

IMPORTANT DRUG WARNING

Alvimopan REMS Dear Healthcare Provider Letter

Subject: Potential risk of myocardial Infarction observed with long-term use of Alvimopan

Prescriber Action: Alvimopan should only be used short-term (no more than 15 doses) and in a hospital inpatient-setting

Dear Healthcare Provider:

The purpose of this letter is to inform you about the potential risk of myocardial infarction observed with long-term use of alvimopan.

The FDA has determined that a **R**isk **E**valuation and **M**itigation **S**trategy (REMS) is necessary to ensure that the benefits of alvimopan outweigh this potential risk by informing/reminding you that alvimopan should only be used short-term (no more than 15 doses) and in a hospital inpatient setting.

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

REMS Requirements

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

Inpatient Hospital Certification

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

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

Alvimopan, a peripherally acting μ -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.

For more information on the Alvimopan REMS visit www.alvimopanREMS.com.

Adverse Events Reporting

To report suspected adverse reactions contact:

- The Alvimopan REMS 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