

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: 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:

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| To become certified to prescribe | <ol style="list-style-type: none">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) | <ol style="list-style-type: none">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 | <ol style="list-style-type: none">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:

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| Before treatment initiation | <ol style="list-style-type: none">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 | <ol style="list-style-type: none">4. Get vision testing, including ophthalmologic assessments, as described in the Patient Guide5. 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:

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| To become certified to dispense | <ol style="list-style-type: none">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 | <ol style="list-style-type: none">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 | <ol style="list-style-type: none">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 | <ol style="list-style-type: none">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:

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| To become certified to dispense | <ol style="list-style-type: none"> 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 | <ol style="list-style-type: none"> 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 | <ol style="list-style-type: none"> 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 | <ol style="list-style-type: none"> 8. Dispense no more than a 15 days' supply. |
| To maintain certification to dispense | <ol style="list-style-type: none"> 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 | <ol style="list-style-type: none"> 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:

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| To be able to distribute | <ol style="list-style-type: none"> 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. |
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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.
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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](#)