STARTING ON VIGADRONE®
AN EQUAL GENERIC SUBSTITUTE WITH BRAND-QUALITY SUPPORT FROM UPSHER-SMITH LABORATORIES, LLC

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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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
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 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

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).

- 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.

- 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).

- 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.

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

**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.

- 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).

- 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.

**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.

- 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.

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**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

tsalliance.org

Child Neurology Foundation

childneurologyfoundation.org/infantilespasms
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

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

Please see Important Safety Information, including an Important Warning for Risk of Permanent Vision Loss on page 2, and accompanying Medication Guide.
What is the most important information I should know about VIGADRONE?

VIGADRONE can cause serious side effects, including:
- Permanent vision loss
- Maintenance of visual function (MRI) changes in babies with intestinal stenoses (IS)

1. Permanent vision loss:
VIGADRONE can damage the vision of anyone who takes it. It can damage vision before damage can happen to your (or your child’s) vision from time to time (periodically) while you (or your baby) are being treated with VIGADRONE, and every 3 months after that until VIGADRONE is stopped. Your vision loss may get worse after you (or your baby) stop taking VIGADRONE.

Your healthcare provider will explain the details of the Vigabatrin REMS Program. VIGADRONE can only be taken if your healthcare provider has determined that the possible benefits of using VIGADRONE in babies are greater than the possible risks. For more information, go to www.vigabatrinREMS.com or call 1-866-244-8175.

2. 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 your healthcare provider decides that the possible benefits of using VIGADRONE in babies are greater than the possible risks. Parents or caregivers are not likely to recognize the symptoms of vision loss in babies until it is severe. If your baby has or ever had vision loss, your healthcare provider will not be able to watch for any vision loss or your (or your child’s) vision may get worse after you (or your child) stop taking VIGADRONE.

- Be sure that your healthcare provider decide to use VIGADRONE for IS and the seizures do not improve. If your child is taking VIGADRONE for IS and the seizures do not improve, your healthcare provider will no longer prescribe VIGADRONE.

Your healthcare provider will determine if you (or your child) should stop taking VIGADRONE if you (or your child) have any of these problems:
- Have or had any nervous or mental illnesses, such as depression, mood disorders, problems, thoughts of suicide, or attempts to harm yourself
- Have or have had low red blood cell counts (anemia)
- Do not drive and your vision is damaged by VIGADRONE, such as having trouble seeing when driving
- Have had suicidal thoughts or actions
- Have had any kidney problems
- Have or have had any nervous or mental illnesses, such as depression, mood disorders, problems, thoughts of suicide, or attempts to harm yourself
- Have or have had low red blood cell counts (anemia)
- Do not drive and your vision is damaged by VIGADRONE, such as having trouble seeing when driving
- Have had suicidal thoughts or actions
- Have had any kidney problems
- Have or have had any nervous or mental illnesses, such as depression, mood disorders, problems, thoughts of suicide, or attempts to harm yourself
- Have or have had low red blood cell counts (anemia)

If you or your child has CPS, before taking VIGADRONE tell your healthcare provider all of your medical conditions, including if you or your child:
- Have had any kidney problems
- Have or have had low red blood cell counts (anemia)
- Have any nervous or mental illnesses, such as depression, mood disorders, problems, thoughts of suicide, or attempts to harm yourself
- Are breastfeeding or planning to breastfeed
- Take any other prescription or nonprescription medicine
- Are pregnant or plan to become pregnant.

Your healthcare provider will explain the details of the Vigabatrin REMS Program. VIGADRONE can only be taken if your healthcare provider has determined that the possible benefits of using VIGADRONE in babies are greater than the possible risks. For more information, go to www.vigabatrinREMS.com or call 1-866-244-8175.

2. Magnetic resonance imaging (MRI) changes in babies with intestinal stenoses:

VIGADRONE is a prescription medicine used along with other medicines. Do not stop taking VIGADRONE suddenly.

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VIGADRONE is a prescription medicine used along with other medicines. Do not stop taking VIGADRONE suddenly.
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?”
- See “What should I avoid while taking VIGADRONE?”
- VIGADRONE may cause your baby to be sleepy. Sleepy babies may have a harder time sucking 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 effects of VIGADRONE in children 3 to 16 years of age in weight gain. Do not expect side effects like these 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 sucking 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.

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