

Alvimopan REMS Program Overview

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

On 12/19/2019, the FDA approved the Alvimopan REMS, which replaces the E.A.S.E.® ENTEREG® REMS Program.

How does the Alvimopan REMS work?

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

To become certified to dispense alvimopan, your pharmacy must be in an inpatient hospital that performs bowel resection surgery.

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 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.

For More Information:

In addition, all REMS materials are available on the Alvimopan REMS Website at www.alvimopanREMS.com.

Adverse Events Reporting

To report suspected adverse reactions contact:

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

Please see alvimopanREMS.com for links to the complete Prescribing Information.