

MEDICATION GUIDE
VIGAFYDE® (VIG-uh-fide)
(vigabatrin)
oral solution

What is the most important information I should know about VIGAFYDE?

VIGAFYDE can cause serious side effects, including:

- **Permanent vision loss**
- **Magnetic resonance imaging (MRI) changes in babies with infantile spasms (IS)**

1. Permanent vision loss:

VIGAFYDE 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, your baby may only be able to see things straight in front of them (sometimes called “tunnel vision”). Your baby may also have blurry vision. If this happens, it will not get better.

- **Vision loss in babies:** Because of the risk of vision loss, VIGAFYDE is used in babies 1 month to 2 years of age with IS only when you and your baby’s healthcare provider decide that the possible benefits of VIGAFYDE are more important than the risks.
 - 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.
 - It is difficult to test vision in babies, but, to the extent possible, all babies should have their vision tested before starting VIGAFYDE or within 4 weeks after starting VIGAFYDE, and every 3 months after that until VIGAFYDE is stopped. Your baby should also have a vision test about 3 to 6 months after VIGAFYDE is stopped.
 - Your baby may not be able to be tested. Your baby’s healthcare provider will determine if your baby can be tested. If your baby cannot be tested, your baby’s healthcare provider may continue prescribing VIGAFYDE, but your baby’s 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:

- not seeing as well as before taking VIGAFYDE.
- 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 caregivers of babies who take VIGAFYDE:

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

- Because VIGAFYDE 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). VIGAFYDE can only be prescribed to people who are enrolled in this program. As part of the Vigabatrin REMS, it is recommended that your baby’s healthcare provider test your baby’s vision from time to time (periodically) while your baby is being treated with VIGAFYDE, and even after your baby stops treatment. Your baby’s healthcare provider will explain the details of the Vigabatrin REMS to you. For more information, go to **www.vigabatrinREMS.com** or call 1-866-244-8175.

2. MRI changes in babies with IS:

Brain pictures taken by MRI show changes in some babies after they are given VIGAFYDE. It is not known if these changes are harmful.

What is VIGAFYDE?

- VIGAFYDE is a prescription medicine used to treat babies 1 month to 2 years of age who have infantile spasms (IS) if you and your baby’s healthcare provider decide the possible benefits of taking VIGAFYDE are more important than the possible risk of vision loss.

What should I tell my baby's healthcare provider before starting VIGAFYDE?

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

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

Tell your baby's healthcare provider about all the medicines your baby takes, including prescription and over-the-counter medicines, vitamins, and herbal supplements. VIGAFYDE and other medicines may affect each other causing side effects.

How should my baby take VIGAFYDE?

- VIGAFYDE comes as an oral solution.
 - **Important: VIGAFYDE is more concentrated than vigabatrin solutions prepared from powder.** The volume of VIGAFYDE solution prescribed by your baby's healthcare provider may be less than the volume prescribed for other vigabatrin solutions prepared from powder. Always double check the volume (mL) that you are to give your baby when you get a new prescription filled.
- Your baby will receive VIGAFYDE from a specialty pharmacy.
- Give VIGAFYDE exactly as your baby's healthcare provider tells you to. VIGAFYDE is usually taken 2 times each day.
- VIGAFYDE may be given by mouth or given through a gastrostomy (G) tube. If VIGAFYDE is given through a gastrojejunal (GJ) tube, the G-port must be used. Give the medicine as directed by your baby's healthcare provider, and flush the tube after administration with the amount of water recommended by your healthcare provider.
- VIGAFYDE may be taken with or without food.
- Before starting to give VIGAFYDE, talk to your baby's healthcare provider about what you should do if a VIGAFYDE dose is missed.
- If your baby is taking VIGAFYDE for IS and the seizures do not improve within 2 to 4 weeks, your baby's healthcare provider will stop prescribing VIGAFYDE.
- **Do not stop taking VIGAFYDE suddenly.** This can cause serious problems. Stopping VIGAFYDE 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 baby's healthcare provider's instructions on how to stop taking VIGAFYDE.
- **Tell your baby's healthcare provider right away about any increase in seizures when VIGAFYDE treatment is being stopped.** Before your baby starts taking VIGAFYDE, speak to your baby's healthcare provider about what to do if your baby misses a dose, vomits, spits up, or only takes part of the dose of VIGAFYDE.
- **Do not stop taking VIGAFYDE without talking to your healthcare provider.** If VIGAFYDE improves your baby's seizures, you and your baby's healthcare provider should talk about whether the benefit of taking VIGAFYDE is more important than the risk of vision loss, and decide if your baby will continue to take VIGAFYDE.
- VIGAFYDE can be given to your baby at the same time as their meal.
- Measure the dose of VIGAFYDE using the syringe given to you by the pharmacy. **A household teaspoon is not an accurate measuring device.**
- Do not add water or other liquids to VIGAFYDE (do not dilute) when measuring the dose.
- **See "Instructions for Use" for detailed information about how to give VIGAFYDE to your baby the right way.**

What are the possible side effects of VIGAFYDE?

VIGAFYDE can cause serious side effects, including:

- See "What is the most important information I should know about VIGAFYDE?"
- **VIGAFYDE 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 who take vigabatrin** (the active ingredient in VIGAFYDE). It is not known if these side effects also happen in babies who take VIGAFYDE.

- **low red blood cell counts (anemia).**
- **nerve problems.** Symptoms of a nerve problem can include numbness and tingling in toes or feet. It is not known if nerve problems will go away after treatment with VIGAFYDE is stopped.
- **swelling.**
- **suicidal thoughts and ideation.**

VIGAFYDE 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 VIGAFYDE in **babies** include:

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

Tell your healthcare provider if your baby has any side effect that bothers them or does not go away. These are not all the possible side effects of VIGAFYDE.

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 VIGAFYDE?

- Store unopened bottles at room temperature between 68°F to 77°F (20°C to 25°C). After opening, store bottle in a refrigerator or at room temperature between 36°F to 86°F (2°C to 30°C).
- Throw away (discard) any opened bottle of VIGAFYDE 90 days after first opening, even if there is still medicine in the bottle.

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

General information about the safe and effective use of VIGAFYDE.

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 VIGAFYDE that is written for health professionals. Do not use VIGAFYDE for a condition for which it was not prescribed. Do not give VIGAFYDE to other people, even if they have the same symptoms. It may harm them.

What are the ingredients in VIGAFYDE?

Active Ingredient: vigabatrin

Inactive Ingredients: methylparaben, peppermint flavor, propylparaben, purified water, and sucralose

Made in the United Kingdom

Distributed by

UPSHER-SMITH LABORATORIES, LLC

Maple Grove, MN 55369

VIGAFYDE is a registered trademark of Pyros Pharmaceuticals, Inc.

For more information, go to **www.VIGAFYDE.com** or call **1-888-650-3789**.

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

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