

MEDICATION GUIDE
VIGADRONE™ (vi-ga-drōne)
(vigabatrin) Powder for oral solution

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

VIGADRONE 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:

VIGADRONE can damage the vision of anyone who takes it. People who take VIGADRONE do not lose all of their vision, but 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 VIGADRONE in adults and children 10 years and older:** Because of the risk of vision loss, VIGADRONE is 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):

- might not be seeing as well as before starting VIGADRONE
- start to trip, bump into things, or are more clumsy than usual
- 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 VIGADRONE or within 4 weeks after starting VIGADRONE, and at least every 3 months after that until VIGADRONE is stopped. It is also recommended that you (or your child) have a vision test about 3 to 6 months after VIGADRONE is stopped.
- 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 VIGADRONE, 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 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 VIGADRONE, but they do allow the healthcare provider to decide if you (or your child) should stop VIGADRONE if vision has gotten worse, which usually will lessen further damage.
- If you do not have these vision tests regularly, your healthcare provider may stop prescribing VIGADRONE.
- If you drive and your vision is damaged by VIGADRONE, 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, VIGADRONE is 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 VIGADRONE 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 VIGADRONE or within 4 weeks after starting VIGADRONE, and every 3 months after that until VIGADRONE is stopped. Your baby should also have a vision test about 3 to 6 months after VIGADRONE is stopped.
- 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 VIGADRONE, 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:

- not seeing as well as before taking VIGADRONE
- 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 serious and permanent.

All people who take VIGADRONE:

- You are at risk for permanent vision loss with any amount of VIGADRONE.
- Your risk of vision loss may be higher the more VIGADRONE 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 VIGADRONE or any time during treatment. It may even happen after treatment has stopped.

- Because VIGADRONE 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. VIGADRONE 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 VIGADRONE, 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 VIGADRONE. It is not known if these changes are harmful.

3. Risk of suicidal thoughts or actions:

Like other antiepileptic drugs, VIGADRONE 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:

- thoughts about suicide or dying
- attempts to commit suicide
- new or worse depression
- new or worse anxiety
- feeling agitated or restless
- panic attacks
- trouble sleeping (insomnia)
- new or worse irritability
- acting aggressive, being angry, or violent
- acting on dangerous impulses
- an extreme increase in activity and talking (mania)
- 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 VIGADRONE without first talking to a healthcare provider.**
- Stopping VIGADRONE 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 is VIGADRONE?

- VIGADRONE is a prescription medicine used along with other treatments to treat adults and children 10 years and older with complex partial seizures (CPS) if:
 - The CPS does not respond well enough to several other treatments, and
 - You and your healthcare provider decide the possible benefit of taking VIGADRONE is more important than the risk of vision loss.

VIGADRONE should not be the first medicine used to treat CPS.

- VIGADRONE is 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 VIGADRONE are more important than the possible risk of vision loss.

What should I tell my healthcare provider before starting VIGADRONE?

If you or your child has CPS, before taking VIGADRONE tell your healthcare provider if you or your child have or had:

- depression, mood problems or suicidal thoughts or behavior
- an allergic reaction to VIGADRONE, such as hives, itching, or

trouble breathing

- any vision problems
- any kidney problems
- low red blood cell counts (anemia)
- any nervous or mental illnesses, such as depression, thoughts of suicide, or attempts at suicide
- any other medical conditions
- are breastfeeding or planning to breastfeed. VIGADRONE 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 VIGADRONE.
- are pregnant or plan to become pregnant. It is not known if VIGADRONE will harm your unborn baby. You and your healthcare provider will have to decide if you should take VIGADRONE while you are pregnant.

Pregnancy Registry:

If you become pregnant while taking VIGADRONE, 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. 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 VIGADRONE 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 VIGADRONE, 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. VIGADRONE and other medicines may affect each other causing side effects.

How should I take VIGADRONE?

- You or your child will receive VIGADRONE from a specialty pharmacy.
- Take VIGADRONE exactly as your healthcare provider tells you to. VIGADRONE is usually taken 2 times each day.
- VIGADRONE may be taken with or without food.
- Before starting to take VIGADRONE, talk to your healthcare provider about what you or your child should do if a VIGADRONE dose is missed.
- If you or your child are taking VIGADRONE for CPS and the seizures do not improve enough within 3 months, your healthcare provider will stop prescribing VIGADRONE.
- If your child is taking VIGADRONE for IS and the seizures do not improve within 2 to 4 weeks, your healthcare provider will stop prescribing VIGADRONE.
- **Do not stop taking VIGADRONE suddenly.** This can cause serious problems. Stopping VIGADRONE 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 VIGADRONE.
- **Tell your healthcare provider right away about any increase in seizures when VIGADRONE treatment is being stopped.** Before your child starts taking VIGADRONE, 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 VIGADRON.

- **Do not stop taking VIGADRON without talking to your healthcare provider.** If VIGADRON improves your (or your child's) seizures, you and your healthcare provider should talk about whether the benefit of taking VIGADRON is more important than the risk of vision loss, and decide if you (or your child) will continue to take VIGADRON.
- If you are giving VIGADRON powder for oral solution to your child, it can be given at the same time as their meal. **VIGADRON for oral solution powder should be mixed with water only.**
- **See "Instructions for Use" for detailed information about how to mix and give VIGADRON powder for oral solution to your baby the right way.**

What should I avoid while taking VIGADRON?

VIGADRON causes sleepiness and tiredness. Adults taking VIGADRON 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 VIGADRON?

VIGADRON can cause serious side effects, including:

- **See "What is the most important information I should know about VIGADRON?"**
- **sleepiness and tiredness.** See "What should I avoid while taking VIGADRON?"
- **VIGADRON 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 VIGADRON.

- **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 VIGADRON.
- **swelling**

If you or your child has CPS, VIGADRON 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 effects of VIGADRON in **adults** include:

- problems walking or feeling uncoordinated
- feeling dizzy
- shaking (tremor)
- joint pain
- memory problems and not thinking clearly
- eye problems: blurry vision, double vision and eye movements that you cannot control

The most common side effects of VIGADRON in **children 10 to 16 years of age** include:

- weight gain
- upper respiratory tract infection
- tiredness
- aggression
- Also expect side effects like those seen in adults

If you are giving VIGADRON to your baby for IS:

VIGADRON 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 VIGADRON in **babies** include:

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

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 VIGADRON?

- Store VIGADRON packets at room temperature, between 20° to 25°C (68° to 77°F).
- Keep VIGADRON powder in the container they come in.

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

General information about the safe and effective use of VIGADRON.

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

What are the ingredients in VIGADRON?

Active Ingredient: vigabatrin

For Medication Guides, please visit www.upsher-smith.com or call 1-888-650-3789.

Manufactured for
UPSHER-SMITH LABORATORIES, LLC
Maple Grove, MN 55369

Made in Germany

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

Revised 0518