



VIGADRONE[®]

(vigabatrin) for Oral Solution



STARTING ON VIGADRONE[®]

AN EQUAL GENERIC SUBSTITUTE
WITH BRAND-QUALITY SUPPORT

FROM UPSHER-SMITH LABORATORIES, LLC

ACCESS PATHWAYS[®] PROGRAM

WARNING: PERMANENT VISION LOSS
*See Medication Guide and full Prescribing Information
for complete information.*

All people who take VIGADRONE:

- You are at risk for permanent vision loss with any amount of vigabatrin.
- Your risk of vision loss may be higher the more vigabatrin 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.

Please see Important Safety Information, including an Important Warning for Risk of Permanent Vision Loss on page 2.

WHAT IS VIGADRONE®?

VIGADRONE® (vigabatrin) powder for Oral Solution is a prescription medicine used for the treatment of:

- **Infantile Spasms (IS)** in babies 1 month to 2 years of age, if you and your healthcare provider decide the possible benefits of taking VIGADRONE® are more important than the possible risk of vision loss.
- **Refractory Complex Partial Seizures (CPS)** used along with other treatments to treat adults and children 2 years and older 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.

Please see Important Safety Information, including an Important Warning for Risk of Permanent Vision Loss starting below, and accompanying Medication Guide.

AN EQUAL GENERIC SUBSTITUTE

VIGADRONE® is a generic version of Sabril® (vigabatrin) Powder for Oral Solution. Compared to Sabril®, VIGADRONE® contains the same active ingredient in the same strength and uses the same dosage form (powder that is mixed with water) and administration method. VIGADRONE® is pure vigabatrin powder with no additional inactive ingredients. And, VIGADRONE® offers brand-quality support services through Access Pathways®.



WHAT IMPORTANT SAFETY INFORMATION SHOULD I KNOW ABOUT VIGADRONE?

- **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. Your healthcare provider will explain the details of this Program to you.**

- **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 looking 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").

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BRAND-QUALITY SUPPORT

ACCESS PATHWAYS® PROGRAM

SAVINGS & SUPPORT FOR VIGADRONE®

Once a physician has determined that a patient should be prescribed vigabatrin, they often direct treatment to start immediately. To help make this process easier, Upsher-Smith developed Access Pathways®, a savings and support program that helps patients get started on therapy as quickly as possible.

Access Pathways® Program Support:

MONDAY - FRIDAY: 8am-8pm EST **Phone:** 1-866-923-1954

Fax prescription forms: 1-877-788-4948

WEEKENDS AND AFTER HOURS: **Phone:** 1-866-923-1954

Fax prescription forms: 1-877-827-0395

VIGABATRIN REMS PROGRAM

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 physician test the patient's vision from time to time (periodically) while the patient is being treated with VIGADRONE®, and even after the patient stops treatment. Your physician 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.

STEP 1

PHYSICIAN ENROLLS YOUR CHILD & PRESCRIBES VIGADRONE®

Your physician will complete and submit the VIGADRONE® Prescription Form.

If your physician didn't have you review and sign a Vigabatrin Patient/Parent/Legal Guardian-Physician Agreement Form, contact your physician immediately. VIGADRONE® can't be dispensed if this step hasn't been completed.



IMPORTANT SAFETY INFORMATION (cont.)

You may also have **blurry vision**. If this happens, it will not get better.

- **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; or if your baby is acting differently than

normal. **These changes can mean that vision damage has occurred.**

- **Regular vision testing is recommended.** It is recommended that your healthcare provider test your (or your child's) vision before or within 4 weeks after starting VIGADRONE, and at least every 3 months during treatment until VIGADRONE is stopped. It is also recommended that vision be tested about 3 to 6 months after VIGADRONE is stopped. It is difficult to test vision in babies, but to the extent possible, all babies should

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STEP 2

ACCESS PATHWAYS® PROGRAM

WE CONFIRM AND DETERMINE PATIENT COVERAGE

- ✓ **We confirm** Step 1 is complete—that both physician and patient Vigabatrin REMS Program documents have been submitted.
- ✓ **We determine** if the patient is:
 - ✓ **Covered**
 - ✓ **Not covered or uninsured**
 - ✓ **Eligible for the co-pay assistance program**
 - ✓ **Or requires a prior authorization**

Prior authorization

If the patient requires a prior authorization we contact their insurance provider. We then fax all necessary forms to your office for you to complete. While this is being done, a VIGADRONE® starter/bridge supply is sent to the patient. Prior authorization support can be provided only for indicated disease states.

IMPORTANT SAFETY INFORMATION (cont.)

- have their vision tested. Your healthcare provider will determine if testing can be done. **Regular vision testing is important because damage can happen before any changes are noticed.**
- **Vision tests cannot prevent the vision damage** that can happen with VIGADRONE, but they do allow VIGADRONE to be stopped if vision has gotten worse, which usually will lessen further damage. Even these regular vision tests may not show vision damage before it is serious and permanent. **Parents, caregivers, and**

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STEP 3

PRESCRIPTION DELIVERED

The prescription is processed by a specialty pharmacy partner and delivered to you.



healthcare providers may not recognize the symptoms, or find vision loss in babies, until it is severe.

- **If you do not have these vision tests regularly, your healthcare provider may stop prescribing VIGADRONE for you (or your child). Some people are not able to complete vision testing. If vision testing cannot be done, your healthcare provider may continue prescribing VIGADRONE, but will not be able to watch for any vision loss.**
- **Magnetic resonance imaging (MRI) changes in babies with IS.** Brain pictures taken by MRI show changes in

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PREPARING AND ADMINISTERING VIGADRONE®

VIGADRONE® (VIGABATRIN) POWDER FOR ORAL SOLUTION

Read this Instructions for Use before your child starts taking VIGADRONE and each time you get a refill. There may be new information. This information does not take the place of talking with your healthcare provider about your child's medical condition or treatment. Talk to your healthcare provider if you have any questions about the right dose of medicine to give your child or how to mix it.

Important Note:

- VIGADRONE comes in a packet
- Each packet contains 500 mg of VIGADRONE powder
- **VIGADRONE powder must be mixed with water only.** The water may be cold or at room temperature.
- Your healthcare provider will tell you:
 - how many packets of VIGADRONE you will need for each dose
 - how many milliliters (mL) of water to use to mix one dose of VIGADRONE

- how many milliliters (mL) of the powder and water mixture you will need for each dose of medicine

- VIGADRONE should be given right away after it is mixed
- Use the oral syringes, provided by the pharmacy, to measure and give the correct dose. Do not use a household teaspoon or tablespoon.

Supplies you will need to mix 1 dose of VIGADRONE:

- The number of packets of VIGADRONE needed for each dose
- 2 clean cups: 1 for mixing and 1 for water. The cup used for mixing VIGADRONE should be clear so you can see if the powder is dissolved
- Water to mix with the VIGADRONE powder
- One small 3 mL oral syringe and one large 10 mL oral syringe which are provided by the pharmacy.
- Small spoon or other clean utensil to stir the mixture
- Scissors



Oral syringe detail



Step 1: Start with 1 of the empty cups and the total number of packets you will need for 1 dose.

Step 2: Before you open the packet, tap it to settle all the powder to the bottom of the packet.

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IMPORTANT SAFETY INFORMATION (cont.)

some babies after they are given VIGADRONE. It is not known if these changes are harmful.

- **Risk of suicidal thoughts or actions.** Like other antiepileptic drugs, VIGADRONE may cause suicidal thoughts and actions in some people (about 1 in 500 people). Call a healthcare provider right away if you (or your child) have any symptoms, especially sudden changes in mood, behaviors, thoughts or feelings, and especially if they are new, worse, or worry you.

- **Do not stop VIGADRONE without first talking to a healthcare provider.** Stopping VIGADRONE suddenly can cause seizures that will not stop.

VIGADRONE can cause serious side effects such as low red blood cell counts (anemia), sleepiness and tiredness, nerve problems, weight gain, and swelling. Because VIGADRONE causes sleepiness and tiredness, do not drive, operate machinery, or perform any hazardous task, unless it is decided that these things can be done safely. VIGADRONE may make certain types of seizures worse. **Tell your healthcare provider right away if seizures get worse.**

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Step 3: Use a pair of scissors to cut open the VIGADRONE packet along the dotted line.

Step 4: Empty the entire contents of the VIGADRONE packet into 1 of the clean empty cups (see Figure A).



Figure A

- Repeat steps 2 to 4 above to open all of the packets needed for 1 dose of VIGADRONE.

Step 5: Take the **second** cup and fill it half way with water (see Figure B). Do not mix VIGADRONE with anything other than water.



Figure B

· You will use the **larger** oral syringe (10 mL) to draw up the water needed to mix with the powder from the packets. **You will need 10 mL of water for each packet of VIGADRONE.**

For example:

- If you are using 1 packet of VIGADRONE, you will need to use 10 mL of water (fill the 10 mL oral syringe 1 time)
- If you are using 2 packets of VIGADRONE, you will need to use 20 mL of water (fill the 10 mL oral syringe 2 times)
- If you are using 3 packets of VIGADRONE, you will need to use 30 mL of water (fill the 10 mL oral syringe 3 times)

Step 6: Use the 10 mL oral syringe to draw up 10 mL of water. To do this, put the **tip** of the oral syringe all the way into the water in your cup. Then pull the plunger up towards you until the edge of the white plunger is at the 10 mL line on the barrel of the oral syringe (see Figure C).



Figure C

· If you see bubbles of air in the oral syringe after drawing up the water, turn the oral syringe so the tip is pointing up (see Figure D). The air will move to the top of the oral syringe. Pull the plunger back towards you and then push it back gently into the oral syringe to get rid of the bubbles. Tiny bubbles are normal.



Figure D

Step 7: Check the oral syringe to make sure it is filled with water up to the 10 mL line (see Figure E).

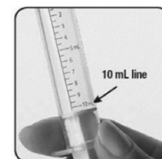


Figure E

Step 8: Get the second cup that contains the VIGADRONE needed for your dose.

Step 9: Hold the 10 mL oral syringe that is filled with water with the tip pointing down over the VIGADRONE.



Figure F

Step 10: **Slowly** push the oral syringe plunger all the way down to empty the water from the oral syringe straight into the cup containing the VIGADRONE (see Figure F).

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IMPORTANT SAFETY INFORMATION *(cont.)*

Before starting VIGADRONE, tell your doctor about all of your (or your child's) medical conditions including depression, mood problems, suicidal thoughts or behavior, any allergic reaction to VIGADRONE, vision problems, kidney problems, low red blood cell counts (anemia), and any nervous or mental illnesses. Tell your doctor about all the medicines you (or your child) take.

If you are breastfeeding or plan to breastfeed, VIGADRONE can pass into breast milk and may harm your baby.

If you 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.

The most common side effects of VIGADRONE in adults include: blurred vision, sleepiness, dizziness, problems walking or feeling uncoordinated, shaking (tremor) and tiredness.

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

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Repeat steps 6 through 10 until all of the water that is needed to mix 1 dose of VIGADRONE has been added to the cup containing the powder.

Step 11: Stir the mixture with the small spoon or other clean utensil until the solution is clear (see Figure G). This means that all of the powder is dissolved and ready for use.



Figure G

· To give a dose of VIGADRONE to your child, you should use the oral syringe to draw up the total number of mLs of the mixture that your healthcare provider tells you to.

- If you are giving **3 mL or less** of the mixture, use the smaller 3 mL oral syringe.
- If you are giving **more than 3 mL** of the mixture, use the larger 10 mL oral syringe (this is the oral syringe that you just used to add the water).

Step 12: Put the **tip** of the oral syringe all the way into the mixture. Pull the plunger up towards you to draw up the mixture. Stop when the edge of the white plunger lines up with the markings on the barrel of the oral syringe that matches the number of mLs of mixture your healthcare provider told you to give (see Figure H).



Figure H

· If you see bubbles of air in the oral syringe after drawing up the mixture,

turn the oral syringe so the tip is pointing up (see Figure I). The air will move to the top of the oral syringe. Pull the plunger back towards you and then gently push it back in the oral syringe in order to get rid of the bubbles. Tiny bubbles are normal.



Figure I

Step 13: Place the tip of the oral syringe into your child's mouth and point the oral syringe towards either cheek (see Figure J). Push on the plunger slowly, **a small amount at a time**, until all of the mixture in the oral syringe is given.



Figure J

· If the dose you are giving your child is more than 10 mLs, repeat steps 12 and 13 until you give the total dose of mixture prescribed by your healthcare provider.

Step 14: Throw away any mixture that is left over.

Do not save or reuse any leftover mixture.

Step 15: Wash the oral syringes and mixing cups in warm water. To clean the oral syringes, remove the plunger by gently pulling it straight out of the barrel. The barrel and plunger can be hand washed with soap and water, rinsed, and allowed to dry.

IMPORTANT SAFETY INFORMATION (cont.)

The most common side effects of VIGADRONE in babies include: sleepiness (sleepy babies may have a harder time suckling and feeding or may be irritable), swelling in the bronchial tubes (bronchitis), ear infection and irritability.

Tell your healthcare provider if you or your child have any side effect that bothers you or that does not go away.

This is the most important information to know about VIGADRONE, but not all of the possible side effects of VIGADRONE. For more information, ask your healthcare

provider or pharmacist, or please see VIGADRONE [Medication Guide](#), full [Prescribing Information](#) including Boxed Warning for risk of permanent vision loss, and [Instructions for Use](#). You can also visit vigadrone.com, upsher-smith.com or call 1-888-650-3789.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-332-1088.

WHAT ARE INFANTILE SPASMS?

Infantile spasms (IS) are a rare seizure type that produce brief, sudden body spasms, which occur in clusters and are associated with developmental delays, making effective treatment during a critical window of a child's development imperative. The possible benefit of treatment with VIGADRONE® is reducing spasm frequency in infants with IS. VIGADRONE® therapy has not been proven to improve an infant's development.

Please see Important Safety Information, including an Important Warning for Risk of Permanent Vision Loss on page 2, and accompanying Medication Guide.

INFANTILE SPASM RESOURCES

Sometimes, the cause of IS is unknown. IS can be caused by different conditions, such as tuberous sclerosis complex. Additional information about IS is available online:



Tuberous Sclerosis Alliance

Tuberous Sclerosis Alliance
tsalliance.org



Child Neurology Foundation
childneurologyfoundation.org/infantilespasms





VIGADRONE[®]

(vigabatrin) for Oral Solution

STARTING ON VIGADRONE[®]

Get started on VIGADRONE[®] with Access Pathways[®], a savings and support program that helps patients begin therapy as quickly as possible.

VIGADRONE.com

ACCESS PATHWAYS[®] PROGRAM

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UPSHER-SMITH

Partners in Health Since 1919

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PM-001146.01

MEDICATION GUIDE
VIGADRONE® (vi-ga-drōne)
(vigabatrīn)
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. 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 2 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. Your vision loss may get worse after you stop taking VIGADRONE.
- 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 (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 VIGADRONE, but they do allow the healthcare provider to decide if you (or your child) should stop VIGADRONE 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 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 severe 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 2 years and older with complex partial seizures (CPS) if:
 - the CPS do 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 about all of your medical conditions, including if you or your child:

- have or had an allergic reaction to VIGADRONE, 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. 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. VIGADRONE can cause harm to 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. Information on the registry can also be found at the website <http://www.aedpregnancy.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 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 VIGADRONE.
- **Do not stop taking VIGADRONE without talking to your healthcare provider.** If VIGADRONE improves your (or your child's) seizures, you and your healthcare provider should talk about whether the benefit of taking VIGADRONE is more important than the risk of vision loss and decide if you (or your child) will continue to take VIGADRONE.
- If you are giving VIGADRONE powder for oral solution to your child, it can be given at the same time as their meal. **VIGADRONE for oral solution powder should be mixed with water only.**
- **See "Instructions for Use" for detailed information about how to mix and give VIGADRONE powder for oral solution to your child the right way.**

What should I avoid while taking VIGADRONE?

VIGADRONE causes sleepiness and tiredness. Adults taking VIGADRONE 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 VIGADRONE?

VIGADRONE can cause serious side effects, including:

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

- **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 VIGADRONE.
- **swelling**

If you or your child has CPS, VIGADRONE 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 VIGADRONE in **adults** include blurred vision, sleepiness, dizziness, problems walking or feeling uncoordinated, shaking (tremor) and tiredness.

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

If you are giving VIGADRONE to your baby for IS:

VIGADRONE 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 VIGADRONE in **babies** include:

- sleepiness – VIGADRONE 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 VIGADRONE.

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 VIGADRONE?

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

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

General information about the safe and effective use of VIGADRONE.

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

What are the ingredients in VIGADRONE?

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

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Made in Germany

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

114463-01

Revised 0220

PM-000019.02