

Alvimopan Shared System REMS Program

The requirements of the shared system REMS for alvimopan apply as of the date of full approval of the first abbreviated new drug application (ANDA) referencing Entereg (alvimopan).

I. Administrative Information

Initial Shared System REMS Approval: 12/2019

II. REMS Goal

The goal of the Alvimopan REMS Program is to mitigate the potential risk of myocardial infarction by:

1. Ensuring that alvimopan is used only for short-term use (no more than 15 doses) in a hospital inpatient setting

III. REMS Requirements

Alvimopan Applicants must ensure that healthcare settings and wholesalers-distributors comply with the following requirements:

1. Healthcare settings that dispense alvimopan must:

To become certified to dispense	<ol style="list-style-type: none">1. Have a pharmacy in an inpatient hospital that performs bowel resection surgery.2. Designate an authorized representative to carry out the certification process and oversee implementation and compliance with the REMS Program on behalf of the hospital pharmacy.3. Have the authorized representative review the Alvimopan REMS Kit.4. Have the authorized representative enroll in the Alvimopan REMS Program by completing the Hospital Pharmacy Enrollment Form and submitting it to the REMS Program.5. Train all relevant staff involved in prescribing, dispensing, or administering on safe use of alvimopan using the Alvimopan REMS Kit materials.6. Establish processes and procedures to verify no more than 15 doses are dispensed to the patient.
Before dispensing	<ol style="list-style-type: none">7. Verify the patient receives no more than 15 doses through the processes and procedures established as a requirement of the REMS Program.

1. Healthcare settings that dispense alvimopan must:

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| At all times | 8. Not dispense alvimopan for outpatient use. |
| | 9. Not distribute, transfer, loan, or sell alvimopan, except to certified healthcare settings. |
| | 10. Re-certify in the Alvimopan REMS if the authorized representative changes. |
| | 11. Comply with audits carried out by alvimopan applicants or a third party acting on behalf of the applicants to ensure that all processes and procedures are in place and are being followed |
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2. Wholesalers-Distributors that distribute alvimopan must:

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| To be able to distribute | 1. Establish processes and procedures to ensure that the drug is distributed only to certified healthcare settings. |
| | 2. Train all relevant staff involved in distributing alvimopan on REMS program requirements. |
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| At all times | 3. Distribute only to certified healthcare settings. |
| | 4. Maintain records of drug distribution. |
| | 5. Comply with audits carried out by the applicants or a third party acting on behalf of the applicants to ensure that all processes and procedures are in place and are being followed. |
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Alvimopan Applicants must provide training materials to healthcare settings that dispense alvimopan.

The training includes the following: [Alvimopan REMS Program Kit](#) which includes the [Alvimopan REMS Program Overview](#), [Dear Healthcare Provider Letter](#), [Prescriber and Pharmacist Information Brochure](#) and [Hospital Pharmacy Enrollment Form](#). The training materials must be available in hard copy and online.

To support REMS Program operations, Alvimopan Applicants must:

1. Establish and maintain a REMS Program website, www.alvimopanREMS.com. The REMS Program website must include the capability to complete hospital pharmacy certification and the option to print the Prescribing Information 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 coordinating/call center.
3. Establish and maintain a REMS Program coordinating/call center for REMS participants at [1-800 278 0340].
4. Establish and maintain a validated, secure database of all REMS participants who are enrolled and/or certified in the Alvimopan REMS Program.
5. Ensure hospital pharmacies are able to enroll in the Alvimopan REMS by fax and online.
6. Provide [Alvimopan REMS Kit](#) including an [Alvimopan REMS Program Overview](#), [Dear Healthcare Provider Letter](#), [Prescriber and Pharmacist Information Brochure](#) and [Hospital Pharmacy Enrollment Form](#), and the Prescribing Information to REMS participants who (1) attempt to dispense alvimopan and are not yet certified or (2) inquire about how to become certified.
7. Maintain a process to ensure that healthcare settings that want to become certified have a pharmacy in an inpatient hospital that performs bowel resection surgeries.

To ensure REMS participants' compliance with the REMS Program, the Alvimopan Applicants must:

8. Verify that the authorized representative's name and contact information correspond to those of the current designated authorized representative for the hospital pharmacy. If different, the hospital pharmacy must be required to re-certify with a new authorized representative before distribution of alvimopan from the wholesaler/distributor resumes.
9. Maintain adequate records to demonstrate that REMS requirements have been met, including, but not limited to records of: alvimopan distribution and dispensing; certification of hospital pharmacies; and audits of REMS vendors. These records must be readily available for FDA inspections.
10. Establish a plan for addressing noncompliance with REMS Program requirements.
11. Monitor hospital pharmacies 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.
12. Audit hospital pharmacies, in accordance with the audit plan, no later than 90 calendar days after they become certified, to ensure that all REMS processes and procedures are in place, functioning, and support the REMS Program requirements.
13. Take reasonable steps to improve implementation of and compliance with the requirements in the Alvimopan REMS Program based on monitoring and evaluation of the Alvimopan REMS Program.

IV. REMS Assessment Timetable

Alvimopan NDA Applicants must submit REMS Assessments to FDA at 12 months following initial REMS approval, then annually, thereafter. 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 days before the submission date for that assessment. Alvimopan 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 Alvimopan REMS Program:

Enrollment Form

1. [Hospital Pharmacy Enrollment Form](#)

Training and Educational Materials

2. [REMS Program Overview](#)
3. [Dear Healthcare Provider Letter](#)
4. [Prescriber and Pharmacist Information Brochure](#)

Other Materials

5. [REMS Program website](#)