



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

PRESCRIBER



For prescriber certification, [click here »](#)

PHARMACY



For pharmacy certification, [click here »](#)

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](#)



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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.



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](#)

[Login](#)



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.

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.

PRESCRIBER INFORMATION

* NPI Number

[CONTINUE](#)



PRESCRIBER ENROLLMENT AND AGREEMENT FORM

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

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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.

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

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

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 <input type="radio"/> Inpatient <input type="radio"/> Outpatient	*NPI <input type="text" value="1234567890"/>	RESET
*Pharmacy Name <input type="text"/>		
*Street Address <input type="text"/>		
*City <input type="text"/>	*State -- Please Select --	*Zip Code <input type="text"/>
*Telephone Number <input type="text"/>	*Fax Number <input type="text"/>	
NCPDP <input type="text"/>		

AUTHORIZED REPRESENTATIVE INFORMATION

*First Name <input type="text"/>	Middle Initial <input type="text"/>	*Last Name <input type="text"/>
*Title/Position <input type="text"/>		
*Telephone Number <input type="text"/>	*Office Fax Number <input type="text"/>	*E-mail <input type="text"/>
*Preferred Method of Communication (please select one) <input type="radio"/> Fax <input type="radio"/> E-mail <input type="radio"/> 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



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

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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



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[CERTIFIED PHARMACY LOOK-UP](#)

[LOGIN](#)

[PRIVACY POLICY](#)

[TERMS OF USE](#)

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



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
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

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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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.



Login

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

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/

ALICE HUGHES
10/02/2020 12:30:33 PM