VIGADRONE™
(vigabatrin) for Oral Solution

PRESCRIPTION FORM

Access Pathways® Program Support:
M-F 8am-9pm EST Phone: 1-866-923-1954 Fax prescription forms: 1-877-788-4948
WEEKENDS: Friday 9pm-Sunday 9pm EST Phone: 1-866-923-1954 Fax prescription forms: 1-877-788-4942

HEALTHCARE PROVIDER INSTRUCTIONS:

1. Have your patient (or patient representative) read the PATIENT CONSENT INFORMATION below. Request that the patient (or patient representative) complete the section in the VIGADRONE PRESCRIPTION FORM under "PATIENT INFORMATION". Then have the patient (or patient representative) sign the form in this section.
2. Complete the rest of the PRESCRIPTION FORM under "HEALTHCARE PROVIDER INFORMATION" and attach a copy of both sides of the patient's pharmacy benefit card(s), if available.
3. Fax the completed PRESCRIPTION FORM along with copies of the patient's pharmacy benefit card(s) (both front and back) to the appropriate fax number above, or mail to PO Box 42458, Cincinnati, OH 45242.
4. The Access Pathways® Program will process the PRESCRIPTION FORM and contact your patient (or the patient representative).
5. Prior authorization assistance will only be provided for the indicated disease states. Medicare, Medicaid and other federal or state program health care patients may be ineligible for certain other aspects of the VIGADRONE ACCESS PATHWAYS® PROGRAM.

PATIENT INSTRUCTIONS:

Your healthcare provider will submit the completed VIGADRONE PRESCRIPTION FORM to the Access Pathways Program; we will process your request. **If you have questions, please contact us at 1-866-923-1954.**

PATIENT CONSENT INFORMATION:

Please read the following. If you agree, sign and date the corresponding section of the VIGADRONE PRESCRIPTION FORM.

Authorization to Share Health Information and Participate in VIGADRONE ACCESS PATHWAYS PROGRAM

By signing this Authorization, I authorize my healthcare provider, my health and prescription insurance company, and my pharmacy providers ("Healthcare Entities") to disclose to Upsher-Smith Laboratories, LLC ("Upsher-Smith"), or companies working with Upsher- Smith, including, but not limited to, Triplefin LLC (collectively, "Upsher-Smith Providers"), health information related to my (or the patient I am representing) medical condition, treatment, and insurance coverage and to provide me with support services (and related information and materials) related to VIGADRONE ("Upsher-Smith Product"), and conduct data analytics and other business activities related to such services. Once my health information has been disclosed to Upsher-Smith Providers, I understand that federal privacy laws no longer protect the information. However, Upsher-Smith Providers agree to protect my health information by using and disclosing it only for purposes authorized in this Authorization or as required by law or regulations. I understand that Upsher-Smith Providers may receive payment from Upsher-Smith in exchange for disclosing my Information to the Program and/or for providing me with therapy support services.

Additionally, I authorize Upsher-Smith Providers to provide me with support services related to Upsher-Smith Products, including, but not limited to: online support, financial assistance services, benefits verification, prior authorization, compliance and persistency and other therapy support services as well as any information or materials related to such services (the "VIGADRONE ACCESS PATHWAYS PROGRAM"). I also authorize Upsher-Smith Providers to contact me to provide such services and information by mail, fax, and telephone call. I also authorize Upsher-Smith Providers to use my health information in connection with the support services related to Upsher-Smith Products and as part of the VIGADRONE ACCESS PATHWAYS PROGRAM, including, without limitation, sharing such information with Healthcare Entities. I understand that I may refuse to sign this Authorization. I further understand that treatment (including with Upsher-Smith Products), payment for treatment, insurance enrollment or eligibility for insurance benefits are not conditioned upon my agreement to sign this Authorization; but if I do not sign it or later cancel it, I will not be able to receive VIGADRONE ACCESS PATHWAYS PROGRAM service benefits.

I may cancel this Authorization at any time by mailing a letter to: PO Box 42458, Cincinnati, OH 45242. Canceling this Authorization will end my consent to further disclosure of my health information to Upsher-Smith Providers by my Healthcare Entities after they are notified of my cancellation, but will not affect previous disclosures by them pursuant to this Authorization. Canceling this Authorization will not affect my ability to receive treatment, payment for treatment, or my eligibility for health insurance. This Authorization expires five (5) years, or such shorter timeframe required by applicable law, from the day I sign it as indicated by the date next to my signature unless otherwise canceled earlier as set forth above. I understand I have a right to have a copy of this form.

Please see Important Safety Information, including Boxed Warning for Risk of Permanent Vision Loss, on page 4.
For more information, please see full Prescribing Information and Medication Guide or go to VIGADRONE.com/PI

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PATIENT INFORMATION

Name (First, Middle, Last)_____ Date of Birth_____

Address_____ Gender: ☐ Male ☐ Female

City_____ State_____ Zip_____ Phone_____

Does the patient have any known allergies? (required) ☐ None Known_____

Please list the names of other medications the patient is currently taking.

☐ None Medications_____

Prescription Drug Coverage & Insurance Information

Please check the following that best describes the patient's coverage:

Primary Insurance Type: ☐ Commercial ☐ Medicare Part D ☐ Medicaid ☐ No Insurance ☐ Other_____

Plan Name_____ Member #_____ Group #_____

Policy Holder Name_____ RxBin #_____ RxPCN #_____

Relationship to Policy Holder_____ Does patient have secondary insurance? ☐ Yes ☐ No

NOTE: Medical insurance information cannot be used to determine prescription benefit.

Authorization to Share Health Information and Participate in VIGADRONE ACCESS PATHWAYS PROGRAM

I have read and understand the PATIENT CONSENT INFORMATION and agree to the terms.

Signature of Patient or Patient Representative_____ Date_____

If signed by patient representative, please print your name below and provide your relationship to the patient:

_____

HEALTHCARE PROVIDER INFORMATION

Prescriber Information

Name (First, Middle, Last)_____ Office contact name_____

Address_____ Best time to contact_____

City_____ State_____ Zip_____ Please include preferred method of contact:

NPI #_____ ☐ Phone_____

State License #_____ ☐ Fax_____

HEALTHCARE PROVIDER: Please include the following documents:

1. Patient's prescription for VIGADRONE (see next page) or **electronically prescribe to E-Scribe (NABP) 1487582. For questions please call 1-877-854-3060.**
2. Copies of the patient's pharmacy benefits card(s) front and back, if available.

Authorized Provider

I authorize Upsher-Smith, on behalf of my patient, to forward to the pharmacy and/or insurer the above information required by the insurer for the purpose of conducting a benefit verification.

Prescriber Signature_____ Date_____

Please see Important Safety Information, including Boxed Warning for Risk of Permanent Vision Loss, on page 4.
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Please submit completed pages 2 & 3 by fax, or mail to PO Box 42458, Cincinnati, OH 45242

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STARTER PRESCRIPTION

This starter prescription is available to patients who have been prescribed VIGADRONE for an indicated disease state. This prescription allows patients access to VIGADRONE while VIGADRONE benefits investigation is ongoing (a limited supply may be provided during this time). This prescription will be filled by CompleteCare Pharmacy.

Patient Name:_____ Weight (kg):_____ Height (in):_____ Date of measurements:_____ (mo./day/year)

Date of Birth _____ Serum creatinine (mg/dL):_____ Date of measurement:_____ (mo./day/year)

Prescription: VIGADRONE 500-mg powder for oral solution Quantity (up to 7 days):_____

Today's date (month/day/year): _____ (up to 3):_____

SIG: _____

Primary ICD-10 Code: _____ Secondary ICD-10 Code: _____

Ship to:
Name _____ Address _____

City _____ State _____ Zip _____ Phone _____

_____ _____

PRESCRIBER SIGNATURE **DATE**
(Physician attests this is his/her legal signature. **NO STAMPS**)

Notes: The prescriber should comply with state-specific prescription requirements. Noncompliance could result in outreach to the prescriber. All Access Pathways terms and conditions apply.

PRESCRIPTION

This prescription will be filled by a certified pharmacy. Up to a 12-month supply may be prescribed.

Patient Name:_____ Weight (kg):_____ Height (in):_____ Date of measurements:_____ (mo./day/year)

Date of Birth _____ Serum creatinine (mg/dL):_____ Date of measurement:_____ (mo./day/year)

Prescription: VIGADRONE 500-mg powder for oral solution Quantity:_____

Today's date (month/day/year): _____ Refill Quantity: _____

SIG: _____

Primary ICD-10 Code: _____ Secondary ICD-10 Code: _____

Ship to:

Name _____ Address _____

City _____ State _____ Zip _____ Phone _____

Prescriber Signature (Sign either line **A** or **B** below.) (Physician attests this is his/her legal signature. **NO STAMPS**)

_____ _____ _____ _____

A. DISPENSE AS WRITTEN* **DATE** **B. PRODUCT SUBSTITUTION PERMITTED** **DATE**

*Certain states require "brand medically necessary" or other language to be handwritten by the prescriber if he/she has made this determination in his/her independent clinical judgment.

Notes: The prescriber should comply with state-specific prescription requirements. Noncompliance could result in outreach to the prescriber. All Access Pathways terms and conditions apply.

Please see Important Safety Information, including Boxed Warning for Risk of Permanent Vision Loss, on page 4. For more information, please see full Prescribing Information and Medication Guide or go to VIGADRONE.com/PI

Please submit completed pages 2 & 3 and accompanying information by fax, or mail to PO Box 42458, Cincinnati, OH 45242

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WHAT IS VIGADRONE™?

VIGADRONE™ (vigabatrin) 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 10 years and older if:
  - o The CPS does not respond well enough to several other treatments, and
  - o 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.

WHAT IMPORTANT SAFETY INFORMATION SHOULD I KNOW ABOUT VIGADRONE?

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 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. 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"). 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 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 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.**

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: problems walking or feeling uncoordinated, feeling dizzy, shaking (tremor), joint pain, memory problems and not thinking clearly, and eye problems like blurry vision, double vision, and eye movements that cannot be controlled.

The most common side effects of VIGADRONE in children 10 to 16 years of age include weight gain, upper respiratory tract infection, tiredness, and aggression. Also expect side effects like those seen in adults.

The most common side effects of VIGADRONE in babies include: sleepiness—some 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.