigabatrin tablets might cause permanent vision loss, it is available to healthcare providers and patients only under a special program called the Vigabatrin Risk Evaluation and Mitigation Strategy (REMS) Program. Vigabatrin tablets can only be prescribed to people who are enrolled in this program. As part of the Vigabatrin REMS Program, it is recommended that your healthcare provider test your (or your child's) vision from time to time (periodically) while you (or your child) are being treated with vigabatrin tablets, and even after you (or your child) stop treatment. Your healthcare provider will explain the details of the Vigabatrin REMS Program to you. For more information, go to www.vigabatrinREMS.com or call 1-866-244-8175.

2. Magnetic resonance imaging (MRI) changes in babies with infantile spasms:

Brain pictures taken by magnetic resonance imaging (MRI) show changes in some babies after they are given vigabatrin tablets. It is not known if these changes are harmful.

3. Risk of suicidal thoughts or actions:

Like other antiepileptic drugs, vigabatrin tablets may cause suicidal thoughts or actions in a very small number of people, about 1 in 500 people taking it. Call a healthcare provider right away if you or your child have any of these symptoms, especially if they are new, worse, or worry you:

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

Suicidal thoughts or actions can be caused by things other than medicines. If you or your child 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 vigabatrin tablets without first talking to a healthcare provider.**
- Stopping vigabatrin tablets suddenly can cause serious problems. Stopping a seizure medicine suddenly can cause seizures that will not stop (status epilepticus) in people who are being treated for seizures.

What are vigabatrin tablets?

- Vigabatrin tablets are a prescription medicine used along with other treatments to treat adults and children 2 years and older with complex partial seizures (CPS) if:
 - o the CPS do not respond well enough to several other treatments, **and**
 - o you and your healthcare provider decide the possible benefit of taking vigabatrin tablets is more important than the risk of vision loss.Vigabatrin tablets should not be the first medicine used to treat CPS.
- Vigabatrin tablets are also used to treat babies 1 month to 2 years of age who have infantile spasms (IS) if you and your healthcare provider decide the possible benefits of taking vigabatrin tablets are more important than the possible risk of vision loss.



What should I tell my healthcare provider before starting vigabatrin tablets?

If you or your child has CPS, before taking vigabatrin tablets tell your healthcare provider about all of your medical conditions, including if you or your child:

- have or had an allergic reaction to vigabatrin tablets, such as hives, itching, or trouble breathing.
- have or had any vision problems.
- have or had any kidney problems.
- have or had low red blood cell counts (anemia).
- have or had any nervous or mental illnesses, such as depression, mood problems, thoughts of suicide, or attempts at suicide.
- are breastfeeding or planning to breastfeed. Vigabatrin tablets can pass into breast milk and may harm your baby. Talk to your healthcare provider about the best way to feed your baby if you take vigabatrin tablets.
- are pregnant or plan to become pregnant. Vigabatrin tablets can cause harm to your unborn baby. You and your healthcare provider will have to decide if you should take vigabatrin tablets while you are pregnant.

Pregnancy Registry:

If you become pregnant while taking vigabatrin tablets, talk to your healthcare provider about registering with the North American Antiepileptic Drug Pregnancy Registry. You can enroll in this registry by calling 1-888-233-2334. Information on the registry can also be found at the website <http://www.aedpregnancyregistry.org/>. The purpose of this registry is to collect information about the safety of antiepileptic medicine during pregnancy.

If you are a parent or caregiver whose baby has IS, before giving vigabatrin tablets to your baby, tell your healthcare provider about all of your baby's medical conditions, including if your baby has or ever had:

- an allergic reaction to vigabatrin tablets, such as hives, itching, or trouble breathing.
- any vision problems.
- any kidney problems.

Tell your healthcare provider about all the medicines you or your child take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Vigabatrin tablets and other medicines may affect each other causing side effects.

How should I take vigabatrin tablets?

- Vigabatrin comes as tablets.
- You or your child will receive vigabatrin tablets from a specialty pharmacy.
- Take vigabatrin tablets exactly as your healthcare provider tells you to. Vigabatrin tablets are usually taken 2 times each day.
- Vigabatrin tablets may be taken with or without food.
- Before starting to take vigabatrin tablets, talk to your healthcare provider about what you or your child should do if a vigabatrin tablets dose is missed.
- If you or your child are taking vigabatrin tablets for CPS and the seizures do not improve enough within 3 months, your healthcare provider will stop prescribing vigabatrin tablets.
- If your child is taking vigabatrin tablets for IS and the seizures do not improve within 2 to 4 weeks, your healthcare provider will stop prescribing vigabatrin tablets.
- **Do not stop taking vigabatrin tablets suddenly.** This can cause serious problems. Stopping vigabatrin tablets or any seizure medicine suddenly can cause seizures that will not stop (status epilepticus) in people who are being treated for seizures. You should follow your healthcare provider's instructions on how to stop taking vigabatrin tablets.
- **Tell your healthcare provider right away about any increase in seizures when vigabatrin tablets treatment is being stopped.** Before your child starts taking vigabatrin tablets, speak to your child's healthcare provider about what to do if your baby misses a dose, vomits, spits up, or only takes part of the dose of vigabatrin tablets.
- **Do not stop taking vigabatrin tablets without talking to your healthcare provider.** If vigabatrin tablets improve your (or your child's) seizures, you and your healthcare provider should talk about whether the benefit of taking vigabatrin tablets is more important than the risk of vision loss, and decide if you (or your child) will continue to take vigabatrin tablets.

What should I avoid while taking vigabatrin tablets?

Vigabatrin tablets causes sleepiness and tiredness. Adults taking vigabatrin tablets should not drive, operate machinery, or perform any hazardous task, unless you and your healthcare provider have decided that you can do these things safely.

What are the possible side effects of vigabatrin tablets?

Vigabatrin tablets can cause serious side effects, including:

- **See "What is the most important information I should know about vigabatrin tablets?"**
- **sleepiness and tiredness.** See "What should I avoid while taking vigabatrin tablets?"
- **vigabatrin tablets may cause your baby to be sleepy.** Sleepy babies may have a harder time suckling and feeding, or may be irritable.
- **weight gain that happens without swelling.**

The following serious side effects happen in **adults**. It is not known if these side effects also happen in babies who take vigabatrin tablets.

- **low red blood cell counts (anemia).**
- **nerve problems.** Symptoms of a nerve problem can include numbness and tingling in your toes or feet. It is not known if nerve problems will go away after you stop taking vigabatrin tablets.
- **swelling.**

If you or your child has CPS, vigabatrin tablets may make certain types of seizures worse. Tell your healthcare provider right away if your (or your child's) seizures get worse.

The most common side effect of vigabatrin tablets in **adults** include blurred vision, sleepiness, dizziness, problems walking or feeling uncoordinated, shaking (tremor), and tiredness.

The most common side effect of vigabatrin tablets in **children 3 to 16 years of age** is weight gain. Also expect side effects like those seen in adults.

If you are giving vigabatrin tablets to your baby for IS:

Vigabatrin tablets may make certain types of seizures worse. You should tell your baby's healthcare provider right away if your baby's seizures get worse. Tell your baby's healthcare provider if you see any changes in your baby's behavior.

The most common side effects of vigabatrin tablets in **babies** include:

- o sleepiness - vigabatrin tablets may cause your baby to be sleepy. Sleepy babies may have a harder time suckling and feeding or may be irritable.
- o swelling in the bronchial tubes (bronchitis)
- o ear infection
- o irritability

Tell your healthcare provider if you or your child have any side effect that bothers you or that does not go away. These are not all the possible side effects of vigabatrin tablets.

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 vigabatrin tablets?

- Store vigabatrin tablets at room temperature between 68°F to 77°F (20°C to 25°C).

Keep vigabatrin tablets and all medicines out of the reach of children.

General information about the safe and effective use of vigabatrin tablets.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. You can ask your pharmacist or healthcare provider for information about vigabatrin tablets that is written for health professionals. Do not use vigabatrin tablets for a condition for which it was not prescribed. Do not give vigabatrin tablets to other people, even if they have the same symptoms that you have. It may harm them.

What are the ingredients in vigabatrin tablets?

Active Ingredient: vigabatrin

Inactive Ingredients: microcrystalline cellulose, povidone, sodium starch glycolate, hypromellose 2910 (15mPas), magnesium stearate, titanium dioxide and polyethylene glycol (MW 8000).

Manufactured by: Dexcel Pharma Technologies Ltd, 10 Hakidma St. Yokneam 2069200, Israel

Distributed by: Edenbridge Pharmaceuticals, LLC, Parsippany, NJ 07054

For more information, call 877-381-3336.

This Medication Guide has been approved by the U.S. Food and Drug Administration
Revised: 08/2022

