NOTE: WEEKEND AND AFTER HOURS FAX NUMBER IS 1-877-827-0395

VIGADRONE®
(vigabatrin)
500 mg for Oral Solution
500 mg Tablets

PRESCRIPTION FORM

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

HEALTHCARE PROVIDER INSTRUCTIONS:

1. Have your patient (or patient representative) read the "AUTHORIZATION TO SHARE HEALTH INFORMATION WITH VIGADRONE ACCESS PATHWAYS PROGRAM." 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: 24 Summit Park Drive, Suite 101, Pittsburgh, PA 15275.
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 the request. **If you have questions, please contact us at 1-866-923-1954.**

AUTHORIZATION TO SHARE HEALTH INFORMATION WITH VIGADRONE ACCESS PATHWAYS PROGRAM:

Patient or Patient Representative(s): Please read the following. If you agree, sign and date the corresponding section of the VIGADRONE PRESCRIPTION FORM.

AUTHORIZATION TO SHARE HEALTH INFORMATION WITH VIGADRONE ACCESS PATHWAYS PROGRAM

By signing this authorization, I authorize and consent to 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 (collectively, "Upsher-Smith Providers") or use, personal information related to my (or the patient I am representing) medical condition, treatment, and insurance coverage ("Information") for the purposes of contacting me or providing me with support services such as online support, financial assistance, benefits verification, prior authorization assistance, compliance and persistency support, and education related to VIGADRONE and conduct data analytics and other business activities related to such services. I understand I may be contacted by mail, email, text, telephone or in person about such services. Once my Information has been disclosed to Upsher-Smith Providers, I understand that federal privacy laws may no longer protect the information and that the Information will be subject to the Upsher-Smith privacy statement located at www.upsher-smith.com. I understand that Upsher-Smith Providers and Healthcare Entities may receive payment from Upsher-Smith in exchange for using or disclosing my Information. I understand that I may refuse to sign this Authorization. I further understand that my treatment is not conditioned upon my agreement to sign this Authorization; but if I do not sign it or later opt-out or cancel it, I will not be able to receive Program services. I may cancel this Authorization or opt-out from receiving communications from Upsher-Smith Providers and Healthcare Entities at any time by clicking on the unsubscribe link in future communications or by mailing a letter to: 24 Summit Park Drive, Suite 101, Pittsburgh, PA 15275. Canceling this authorization will not affect previous disclosures pursuant to this authorization. This authorization expires five (5) years from the day I sign it as indicated by the date next to my signature unless I revoke it before. I understand I have a right to have a copy of this form. Please sign in the space in the PATIENT INFORMATION section on the following page to authorize your consent.

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

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PATIENT INFORMATION

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

Address_____ Gender: ☐ Male ☐ Female

City_____State_____Zip_____Phone_____Email_____

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 WITH VIGADRONE ACCESS PATHWAYS PROGRAM

I have read and understand the Authorization to Share Health Information with VIGADRONE ACCESS PATHWAYS PROGRAM 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) 6001565. For prescribing questions please call 1-866-500-4570.**
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.
For more information, please see full Prescribing Information and Medication Guide or go to VIGADRONE.com

Please submit completed pages 2 & 3 and accompanying information by fax, or mail to: 24 Summit Park Drive, Suite 101, Pittsburgh, PA 15275

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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 PANTHERx® Specialty Pharmacy.

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

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)

Today's date (month/day/year): _____ Refills (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 PANTHERx® Specialty Pharmacy. Up to a 12-month supply may be prescribed.

Prescription: ☐ VIGADRONE 500 mg **powder for oral solution** ☐ VIGADRONE 500 mg **tablets** Quantity:_____

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)

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

Please submit completed pages 2 & 3 and accompanying information by fax, or mail to: 24 Summit Park Drive, Suite 101, Pittsburgh, PA 15275

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WHAT IMPORTANT SAFETY INFORMATION SHOULD I KNOW ABOUT VIGADRONE® (vigabatrin)?

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.** 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 patients 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 patients,** 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 patients with infantile spasms (IS).** Brain pictures taken by MRI show changes in some patients after they are given VIGADRONE. It is not known if these changes are harmful.
- **A type of swelling in the brain called intramyelinic edema (IME) has been seen** in autopsy examination of patients treated with vigabatrin.
- **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. Breastfeeding is not recommended.

If you are pregnant or plan to become pregnant, VIGADRONE can cause 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.

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 it is not all the safety information. For more information, ask your healthcare provider or pharmacist, or please see the 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 IS VIGADRONE?

VIGADRONE (vigabatrin) is a prescription medicine used to treat:

- **Infantile Spasms (IS)** in patients 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)** in adults and children 2 years and older with refractory complex partial seizures (CPS) along with other treatments if:
    - o The CPS do 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.