CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

217684Orig1s000

REMS

Risk Evaluation and Mitigation Strategy (REMS) Document
Vigabatrin Shared System REMS Program

I. Administrative Information

Initial Shared System REMS Approval: 04/2017

Most Recent REMS Update: 06/2024

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:	
Before treatment initiation	1. Review the Patient Guide. 2. Enroll in the REMS Program by completing the Patient/Parent/Legal-Guardian-Physician Agreement Form with the prescriber. Enrollment information will be provided to the REMS Program.

	3. Receive counseling from the prescriber on the risk of vision loss, the need for periodic visual monitoring, including ophthalmologic assessments.
At all times	4. Get vision testing, including ophthalmologic assessments, as described in the Patient Guide. 5. Inform the prescriber if you experience any problems when using vigabatrin or if you stop taking vigabatrin.
3. Outpatient 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.
Before dispensing	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.
To maintain certification to dispense	5. Have the new authorized representative enroll in the REMS Program by completing the Pharmacy Enrollment Form if the authorized representative changes.
At all times	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.
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 90 calendar days of the REMS Program modification (06/17/2024).

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 every two years beginning on 4/27/2022. 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

REMS Program website

VIGABATRIN
REMS PROGRAM

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.

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 NPI#** _____

VIGABATRIN
REMS PROGRAM

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** _____ (Area Code/Telephone Number) **Alternative 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

VIGABATRIN
REMS PROGRAM

PATIENT/PARENT/LEGAL GUARDIAN–PHYSICIAN AGREEMENT FORM

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.
PRINT First Name Last Name

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.
PRINT First Name Last Name

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.
SIGN First Name Last Name

Prescriber NPI# _____

Form continues on page 2.

Reference ID: 5[illegible]56

PATIENT/PARENT/LEGAL GUARDIAN–PHYSICIAN AGREEMENT FORM

VIGABATRIN REMS PROGRAM

Form continued from page 1.

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.
   PRINT First Name Last Name

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

Note: fields marked with an * are REQUIRED

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

***Signature** _____ ***Date** _____
Month/Day/Year

***Patient Name** _____ **Telephone** _____
Area Code/Telephone Number

Patient/Parent/Legal Guardian Email Address _____

Patient Address _____ _____ _____ _____
Street City State ZIP Code

***Patient Date of Birth** _____
Month/Day/Year

*Physician Agreement

I, _____ , have fully explained to the patient/parent/legal
PRINT First Name Last Name
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** _____
Month/Day/Year

Prescriber NPI# _____

To report Adverse Events, please contact the Vigabatrin REMS Program at 1-866-244-8175

VIGABATRIN
REMS PROGRAM

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)

VIGABATRIN
REMS PROGRAM

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).

VIGABATRIN
REMS PROGRAM

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?

SABRIL (vigabatrin) and its approved generic products (Tablets or Powder for Oral Solution 50 mg/mL) are prescription medications:

- 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 potential risk of vision loss.
- 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.

VIGAFYDE (vigabatrin) oral solution (100 mg/mL) is a prescription medication:

- 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 products are available only through certified healthcare providers and pharmacies.

What Is the Most Serious Risk Information About Vigabatrin Treatment?

- **Vigabatrin can cause <u>permanent vision damage</u> 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. <u>If this happens, it will not get better.</u>

- **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 VIGABATRIN.

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 Tablets or Vigabatrin Powder for Oral Solution (reconstituted to 50 mg/mL)?

- 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 (reconstituted to 50mg/mL) to your child the right way

How Should I Take Vigafyde (Vigabatrin) Solution (100 mg/mL)?

Vigafyde (vigabatrin) comes as an oral solution (100 mg/mL) and is more concentrated than vigabatrin solutions prepared from powder (50 mg/mL). If your baby was previously prescribed another vigabatrin product, your baby's doctor will prescribe a lesser volume of Vigafyde. **Check to see if your doctor has prescribed a lesser volume of solution than before.**

- Vigabatrin 100mg/mL oral solution should be given to your baby exactly as your baby's healthcare provider tells you to
- Vigabatrin is usually taken 2 times each day
- Vigabatrin may be taken with or without food
- Do not stop vigabatrin without talking to your baby's healthcare provider. This can cause serious problems
- Do not add water or other liquids (do not dilute) to vigabatrin solution (100mg/mL) when measuring the dose
- See "Instructions for Use" for detailed information about how to give vigabatrin oral solution (100mg/mL) to your child the right way

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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

Sabril (vigabatrin) and its associated generic products are 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, 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.

Vigafyde (vigabatrin) is indicated:

- As monotherapy for the treatment of infantile spasms in pediatric patients 1 month to 2 years of age 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

For Vigabatrin REMS Program Information call:
PHONE: 1-866-244-8175
FAX: 1-866-205-3072

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

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

Sabril (vigabatrin) and its associated generic products are indicated:

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LIST OF PRODUCTS COVERED UNDER THE VIGABATRIN REMS PROGRAM

BRAND NAME PRODUCTS

Trade Name	Generic Name	Dosage Form(s)	Company	Contact	Links

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

Drug Name	Generic Name	Dosage Form(s)	Company	Contact	Links

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.

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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 - Physican 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 - Physican Agreement Form

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

Certified Pharmacy Look-Up

Login

For Vigabatrin REMS Program Information call:
PHONE: 1-866-244-8175
FAX: 1-866-205-3072

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Visit www.fda.gov/medwatch or call 1-800-FDA-1088

PRESCRIBER ENROLLMENT AND AGREEMENT FORM

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.

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

CONTINUE

For Vigabatrin REMS Program Information call:
PHONE: 1-866-244-8175
FAX: 1-866-205-3072

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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

RESET

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

*First Name | Middle Initial | *Last Name

Institution Name (if applicable)

*Street Address

*City | *State | *Zip code

*Telephone Number | Alternative Telephone Number | *Office Fax Number

*E-mail

Prescriber Degree
- MD
- DO
- NP
- PA
- Other

Specialty
- Epileptology
- Neurology
- Pediatric Neurology
- Internal Medicine
- Other

OFFICE CONTACT INFORMATION

First Name | Last Name | Phone Number

SECOND CONTACT INFORMATION

First Name | Last Name | Phone Number

PRESCRIBER REMS AGREEMENT

By completing, checking the below attestation 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:**
  - 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 email address provided.

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

☐ *Signature

SUBMIT

For Vigabatrin REMS Program Information call:
PHONE: 1-866-244-8175
FAX: 1-866-205-3072

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PHARMACY CERTIFICATION

Pharmacies must be certified in the Vigabatrin REMS program in order to prescribe vigabatrin.

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 1-866-244-8175 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 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

Pharmacy Resources

Click on the PDF icon to download the resource.

Pharmacy Enrollment Form

Login

For Vigabatrin REMS Program Information call:
PHONE: 1-866-244-8175
FAX: 1-866-205-3072

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PHARMACY ENROLLMENT FORM

INSTRUCTIONS

- Review and complete this Pharmacy Enrollment Form *(this is a one-time enrollment)*
- To submit this form, please complete all required fields below. Required fields are denoted by "*".
  You will receive confirmation of your certification and log-in credentials for the assigned authorized representative via e-mail.

PHARMACY LOCATION INFORMATION

*Pharmacy Type
(•) Inpatient ( ) Outpatient

*NPI
1234567890

RESET

*Pharmacy Name

*Street Address

*City

*State
-- Please Select --

*Zip Code

*Telephone Number

*Fax Number

NCPDP

AUTHORIZED REPRESENTATIVE INFORMATION

*First Name

Middle Initial

*Last Name

*Title/Position

*Telephone Number

*Office Fax Number

*E-mail

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

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 at 1-866-244-8175.

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

☐ *Signature

SUBMIT

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 - Physican Agreement Form

PATIENT RESOURCES

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

PHARMACY RESOURCES

Pharmacy Enrollment Form

For Vigabatrin REMS Program Information call:
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FAX: 1-866-205-3072

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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

Name	Phone Number	Fax Number	Pharmacy Type

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.

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This site is intended for U.S. Healthcare Professionals Only

Prescribing Information | Medication Guide | Instructions for Use | Certified Pharmacy Look-Up | Login

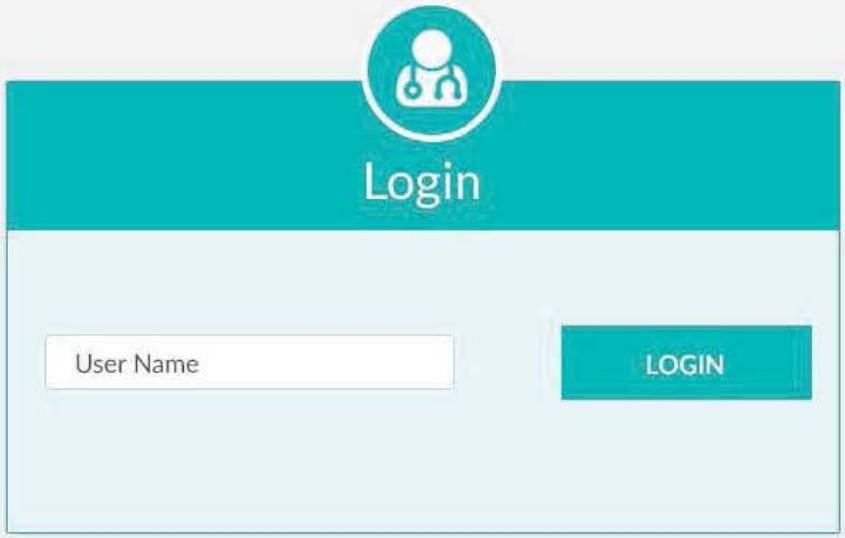
VIGABATRIN REMS PROGRAM

HOME | PRESCRIBER | PHARMACY | RESOURCES

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.



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This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

PAUL R LEE
06/17/2024 12:55:41 PM