

# Alvimopan REMS Prescriber and Pharmacist Information Brochure

**Dear Prescriber/Pharmacist:**

On 12/19/2019, the Food and Drug Administration (FDA) approved the Alvimopan Risk Evaluation and Mitigation Strategy (REMS), which replaces the E.A.S.E.® ENTEREG® REMS Program.

Alvimopan is only available to hospital pharmacies that are certified in the Alvimopan REMS. Hospital pharmacies that were not certified in the E.A.S.E.® ENTEREG® REMS Program but would like to dispense alvimopan must certify in the Alvimopan REMS. Visit [www.alvimopanREMS.com](http://www.alvimopanREMS.com) to complete the Alvimopan REMS Hospital Pharmacy Enrollment Form or contact the Alvimopan REMS at 1-800-278-0340.

Updated materials for hospital pharmacies previously enrolled in the E.A.S.E.® ENTEREG® REMS Program are available at the new website [www.alvimopanREMS.com](http://www.alvimopanREMS.com). If your authorized representative has changed, please complete a new enrollment form for continued access to alvimopan.

**\*\*There is no action needed if your hospital pharmacy was previously certified in the E.A.S.E.® ENTEREG® REMS Program\*\***

## **What is the Alvimopan REMS?**

This **R**isk **E**valuation and **M**itigation **S**trategy (REMS) is a strategy to mitigate the potential risk of myocardial infarction associated with long-term use of alvimopan.

The REMS is required by the FDA to ensure that the benefits of alvimopan outweigh this potential risk by informing/reminding healthcare providers that alvimopan should only be used short-term (no more than 15 doses) and in a hospital inpatient setting.

## **How does the Alvimopan REMS work?**

Hospital pharmacies that dispense alvimopan, must become certified in the REMS.

**To become certified, your hospital pharmacy must be enrolled in the Alvimopan REMS before you can prescribe alvimopan.**

## **What are the requirements of the Alvimopan REMS?**

The Program requires that an authorized representative designated by the hospital pharmacy attests that:

- The Alvimopan REMS Kit has been received by the hospital and that all healthcare providers who are responsible for prescribing, dispensing, or administering alvimopan are educated on the benefits and risks of alvimopan
- The authorized representative understands the risks and benefits of alvimopan and has read the materials in the Alvimopan REMS Kit before alvimopan is dispensed.
- The certified hospital pharmacy has policies and procedures in place to limit the use of alvimopan to no more than 15 doses per patient for administration in the hospital inpatient setting only
- The certified hospital pharmacy will not dispense alvimopan for outpatient use and will not transfer alvimopan to any hospital pharmacy not enrolled with the Alvimopan REMS
- The certified hospital pharmacy must re-certify in the program if the authorized representative changes

The Alvimopan REMS Kit includes all REMS materials and a copy of the alvimopan Prescribing Information.

### **How do I order Alvimopan?**

In order to receive alvimopan, your hospital pharmacy must enroll and certify in the Alvimopan REMS. Upon certification:

- Alvimopan can be ordered directly from wholesalers
- Alvimopan will be shipped directly to your inpatient hospital pharmacy by the distributor
- Alvimopan cannot be transferred from a certified to a non-certified hospital pharmacy

### **For More Information:**

In addition, all REMS materials are available on the Alvimopan REMS Program Website at [www.alvimopanREMS.com](http://www.alvimopanREMS.com).

### **Adverse Events Reporting**

To report suspected adverse reactions contact:

- Alvimopan REMS at 1-800-278-0340.
- FDA at 1-800-FDA-1088 (1-800-332-1088) or at [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

Please see [alvimopanREMS.com](http://alvimopanREMS.com) for links to the complete Prescribing Information

a peripherally acting  $\mu$ -opioid receptor antagonist

[Important Safety Information](#)

[Prescribing Information](#)

## What is the Alvimopan REMS (Risk Evaluation and Mitigation Strategy)?

The Alvimopan REMS is a safety program to mitigate **the potential risk of myocardial infarction by:**

- Ensuring that alvimopan will only be used short-term (no more than 15 doses) and in a hospital inpatient setting

**Alvimopan is available only to hospitals that perform bowel resection surgeries and are enrolled in the Alvimopan REMS.**

The REMS is required by the U.S. Food and Drug Administration (FDA) to ensure the benefits of alvimopan outweigh its risks.

## Alvimopan REMS Program Overview

As part of the REMS requirements, an authorized representative designated by the hospital pharmacy attests that:

- The Alvimopan REMS Kit has been received by the hospital and that all healthcare providers who are responsible for prescribing, dispensing, or administering alvimopan are educated on the benefits and risks of alvimopan
- The certified hospital pharmacy has policies and procedures in place to limit the use of alvimopan to no more than 15 doses per patient for administration in the hospital inpatient setting only
- The certified hospital pharmacy will not dispense alvimopan for outpatient use and will not transfer alvimopan to any hospital pharmacy not enrolled with the Alvimopan REMS

Alvimopan, a peripherally acting  $\mu$ -opioid receptor antagonist, is indicated to accelerate the time to upper and lower gastrointestinal (GI) recovery following surgeries that include partial bowel resection with primary anastomosis.

## Adverse Event Reporting

Healthcare professionals should report all suspected adverse events associated with the use of alvimopan.

To report suspected adverse reactions, contact 1-XXX-XXX-XXXX or FDA at 1-800-FDA-1088 (1-800-332-1088) or at [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

Alvimopan REMS Kit
<ul style="list-style-type: none"><li>• <a href="#">Alvimopan REMS Program Overview</a></li><li>• <a href="#">Alvimopan REMS Dear Healthcare Provider Letter</a></li><li>• <a href="#">Alvimopan REMS Prescriber and Pharmacist Information Brochure</a></li><li>• <a href="#">Prescribing Information</a></li></ul>
<b>Hospital Pharmacies Enroll Here</b>
<ul style="list-style-type: none"><li>• <a href="#">Alvimopan REMS Hospital Pharmacy Enrollment Form</a></li></ul>

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a peripherally acting  $\mu$ -opioid receptor antagonist

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## Prescribing Information

TRADE NAME	COMPANY	PHONE NUMBER	INFORMATION LINKS

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### Alvimopan REMS Kit

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- Alvimopan REMS Dear Healthcare Provider Letter
- Alvimopan REMS Prescriber and Pharmacist Information Brochure
- Prescribing Information

### Hospital Pharmacies Enroll Here

- Alvimopan REMS Hospital Pharmacy Enrollment Form

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