



Patients/Parents/Legal Guardians:

Before beginning vigabatrin therapy, your healthcare provider will go over the risks associated with vigabatrin and provide this patient guide to you. It is very important that you read this and ask any questions you might have about vigabatrin before or during your or your child's treatment. Keep this guide for important safety information about serious risks involved with taking vigabatrin.

What Is Vigabatrin?

SABRIL (vigabatrin) and its approved generic products (Tablets or Powder for Oral Solution 50 mg/mL) are prescription medications:

- used with other treatments in adults and children 2 years of age and older with refractory complex partial seizures (CPS), who have not responded well enough to several other treatments and for whom the potential benefits outweigh the potential risk of vision loss.
- used to treat babies 1 month to 2 years of age who have infantile spasms (IS) and for whom the potential benefits outweigh the potential risk of vision loss.

VIGAFYDE (vigabatrin) oral solution (100 mg/mL) is a prescription medication:

- used to treat babies 1 month to 2 years of age who have infantile spasms (IS) and for whom the potential benefits outweigh the potential risk of vision loss.

Vigabatrin products are available only through certified healthcare providers and pharmacies.

What Is the Most Serious Risk Information About Vigabatrin Treatment?

- **Vigabatrin can cause permanent vision damage to anyone who takes it**
Some people can have severe vision 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 can occur with any amount of vigabatrin**

It is not possible for your healthcare provider to know when vision loss will happen. It could happen soon after starting vigabatrin or any time during treatment. It may even happen after treatment has stopped. Your vision loss may get worse after you stop taking VIGABATRIN.

Your healthcare provider will discuss periodic vision monitoring with you. Even if your or your child's vision seems fine, it is important that regular vision tests are done 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, but they do allow the healthcare provider to decide if you or your child should stop taking vigabatrin if vision has gotten worse. Vision testing may not detect vision loss before it is severe.

What Are the Signs of Vision Loss With Vigabatrin Treatment?

Symptoms of vision loss from vigabatrin are unlikely to be recognized by patients or parents/legal guardians before it is severe.

Tell your healthcare provider right away if you notice any of the following signs in you or your child, as these changes can mean that vision damage has occurred:

- Loss in the ability to see to the side when looking straight ahead (peripheral vision)
- Blurry vision
- Not seeing as well as before starting vigabatrin
- Starting to trip, bump into things, or being more clumsy than usual
- Being surprised by people or things coming in front of you that seem to come out of nowhere
- Your baby is acting differently than normal

These are **NOT** all the possible side effects of vigabatrin. Refer to the vigabatrin Medication Guide that will be given to you when you receive your prescription and talk to your healthcare provider for medical advice about other side effects.

What Can I Do to Help Reduce the Risk of Vision Loss With Vigabatrin?

- **Before starting treatment with vigabatrin, discuss how often vision testing should be done with your or your child's healthcare provider**

Regular visits to an ophthalmologist or optometrist may help you decide if or when you or your child should stop vigabatrin, but it will not prevent vision loss.

- **Visit an ophthalmologist or optometrist as recommended by your healthcare provider**
Report any changes in your or your child's vision to your doctor as soon as possible.
 - **Tell your healthcare provider right away if you notice any of the following in you or your child:**
 - Not seeing as well as before starting vigabatrin
 - Starting to trip or bump into things, or being more clumsy than usual
 - Being surprised by people or things coming in front of you that seem to come out of nowhere
 - Your baby is acting differently than normal
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How Should I Take Vigabatrin Tablets or Vigabatrin Powder for Oral Solution (reconstituted to 50 mg/mL)?

- Take vigabatrin exactly as the healthcare provider tells you to
- Vigabatrin is usually taken 2 times each day
- Vigabatrin may be taken with or without food
- Do not stop taking vigabatrin without talking to your healthcare provider. This can cause serious problems.
- See "Instructions for Use" for detailed information about how to mix and give vigabatrin powder for oral solution (reconstituted to 50mg/mL) to your child the right way

How Should I Take Vigafyde (Vigabatrin) Solution (100 mg/mL)?

Vigafyde (vigabatrin) comes as an oral solution (100 mg/mL) and is more concentrated than vigabatrin solutions prepared from powder (50 mg/mL). If your baby was previously prescribed another vigabatrin product, your baby's doctor will prescribe a lesser volume of Vigafyde. **Check to see if your doctor has prescribed a lesser volume of solution than before.**

- Vigabatrin 100mg/mL oral solution should be given to your baby exactly as your baby's healthcare provider tells you to
- Vigabatrin is usually taken 2 times each day
- Vigabatrin may be taken with or without food
- Do not stop vigabatrin without talking to your baby's healthcare provider. This can cause serious problems.
- Do not add water or other liquids (do not dilute) to vigabatrin solution (100mg/mL) when measuring the dose.
- See "Instructions for Use" for detailed information about how to give vigabatrin oral solution (100mg/mL) to your child the right way

Where Can I Get More Information About Vigabatrin?

You should receive a vigabatrin Medication Guide with each prescription. You can also find more information at www.vigabatrinREMS.com or call the Vigabatrin REMS at the toll-free number 1-866-244-8175.