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

I. Administrative Information

Risk: Vision loss

Initial Shared System REMS Approval: 04/2017

Most Recent REMS Update: 03/2026

II. REMS Goal

The goal of the Vigabatrin REMS 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 must:	
To become certified to prescribe	1. Review the drug's Prescribing Information. 2. Enroll by completing and submitting the Prescriber Enrollment and Agreement Form to the REMS.
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. 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.
2. Patients who are prescribed vigabatrin:	
Before treatment initiation	1. Review the Patient Guide.

	2. Enroll in the REMS by completing the Patient/Parent/Legal-Guardian-Physician Agreement Form with the prescriber. Enrollment information will be provided to the REMS. 3. Receive counseling from the prescriber on the risk of vision loss and 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 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 on behalf of the pharmacy. 2. Have the authorized representative enroll by completing and submitting the Pharmacy Enrollment Form to the REMS. 3. Train all relevant staff involved in dispensing on the REMS requirements.
Before dispensing	4. Obtain authorization to dispense each prescription by contacting the REMS or via the REMS Website. Document the confirmed prescriber and patient identification numbers, and authorization code.
To maintain certification to dispense	5. Have a new authorized representative enroll by completing and submitting the Pharmacy Enrollment Form to the REMS, if the authorized representative changes.
At all times	6. Comply with audits carried out by the 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 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 on behalf of the pharmacy. 2. Have the authorized representative enroll by completing and submitting the Pharmacy Enrollment Form to the REMS. 3. Train all relevant staff involved in dispensing on the REMS requirements.

	4. Establish processes and procedures to verify the patient is enrolled in the REMS 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. Document the patient identification number.
During treatment, within 15 days of inpatient admission	7. Obtain authorization to continue dispensing by contacting the REMS or via the REMS 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 a new authorized representative enroll by completing and submitting the Pharmacy Enrollment Form to the REMS, if the authorized representative changes.
At all times	10. Comply with audits carried out by the 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 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 requirements.
At all times	3. Distribute only to certified pharmacies. 4. Maintain and submit records of all distributions to the REMS. 5. Comply with audits carried out by the 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.

To support REMS operations, the Vigabatrin Applicants must:

1. Establish and maintain a REMS website, www.vigabatrinREMS.com. The REMS 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 website. The REMS website must not link back to the promotional product website(s).

2. Make the REMS Website fully operational and all REMS materials available through the website and the call center within 90 calendar days of the REMS modification (09/12/2024).

3. Establish and maintain a REMS 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.

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 adverse events 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.

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 2 business days after they become certified in the REMS.

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, the Vigabatrin Applicants must:

18. Verify annually that the authorized representative's name and contact information correspond to those of the current designated authorized representative for the certified pharmacy. If different, the pharmacy must be required to 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 and pharmacies, authorized wholesalers-distributors, enrolled patients, and audits of REMS participants. These records must be readily available for FDA inspections.

20. Establish and maintain a plan for addressing noncompliance with REMS 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 all pharmacies no later than 180 calendar days after they become certified, to ensure that all REMS processes and procedures are in place, functioning, and comply with the REMS requirements. Annually audit 20% of certified inpatient pharmacies and 20% of certified outpatient pharmacies that have received at least one shipment.

23. Audit all wholesalers-distributors no later than 180 calendar days after they are authorized to distribute to ensure that all REMS processes and procedures are in place, functioning, and comply with the REMS requirements. Annually audit all wholesaler-distributors that have made at least one commercial distribution in the previous 12 months.

24. Take reasonable steps to improve operations of and compliance with the requirements in the Vigabatrin REMS based on monitoring and evaluation of the Vigabatrin REMS.

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

5. REMS website

VI. Statutory Elements

This REMS is required under section 505-1 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355-1) and consists of the following elements:

1. Elements to Assure Safe Use (ETASU):
   - Healthcare providers who prescribe vigabatrin are specially certified under 505-1(f)(3)(A)
   - Pharmacies that dispense vigabatrin are specially certified under 505-1(f)(3)(B)
   - Vigabatrin is dispensed to patients with evidence or other documentation of safe-use conditions under 505-1(f)(3)(D)
2. Implementation System
3. Timetable for Submission of Assessments