I. Administrative Information

Initial Shared System REMS Approval: 04/2017
Most Recent REMS Update: 10/2020

II. REMS Goal

The goal of the Vigabatrin REMS Program is to mitigate the risk of vision loss associated with vigabatrin by:

1. Ensuring that healthcare providers are educated about the risk of vision loss, the need to counsel patients about the risk, and the need for periodic visual monitoring.

2. Ensuring that vigabatrin is only dispensed to patients with documentation that patients are informed about the risk of vision loss associated with vigabatrin and the need for periodic visual monitoring.

III. REMS Requirements

The Vigabatrin Applicants must ensure that healthcare providers, patients, pharmacies, and wholesalers-distributors comply with the following requirements:

1. Healthcare Providers who prescribe vigabatrin products must:

   To become certified to prescribe
   
   1. Review the drug’s Prescribing Information.
   
   2. Enroll in the REMS by completing the Prescriber Enrollment and Agreement Form and submitting it to the REMS Program.

   Before treatment initiation (first dose)

   3. Counsel the patient on the risks associated with vigabatrin, including vision loss, and the need for periodic visual monitoring.

   4. Provide the patient with the Patient Guide.

   5. Enroll the patient by completing and submitting the Patient/Parent/Legal Guardian-Physician Agreement Form to the REMS Program. Provide a completed copy of the form to the patient. Retain a completed copy in the patient’s record.

   At all times

   6. Assess the patient’s vision, including ophthalmologic assessments, as described in the Prescribing Information.

   7. Report any adverse event suggestive of vision loss to the REMS Program.
2. Patients who are prescribed vigabatrin products:

<table>
<thead>
<tr>
<th>Before treatment initiation</th>
<th>1. Review the <a href="#">Patient Guide</a>.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2. Enroll in the REMS Program by completing the <a href="#">Patient/Parent/Legal-Guardian-Physician Agreement Form</a> with the prescriber. Enrollment information will be provided to the REMS Program.</td>
</tr>
<tr>
<td></td>
<td>3. Receive counseling from the prescriber on the risk of vision loss, the need for periodic visual monitoring, including ophthalmologic assessments.</td>
</tr>
<tr>
<td>At all times</td>
<td>4. Get vision testing, including ophthalmologic assessments, as described in the <a href="#">Patient Guide</a>.</td>
</tr>
<tr>
<td></td>
<td>5. Inform the prescriber if you experience any problems when using vigabatrin or if you stop taking vigabatrin.</td>
</tr>
</tbody>
</table>

3. Outpatient pharmacies that dispense vigabatrin products must:

<table>
<thead>
<tr>
<th>To become certified to dispense</th>
<th>1. Designate an authorized representative to carry out the certification process and oversee implementation and compliance with the REMS Program on behalf of the pharmacy.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2. Have the authorized representative enroll in the REMS Program by completing the <a href="#">Pharmacy Enrollment Form</a> and submitting it to the REMS Program.</td>
</tr>
<tr>
<td></td>
<td>3. Train all relevant staff involved in dispensing on the REMS Program requirements.</td>
</tr>
<tr>
<td>Before dispensing</td>
<td>4. Obtain authorization to dispense each prescription by contacting the REMS program or via the REMS Program Website. Document the confirmed prescriber and patient identification numbers, and authorization code.</td>
</tr>
<tr>
<td>To maintain certification to dispense</td>
<td>5. Have the new authorized representative enroll in the REMS Program by completing the <a href="#">Pharmacy Enrollment Form</a> if the authorized representative changes.</td>
</tr>
<tr>
<td>At all times</td>
<td>6. Comply with audits carried out by Vigabatrin Applicants, or a third party acting on behalf of the Vigabatrin Applicants to ensure that all processes and procedures are in place and are being followed.</td>
</tr>
</tbody>
</table>

4. Inpatient pharmacies that dispense vigabatrin products must:
To become certified to dispense

1. Designate an authorized representative to carry out the certification process and oversee implementation and compliance with the REMS Program on behalf of the pharmacy.

2. Have the authorized representative enroll in the REMS Program by completing the Pharmacy Enrollment Form and submitting it to the REMS Program.

3. Train all relevant staff involved in dispensing on the REMS Program requirements.

4. Establish processes and procedures to verify the patient is enrolled in the REMS Program before dispensing.

5. Establish processes and procedures to verify that within 15 days of inpatient admission a certified prescriber authorizes continuing treatment for an enrolled patient.

Before dispensing

6. Verify the patient is enrolled through the processes and procedures established as a requirement of the REMS Program. Document the patient identification number.

During treatment, within 15 days of inpatient admission

7. Obtain authorization to continue dispensing by contacting the REMS program or via the REMS Program Website to verify a certified prescriber authorizes continuing vigabatrin for an enrolled patient. Document the confirmed prescriber and patient identification numbers and authorization code.

Upon discharge

8. Dispense no more than a 15 days’ supply.

To maintain certification to dispense

9. Have the new authorized representative enroll in the REMS Program by completing the Pharmacy Enrollment Form if the authorized representative changes.

At all times

10. Comply with audits carried out by Vigabatrin Applicants, or a third party acting on behalf of the Vigabatrin Applicants to ensure that all processes and procedures are in place and are being followed.

5. Wholesalers-distributors that distribute vigabatrin products must:

To be able to distribute

1. Establish processes and procedures to ensure that the drug is distributed only to certified pharmacies.

2. Train all relevant staff involved in distributing on the REMS program requirements.
At all times

3. Distribute only to certified pharmacies.

4. Maintain and submit records of all distributions to the REMS Program.

5. Comply with audits carried out by Vigabatrin Applicants, or a third party acting on behalf of Vigabatrin Applicants to ensure that all processes and procedures are in place and are being followed.
To support REMS Program operations, the Vigabatrin Applicants must:

1. Establish and maintain a REMS Program website, www.vigabatrinREMS.com. The REMS Program website must include the capability to complete prescriber and pharmacy certification online, to enroll patients online, to obtain authorization to dispense, and the option to print the Prescribing Information, Medication Guide and REMS Materials. All product websites for consumers and healthcare providers must include prominent REMS-specific links to the REMS Program website. The REMS Program website must not link back to the promotional product website(s).
2. Make the REMS Program website fully operational and all REMS materials available through the website and the call center within 30 calendar days after approval of the Vigabatrin REMS Program.
3. Establish and maintain a REMS Program call center for all REMS participants at 1-866-244-8175.
4. Establish and maintain a validated, secure database of all REMS participants who are enrolled and/or certified in the Vigabatrin REMS Program.
5. Ensure that prescribers are able to become certified in the REMS by mail, fax, and online.
6. Ensure that prescribers are able to enroll patients in the REMS by mail, fax and online.
7. Ensure that pharmacies are able to become certified in the REMS by mail, fax and online.
8. Ensure outpatient pharmacies are able to obtain authorization to dispense including the prescriber and patient identification numbers and authorization code by phone or online.
9. Ensure inpatient pharmacies are able to verify patient enrollment and obtain authorization to continue vigabatrin treatment including the prescriber and patient identification numbers and authorization code by phone or online.
10. Ensure wholesalers-distributors are able to verify pharmacy certification and obtain shipment authorization by phone or online.
11. Ensure prescribers are able to report any adverse event suggestive of vision loss by phone.
12. Provide the Prescriber Enrollment and Agreement Form and the Prescribing Information to healthcare providers who (1) attempt to prescribe vigabatrin and are not yet certified, or (2) inquire about how to become certified.
13. Notify prescribers within 2 business days after they become certified in the REMS program.
14. Provide the Pharmacy Enrollment Form to pharmacies who (1) attempt to dispense vigabatrin and are not yet certified or (2) inquire about how to become certified.
15. Notify pharmacies within two business days after they become certified in the REMS Program.
16. Provide certified prescribers access to the database of certified pharmacies and enrolled patients.
17. Provide certified pharmacies access to the database of certified prescribers and enrolled patients.

To ensure REMS participants’ compliance with the REMS Program, the Vigabatrin Applicants must:

18. Verify annually that the designated authorized representative for the certified pharmacy remains the same. If different, the pharmacy must recertify with a new authorized representative.
19. Maintain adequate records to demonstrate that REMS requirements have been met, including, but not limited to records of: vigabatrin distribution and dispensing; certification of prescribers, pharmacies, and wholesalers-distributors; enrolled patients; and audits of REMS participants. These records must be readily available for FDA inspections.

20. Establish a plan for addressing noncompliance with REMS Program requirements.

21. Monitor prescribers, pharmacies and wholesalers-distributors on an ongoing basis to ensure the requirements of the REMS are being met. Take corrective action if non-compliance is identified, including de-certification.

22. Audit pharmacies and wholesalers-distributors no later than 90 calendar days after they become certified/authorized, to ensure that all REMS processes and procedures are in place, functioning, and support the REMS Program requirements. Include 20% of certified inpatient pharmacies and 20% of certified outpatient pharmacies in the ongoing annual audit plan.

23. Take reasonable steps to improve implementation of and compliance with the requirements in the Vigabatrin REMS Program based on monitoring and evaluation of the Vigabatrin REMS Program.

IV. **REMS Assessment Timetable**

The Vigabatrin NDA Applicants must submit REMS Assessments annually from the date of the initial approval of the REMS (04/27/2017). To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than 60 calendar days before the submission date for that assessment. The Vigabatrin REMS NDA Applicants must submit each assessment so that it will be received by the FDA on or before the due date.

V. **REMS Materials**

The following materials are part of the Vigabatrin REMS:

**Enrollment Forms:**
- Prescriber:
  1. Prescriber Enrollment and Agreement Form
- Patient:
  2. Patient/Parent/Legal-Guardian-Physician Agreement Form
- Pharmacy:
  3. Pharmacy Enrollment Form

**Training and Educational Materials**
- Patient:
  4. Patient Guide

**Other Materials**
- 5. REMS Program website
PRESCRIBER ENROLLMENT AND AGREEMENT FORM

For real-time processing of the Vigabatrin REMS Program Prescriber Enrollment and Agreement Form, go to www.vigabatrinREMS.com to enroll online. To submit this form via fax, please complete all required fields below and fax both pages to the Vigabatrin REMS Program at 1-866-205-3072. You will receive confirmation of your certification via e-mail.

Vigabatrin is available only through a restricted distribution REMS program called the Vigabatrin REMS Program. The Vigabatrin REMS Program is available to answer questions regarding this program and initiating treatment with vigabatrin. Please call 1-866-244-8175 for assistance.

Vigabatrin is indicated as monotherapy for pediatric patients 1 month to 2 years of age with infantile spasms (IS) and as adjunctive therapy for patients 2 years of age and older with refractory complex partial seizures (CPS) who have inadequately responded to several alternative treatments, for whom the potential benefits outweigh the potential risk of vision loss. Vigabatrin is not indicated as a first line agent for CPS.

By completing, signing, and submitting this form, I acknowledge that I have reviewed the Prescribing Information for vigabatrin, and I agree to be enrolled in the Vigabatrin REMS Program.

As a condition of certification:

- I will enroll each patient in the Vigabatrin REMS Program by:
  - Counseling the patients/parents/legal guardians considering treatment on the benefits and risks of vigabatrin, including permanent vision loss and the need for periodic monitoring of vision, and providing them with a copy of What You Need to Know About Vigabatrin Treatment: A Patient Guide
  - Completing the Vigabatrin REMS Program Patient/Parent/Legal Guardian–Physician Agreement Form for each patient and providing a completed copy to the patient/parent/legal guardian. I will submit the completed form to the Vigabatrin REMS Program and store a copy in the patient’s records

- Ensuring that periodic monitoring of vision, as described in the Prescribing Information, is performed on an ongoing basis for each patient

- Reporting any adverse event suggestive of vision loss to the Vigabatrin REMS Program with all available information

I understand that if I do not maintain compliance with the requirements of the Vigabatrin REMS, I will no longer be able to prescribe vigabatrin

Prior to dispensing vigabatrin, the Vigabatrin REMS Program will provide a confirmation of certification to the e-mail address listed on page 2.

For additional information, visit www.vigabatrinREMS.com or call the Vigabatrin REMS Program at 1-866-244-8175.

Form continues on page 2.
PRESCRIBER ENROLLMENT AND AGREEMENT FORM

Form continued from page 1.

For real-time processing of the Vigabatrin REMS Program Prescriber Enrollment and Agreement Form, go to www.vigabatrinREMS.com to enroll online. To submit this form via fax, please complete all required fields below and fax both pages to the Vigabatrin REMS Program at 1-866-205-3072. You will receive confirmation of your certification via e-mail.

Note: Fields marked with an * are REQUIRED.

*First Name ___________________________ Middle Initial ___________________________ Last Name ___________________________

*Prescriber NPI# ___________________________

Institution Name (if applicable) ___________________________

*Prescriber Address

Street ___________________________ City ___________________________ State ___________________________ ZIP Code ___________________________

*Telephone Number ___________________________ Alternative Telephone Number ___________________________

Area Code/Telephone Number ___________________________ Area Code/Telephone Number ___________________________

*Office Fax Number ___________________________

Area Code/Fax Number ___________________________

*Email ___________________________

Prescriber Degree  

☐ MD  ☐ DO  ☐ NP  ☐ PA  ☐ Other

Specialty  

☐ Epileptology  ☐ Neurology  ☐ Pediatric Neurology  ☐ Internal Medicine  ☐ Other

Office Contact Name

First ___________________________ Last ___________________________ Area Code/Telephone Number ___________________________

Second Contact Name

First ___________________________ Last ___________________________ Area Code/Telephone Number ___________________________

*Prescriber Signature ___________________________ *Date ___________________________

Month/Day/Year

By completing, signing, and submitting this form and receiving certification confirmation by e-mail, you will be certified in the Vigabatrin REMS Program and may begin prescribing vigabatrin. You only need to enroll and complete the certification in the program once, and you are under no obligation to prescribe vigabatrin.

To report Adverse Events, please contact the Vigabatrin REMS Program at 1-866-244-8175
For real-time processing of the Vigabatrin REMS Program Patient/Parent/Legal Guardian–Physician Agreement Form, go to www.vigabatrinREMS.com to enroll online. To submit this form via fax, please complete all required fields below and fax both pages to the Vigabatrin REMS Program at 1-866-205-3072.

Vigabatrin is available only through a restricted distribution Risk Evaluation and Mitigation Strategy (REMS) program called the Vigabatrin REMS Program. The Vigabatrin REMS Program is available to answer questions regarding this program and initiating treatment with vigabatrin. Please call 1-866-244-8175 for assistance.

To the Physician:

Completed forms must be submitted to the Vigabatrin REMS Program prior to treatment initiation. Place the original signed document in the patient’s medical record and provide a copy to the patient, parent, or legal guardian.

For the Patient or Parent/Legal Guardian:

Patient: I, ________________________________, am the patient. I am able to read and understand this document and will sign for myself.

OR

Parent/Legal Guardian: I am the parent/legal guardian of ________________________________, who is the patient. I am able to read and understand this document and will sign it where appropriate on behalf of the patient.

To use vigabatrin appropriately, the patient/parent/legal guardian should:

- Be aware that vigabatrin can cause serious vision problems in some people
- Be provided and have read What You Need to Know About Vigabatrin Treatment: A Patient Guide
- Be counseled by the prescriber regarding the risks associated with vigabatrin, including permanent vision loss
- Be counseled by the prescriber regarding the need for periodic monitoring of vision, including ophthalmologic assessments, based on the recommendations in the Prescribing Information
- Report to the doctor any problems you or your child might experience when using vigabatrin as soon as they happen
- Visit the doctor regularly to make sure that taking vigabatrin continues to be right for you/your child to take

This agreement is to be completed and signed by the patient/parent/legal guardian and the doctor. Each person who signs must read each item below and, if every item is understood, sign where indicated at the end of this agreement. Do not sign this agreement, or take vigabatrin yourself, or give vigabatrin to your child, if there are any unanswered questions.

I, ________________________________, have been provided and have read What You Need to Know About Vigabatrin Treatment: A Patient Guide. The doctor has explained the risk of permanent vision loss, as well as the need for periodic vision testing and the recommended times that the tests should be done.

Prescriber NPI# __________________________  Form continues on page 2.
For real-time processing of the Vigabatrin REMS Program Patient/Parent/Legal Guardian–Physician Agreement Form, go to www.vigabatrinREMS.com to enroll online. To submit this form via fax, please complete all required fields below and fax both pages to the Vigabatrin REMS Program at 1-866-205-3072.

1. The doctor and I have talked about my/my child’s epilepsy. We have also talked about the potential benefits and risks of taking vigabatrin.
2. I understand that vigabatrin will be prescribed for me or my child only. I will not share vigabatrin with other people.
3. The doctor has discussed with me other treatments for my/my child’s epilepsy. We have decided that vigabatrin is the right treatment. I understand that vigabatrin can be discontinued at any time. I also know that I/my child cannot stop taking vigabatrin without the doctor telling me to do so.
4. I agree to tell the doctor if a decision is made to stop taking vigabatrin. I understand that if my/my child’s treatment is abruptly stopped, my/my child’s seizures might increase or return.
5. All my questions were answered to my satisfaction. I now authorize the doctor, ________________________________, to begin my/my child’s treatment with vigabatrin.

I have read and understood all of the information presented above and agree to use vigabatrin therapy and agree to participate in the Vigabatrin REMS Program.

**Patient/Parent/Legal Guardian Agreement**

To be signed by patient/parent/legal guardian when starting of vigabatrin therapy.

*Signature* ________________________________  *Date* __________

*Patient Name* ________________________________  Telephone ________________________________

Patient/Parent/Legal Guardian Email Address ________________________________

Patient Address

Street

City  State  ZIP Code

*Patient Date of Birth* __________

*Physician Agreement*

I, ________________________________, have fully explained to the patient/parent/legal guardian the potential benefits and risks of vigabatrin treatment, including permanent vision loss and the need for periodic vision monitoring. I have provided the patient/parent/legal guardian with the document, What You Need to Know About Vigabatrin Treatment: A Patient Guide, and have answered all questions regarding therapy with vigabatrin. Upon completion of this agreement form, I will store a copy of the form in the patient’s record and will provide the patient/parent/legal guardian a copy of the form.

To be signed by physician upon initiation of vigabatrin therapy.

*Signature* ________________________________  *Date* __________

Prescriber NPI# ________________________________
Pharmacy Enrollment Form

INSTRUCTIONS

• Review and complete this Pharmacy Enrollment Form (this is a one-time enrollment)
• Enroll online at www.vigabatrinREMS.com or complete all required fields below and fax all pages to Vigabatrin REMS at 1-866-205-3072.

You will receive confirmation of your certification and log-in credentials for the assigned authorized representative via e-mail.

*Authorized Representative Name
First Name
Last Name
Middle Initial

*Authorized Representative Title/Position

*Telephone Number
Area Code/Telephone Number

*Office Fax Number
Area Code/Fax Number

*E-mail

*Preferred Method of Communication (please select one)
Fax
E-mail
Phone

*Authorized Representative Signature

*Date
Month/Day/Year

Pharmacy Location Information

*Pharmacy Name

*Pharmacy Address
Street
City
State
ZIP Code

*Pharmacy Phone Number
Area Code/Telephone Number

*Pharmacy Fax Number
Area Code/Fax Number

*Select either inpatient or outpatient below and provide the appropriate identifier(s).

☐ Inpatient Pharmacy Identifiers

☐ Outpatient Pharmacy Identifiers

*NPI: ________________________________  NCPDP: ________________________________

☐ If you are enrolling more than one pharmacy location, check this box and provide the information on page 3 for each site. Use as many forms as necessary.

By completing and submitting this form as directed above and receiving certification confirmation, your pharmacy will be certified in the Vigabatrin REMS.

Authorized Representative: Please PRINT your name and phone number here. This will ensure that all pages of your enrollment record are collated accurately.

*Name
Last
First
Middle Initial

*Telephone Number
Area Code/Telephone Number
Authorized Representative Responsibilities

I am the authorized representative designated by my pharmacy to coordinate the activities of the Vigabatrin REMS and I understand:

☐ Pharmacies must be certified in the Vigabatrin REMS to order and dispense vigabatrin
☐ As the authorized representative for my pharmacy, I must oversee the implementation and compliance with the Vigabatrin REMS requirements
☐ The pharmacy must recertify if the name and contact information for the authorized representative is changed

As the authorized representative designated by my pharmacy to coordinate the activities of the Vigabatrin REMS, I agree on behalf of my pharmacy to comply with the following program requirements:

☐ My pharmacy must establish procedures and protocols designed to ensure compliance with the Vigabatrin REMS, including the following, prior to dispensing vigabatrin:
  ☐ Ensure that all relevant staff involved in dispensing vigabatrin are trained on the Vigabatrin REMS requirements
  ☐ Comply with requests by the Sponsors (manufacturers of vigabatrin), and/or their designated third party to be audited at any time to ensure that all Vigabatrin REMS processes and procedures are in place and are being followed, and appropriate documentation is maintained and available upon request
  ☐ The pharmacy must recertify if the name and contact information for the authorized representative are changed

For Outpatient Pharmacies only:

☐ For each prescription, verify that the prescriber is certified and the patient is enrolled in the Vigabatrin REMS prior to each dispensing of vigabatrin by logging on to www.vigabatrinREMS.com. Document confirmed prescriber and patient identification numbers as well as the authorization code to dispense, as assigned by the Vigabatrin REMS. If a prescriber or patient is not properly enrolled in the program, the pharmacy should direct the prescriber to www.vigabatrinREMS.com for enrollment information or contact the Vigabatrin REMS to facilitate prescriber enrollment

For Inpatient Pharmacies only:

☐ Verify the patient is enrolled in the Vigabatrin REMS prior to dispensing vigabatrin by logging on to www.vigabatrinREMS.com. Document the patient identification number.
☐ Obtain authorization to continue dispensing by contacting the REMS Program to verify a certified prescriber authorizes continuing vigabatrin treatment within 15 days of the patient’s admission to the healthcare facility. Document confirmed prescriber and patient identification numbers as well as the authorization code to dispense, as assigned by the Vigabatrin REMS.
☐ Do not dispense more than a 15-day temporary supply of vigabatrin to a patient upon discharge from the healthcare facility

If I do not maintain compliance with the requirements of the Vigabatrin REMS, I will no longer be able to dispense vigabatrin

Please note: Enrolled pharmacies are only authorized to order vigabatrin from Vigabatrin REMS sponsors or contracted distributors. If you have any questions or require additional information, please visit the Vigabatrin REMS website (www.vigabatrinREMS.com) or call the Vigabatrin REMS (1-866-244-8175).
Access this form and enroll online at www.vigabatrinREMS.com.
To submit this form via fax, please complete all required fields below and fax all pages to the Vigabatrin REMS at 1-866-205-3072.

Note: Fields marked with an * are REQUIRED.

If you are enrolling more than one pharmacy location, the following information will need to be provided for each site. Use additional forms as necessary.

### Pharmacy Location Information

<table>
<thead>
<tr>
<th>*Pharmacy Name</th>
<th>*Pharmacy Address</th>
<th>*Pharmacy Phone Number</th>
<th>*Pharmacy Fax Number</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Street</td>
<td>City</td>
<td>State</td>
</tr>
<tr>
<td></td>
<td>City</td>
<td>State</td>
<td>ZIP Code</td>
</tr>
<tr>
<td></td>
<td>Area Code/Telephone Number</td>
<td>Area Code/Fax Number</td>
<td></td>
</tr>
</tbody>
</table>

*Select either inpatient or outpatient below and provide the appropriate identifier(s).

- [ ] Inpatient Pharmacy Identifiers
- [ ] Outpatient Pharmacy Identifiers

<table>
<thead>
<tr>
<th>*NPI:</th>
<th>NCPDP:</th>
</tr>
</thead>
</table>

Reference ID: 4679228
WHAT YOU NEED TO KNOW ABOUT VIGABATRIN TREATMENT: A PATIENT GUIDE

Patients/Parents/Legal Guardians:
Before beginning vigabatrin therapy, your healthcare provider will go over the risks associated with vigabatrin and provide this patient guide to you. It is very important that you read this and ask any questions you might have about vigabatrin before or during your or your child’s treatment. Keep this guide for important safety information about serious risks involved with taking vigabatrin.

Healthcare Providers:
Please review the risks associated with vigabatrin, including vision loss and the need for periodic monitoring with your patient and/or parent/legal guardian. Please also provide a copy of this patient guide for them to take home. Healthcare providers should ensure that periodic visual monitoring, as described in the Prescribing Information, is performed on an ongoing basis.

What Is Vigabatrin?
Vigabatrin is a prescription medication used with other treatments in adults and children 2 years of age and older with refractory complex partial seizures (CPS), who have not responded well enough to several other treatments and for whom the potential benefits outweigh the risk of vision loss.

Vigabatrin is also used to treat babies 1 month to 2 years of age who have infantile spasms (IS) and for whom the potential benefits outweigh the potential risk of vision loss.

Vigabatrin is available only through certified healthcare providers and pharmacies.

What Is the Most Serious Risk Information About Vigabatrin Treatment?
- Vigabatrin can cause permanent vision damage to anyone who takes it
  Some people can have severe vision 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 can occur with any amount of vigabatrin
  It is not possible for your healthcare provider to know when vision loss will happen. It could happen soon after starting vigabatrin or any time during treatment. It may even happen after treatment has stopped. Your vision loss may get worse after you stop taking SABRIL.
  Your healthcare provider will discuss periodic vision monitoring with you. Even if your or your child’s vision seems fine, it is important that regular vision tests are done 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 vigabatrin, but they do allow the healthcare provider to decide if you or your child should stop taking vigabatrin if vision has gotten worse. Vision testing may not detect vision loss before it is severe.
What Are the Signs of Vision Loss With Vigabatrin Treatment?

Symptoms of vision loss from vigabatrin are unlikely to be recognized by patients or parents/legal guardians before it is severe.

Tell your healthcare provider right away if you notice any of the following signs in you or your child, as these changes can mean that vision damage has occurred:

- Loss in the ability to see to the side when looking straight ahead (peripheral vision)
- Blurry vision
- Not seeing as well as before starting vigabatrin
- Starting to trip, bump into things, or being more clumsy than usual
- Being surprised by people or things coming in front of you that seem to come out of nowhere
- Your baby is acting differently than normal

These are NOT all the possible side effects of vigabatrin. Refer to the vigabatrin Medication Guide that will be given to you when you receive your prescription and talk to your healthcare provider for medical advice about other side effects.

What Can I Do to Help Reduce the Risk of Vision Loss With Vigabatrin?

- Before starting treatment with vigabatrin, discuss how often vision testing should be done with your or your child’s healthcare provider
  Regular visits to an ophthalmologist or optometrist may help you decide if or when you or your child should stop vigabatrin, but it will not prevent vision loss.

- Visit an ophthalmologist or optometrist as recommended by your healthcare provider
  Report any changes in your or your child’s vision to your doctor as soon as possible.

- Tell your healthcare provider right away if you notice any of the following in you or your child:
  - Not seeing as well as before starting vigabatrin
  - Starting to trip or bump into things, or being more clumsy than usual
  - Being surprised by people or things coming in front of you that seem to come out of nowhere
  - Your baby is acting differently than normal

How Should I Take Vigabatrin?

- Take vigabatrin exactly as the healthcare provider tells you to
- Vigabatrin is usually taken 2 times each day
- Vigabatrin may be taken with or without food
- Do not stop taking vigabatrin without talking to your healthcare provider. This can cause serious problems
- See “Instructions for Use” for detailed information about how to mix and give vigabatrin powder for oral solution to your child the right way

Where Can I Get More Information About Vigabatrin?

You should receive a vigabatrin Medication Guide with each prescription. You can also find more information at www.vigabatrinREMS.com or call the Vigabatrin REMS Program at the toll-free number 1-866-244-8175.
VIGABATRIN RISK EVALUATION AND MITIGATION STRATEGY (REMS) PROGRAM

What is the Vigabatrin REMS Program?
A REMS is a strategy to manage known or potential serious risks associated with a drug product, and is required by the Food and Drug Administration (FDA) to ensure the benefits of a drug outweigh its risks.

The purpose of the Vigabatrin REMS Program is to mitigate vision loss associated with vigabatrin by:

• Ensuring that healthcare providers are educated about the risk of vision loss, the need to counsel patients about the risk, and the need for periodic visual monitoring
• Ensuring that vigabatrin is dispensed only to patients with documentation that they are informed about the risk of vision loss associated with vigabatrin and the need for periodic visual monitoring

INDICATIONS AND USAGE

Refractory Complex Partial Seizures (CPS)
Vigabatrin is indicated as adjunctive therapy for patients 2 years of age and older with refractory complex partial seizures (CPS) who have inadequately responded to several alternative treatments and for whom the potential benefits outweigh the risk of vision loss. Vigabatrin is not indicated as a first line agent for CPS.

Infantile Spasms (IS)
Vigabatrin is indicated as monotherapy for pediatric patients 1 month to 2 years of age with infantile spasms (IS) for whom the potential benefits outweigh the potential risk of vision loss.

Click here for a list of products covered under the Vigabatrin REMS Program
VIGABATRIN RISK EVALUATION AND MITIGATION STRATEGY (REMS) PROGRAM

What is the VIGABATRIN REMS Program?
A REMS is a strategy to manage known or potential serious risks associated with a drug product, and is required by the Food and Drug Administration (FDA) to ensure the benefits of a drug outweigh its risks.

The purpose of the VIGABATRIN REMS Program is to mitigate vision loss associated with vigabatrin by:

- Ensuring that healthcare providers are educated about the risk of vision loss, the need to counsel patients about the risk, and the need for periodic visual monitoring.
- Ensuring that vigabatrin is dispensed only to patients with documentation that they are informed about the risk of vision loss associated with vigabatrin and the need for periodic visual monitoring.

INDICATIONS AND USAGE

Refractory Complex Partial Seizures (CPS)
Vigabatrin is indicated as adjunctive therapy for patients 2 years of age and older with refractory complex partial seizures (CPS) who have inadequately responded to several alternative treatments and for whom the potential benefits outweigh the risk of vision loss. Vigabatrin is not indicated as a first line agent for CPS.

Infantile Spasms (IS)
Vigabatrin is indicated as monotherapy for pediatric patients 1 month to 2 years of age with infantile spasms (IS) for whom the potential benefits outweigh the potential risk of vision loss.

Click here for a list of products covered under the VIGABATRIN REMS Program.
LIST OF PRODUCTS COVERED UNDER THE VIGABATRIN REMS PROGRAM

BRAND NAME PRODUCTS

<table>
<thead>
<tr>
<th>Trade Name</th>
<th>Generic Name</th>
<th>Dosage Form(s)</th>
<th>Company</th>
<th>Contact</th>
<th>Links</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The vigabatrin REMS sponsors attest that the table above (intentionally left blank) will only include products listed in the link titled 'What medicines are included in the REMS' on the FDA Approved REMS website.

GENERIC PRODUCTS

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Generic Name</th>
<th>Dosage Form(s)</th>
<th>Company</th>
<th>Contact</th>
<th>Links</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The vigabatrin REMS sponsors attest that the table above (intentionally left blank) will only include products listed in the link titled 'What medicines are included in the REMS' on the FDA Approved REMS website.
Prescriber Certification

Healthcare providers must be certified in the Vigabatrin REMS Program in order to prescribe vigabatrin.

Vigabatrin REMS Program Enrollment and Treatment Initiation, Step by Step

**NOTE:** All currently certified prescribers in the SABRIL REMS Program will be transitioned to the Vigabatrin REMS Program without the requirement to recertify.

1. **Review**
   - Review the Prescribing Information for vigabatrin
   - Complete and submit the Prescriber Enrollment and Agreement Form
     - online
     - fax/email
     - An email will be sent to confirm your enrollment

2. **Counsel**
   - Counsel the patient/parent/legal guardian on benefits and risks associated with vigabatrin
   - Provide a copy of What you need to Know About Vigabatrin Treatment: A Patient Guide
   - Complete the Patient/Parent/Legal Guardian - Physician Agreement Form

3. **Submit**
   - Submit your patient's prescription for vigabatrin by clicking on the Certified Pharmacy Look-Up button and searching for a pharmacy certified to dispense vigabatrin.

Report any adverse event suggestive of vision loss with all available information to the Vigabatrin REMS Program at 1-866-244-8175.

Prescriber Resources

Click on the PDF icon to download the resource.

- Prescriber Enrollment and Agreement Form
- Patient/Parent/Legal Guardian - Physician Agreement Form
- What you need to Know About Vigabatrin Treatment: A Patient Guide
- Certified Pharmacy Look-Up

Reference ID: 4679228
To submit this form, please complete all required fields below. Required fields are denoted by ***.

Vigabatrin is available only through a restricted distribution REMS program called the Vigabatrin REMS Program. The Vigabatrin REMS Program is available to answer questions regarding this program and initiating treatment with vigabatrin. Please call 1-866-244-8175 for assistance.

Vigabatrin is indicated as monotherapy for pediatric patients 1 month to 2 years of age with infantile spasms (IS) and as adjunctive therapy for patients 2 years of age and older with refractory complex partial seizures (CPS) who have inadequately responded to several alternative treatments, for whom the potential benefits outweigh the potential risk of vision loss. Vigabatrin is not indicated as a first line agent for CPS.

By completing, attesting, and submitting this form, I acknowledge that I have reviewed the Prescribing Information for vigabatrin, and I agree to be enrolled in the Vigabatrin REMS Program.

**NPI Number**

[CONTINUE]
To submit this form, please complete all required fields below. Required fields are denoted by **.

Vigabatrin is available only through a restricted distribution REMS program called the Vigabatrin REMS Program. The Vigabatrin REMS Program is available to answer questions regarding this program and to initiate treatment with vigabatrin. Please call 1-866-244-8175 for assistance.

Vigabatrin is indicated as monotherapy for pediatric patients 1 month to 2 years of age with Infantile Spasms (IS) and as adjunctive therapy for patients 2 years of age and older with refractory complex partial seizures (CPS) who have insufficiently responded to other alternative treatments, for whom the potential benefits outweigh the potential risk of vision loss. Vigabatrin is not indicated as a trike epilepsy agent for CPS.

By completing, attesting, and submitting this form, I acknowledge that I have reviewed the Prescribing Information for vigabatrin, and I agree to be enrolled in the Vigabatrin REMS Program.

**Prescriber Information**

- **NPI Number**: [Enter NPI Number]

**Please confirm the address information is correct. This is the address the program will use to communicate with you.**

- **First Name**: [Enter First Name]
- **Middle Initial**: [Enter Middle Initial]
- **Last Name**: [Enter Last Name]
- **Institution Name (if applicable)**: [Enter Institution Name]
- **Street Address**: [Enter Street Address]
- **City**: [Enter City]
- **State**: [Select State]
- **Zip code**: [Enter Zip Code]
- **Telephone Number**: [Enter Telephone Number]
- **Alternative Telephone Number**: [Enter Alternative Telephone Number]
- **Office Fax Number**: [Enter Office Fax Number]
- **E-mail**: [Enter E-mail]

**Prescriber Degree**: [Select Degree]
- MD
- DO
- NP
- PA
- Other

**Specialty**: [Select Specialty]
- Neurology
- Internal Medicine
- Other

**Office Contact Information**

- **First Name**: [Enter First Name]
- **Last Name**: [Enter Last Name]
- **Phone Number**: [Enter Phone Number]

**Second Contact Information**

- **First Name**: [Enter First Name]
- **Last Name**: [Enter Last Name]
- **Phone Number**: [Enter Phone Number]

**Prescriber REMS Agreement**

By completing, attesting to the below statement and submitting this form, I acknowledge and agree that I have reviewed the Prescribing Information for vigabatrin, and I agree to be enrolled in the Vigabatrin REMS Program.

As a condition of certification:

- I will enroll each patient in the Vigabatrin REMS Program by:
  - Knowledgeably confirming the patient/parent/legal guardian’s understanding of the benefits and risks of vigabatrin, ensuring permanent treatment information is included on the permanent medical record, and providing them with a copy of the Vigabatrin REMS Program Patient/Parent/Legal Guardan Education and Source Information provider with a completed copy to the patient/parent/legal guardian.
  - I will submit the completed form to the Vigabatrin REMS Program and store a copy in the patient’s record.
  - Ensuring that periodic monitoring of vision, as described in the Prescribing Information, is performed on an ongoing basis for each patient.
  - Reporting any adverse event suggestive of visual loss to the Vigabatrin REMS Program with all available information.

I understand that if I do not maintain compliance with the requirements of the Vigabatrin REMS, I will no longer be able to prescribe vigabatrin.

Prior to dispersing vigabatrin, the Vigabatrin REMS Program will provide a confirmation of certification to the email address provided.

For additional information, visit [www.vigabatrinREMS.com](http://www.vigabatrinREMS.com) or call the Vigabatrin REMS Program at 1-866-244-8175.

**Signature**: [Signature]
VIGABATRIN REMS PROGRAM PHARMACY ENROLLMENT, STEP BY STEP

Outpatient pharmacy enrollment has been limited to a select number of specialty pharmacies based on the manufacturers' predefined qualifications.

Pharmacies that dispense vigabatrin must be certified. Certification includes the following steps:

NOTE: All currently certified pharmacies in the SABRIL REMS Program will be transitioned to the Vigabatrin REMS Program without the requirement to recertify.

1. ENROLL
   - Complete a Pharmacy Enrollment Form for vigabatrin.
     - online
     - fax/email
   An email will be sent to confirm your enrollment. Instructions for Login are included in this email.

2. TRAIN
   - Oversee the necessary staff training and processes to comply with the Vigabatrin REMS Program requirements.

3. VERIFY
   - Prior to each dispensing of vigabatrin, verify (via Login) that the prescriber is certified and that the patient is enrolled in the Vigabatrin REMS Program.
   - Document all enrolled prescriber and patient ID numbers.
   - If the prescriber or patient is not enrolled in the program, contact the Vigabatrin REMS Program at 1-866-244-8173 or direct the prescriber to www.vigabatrinREMS.com

4. DISPENSE
   - Dispense vigabatrin to enrolled patients.
     - For outpatient pharmacies only:
       - For each prescription, verify that the prescriber is certified and the patient is enrolled in the Vigabatrin REMS prior to each dispensing of vigabatrin by logging on to www.vigabatrinREMS.com. Document confirmed prescriber and patient identification numbers as well as the authorization code to dispense, as assigned by the Vigabatrin REMS. If a prescriber or patient is not properly enrolled in the program, the pharmacy should direct the prescriber to www.vigabatrinREMS.com for enrollment information or contact the Vigabatrin REMS to facilitate prescriber enrollment.
     - For inpatient pharmacies only:
       - Verify the patient is enrolled in the Vigabatrin REMS prior to dispensing vigabatrin by logging on to www.vigabatrinREMS.com. Document the patient identification number.
       - Obtain authorization to continue dispensing by contacting the REMS Program to verify a certified prescriber authorizes continuing vigabatrin in treatment within 15 days of the patient's admission to the healthcare facility. Document confirmed prescriber and patient identification numbers as well as the authorization code to dispense, as assigned by the Vigabatrin REMS.
       - Do not dispense more than a 15-day temporary supply of vigabatrin to a patient upon discharge from the healthcare facility.
FINI: HUHQUIH

Reference ID: 4679228
RESOURCES

Below, you will find the forms associated with the Vigabatrin REMS Program. Click on the PDF icon to download the resource.

PRESCRIBER RESOURCES
Prescriber Enrollment and Agreement Form
Patient/Parent/Legal Guardian - Physician Agreement Form

PATIENT RESOURCES
What you need to Know About Vigabatrin Treatment: A Patient Guide

PHARMACY RESOURCES
Pharmacy Enrollment Form
CERTIFIED PHARMACY LOOK-UP

Below is a list of all pharmacies dispensing vigabatrin.

- Download the list to spreadsheet format by clicking on the Excel icon just above the column headers
- Search/Filter the list by entering information in the textbox below any column header
- Sort the list by clicking on any column header

<table>
<thead>
<tr>
<th>Name</th>
<th>Phone Number</th>
<th>Fax Number</th>
<th>Pharmacy Type</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

This table is intentionally left blank. The live website will be updated, as needed, to include a list of specialty pharmacies and inpatient pharmacies currently certified in the Vigabatrin REMS Program.
LOGIN

Please enter your User Name

If you have not been assigned login information, please contact the Vigabatrin REMS Program at 1-866-244-8175.