ENTEREG® (alvimopan) | E.A.S.E.®
ENTEREG Access Support & Education Program

Welcome to the ENTEREG Access Support & Education Program

Cubist is pleased to present ENTEREG and the E.A.S.E. Program. Enrollment in the E.A.S.E. Program permits hospitals performing bowel resection surgeries to receive ENTEREG. It is important that you understand this program in order to help your pharmacy order, stock, and dispense ENTEREG. Information about the E.A.S.E. Program to help educate healthcare professionals at your hospital is available from your Cubist account manager. It can also be downloaded in PDF form at www.entereg.com.

ENTEREG, a peripherally acting μ-opioid receptor antagonist, is indicated to accelerate the time to upper and lower gastrointestinal (GI) recovery following partial large or small bowel resection with primary anastomosis. ENTEREG is approved for short-term use in the hospital setting. ENTEREG is available only to hospitals that perform bowel resections and are enrolled in the E.A.S.E. Program.

In one long-term (12-month) clinical study of alvimopan in patients treated with opioids for chronic pain, a numeric imbalance was seen in the incidence of ischemic cardiovascular events. As a result, the E.A.S.E. Program was developed to ensure that ENTEREG is administered only short-term in inpatient hospital settings and for no more than 15 doses. See Important Safety Information.

The E.A.S.E. Program requires that:

- The E.A.S.E. Program Educational Materials have been received by the hospital and provided to the healthcare practitioners who are responsible for the ordering, dispensing, or administration of ENTEREG
- The hospital has systems, order sets, protocols, or other measures in place to limit the use of ENTEREG to no more than 15 doses per patient for administration in the hospital only
- The hospital will not dispense ENTEREG for outpatient use and will not transfer ENTEREG to any hospital not registered with the E.A.S.E. Program

The enclosed E.A.S.E. Program kit contains all materials necessary to register your inpatient hospital pharmacy:

- Registration Form
- Ordering Information
- Hospital Brochure
- Complete Prescribing Information for ENTEREG® (alvimopan) Capsules

In addition, these pieces are available on the Web site for ENTEREG at www.entereg.com.

Important Safety Information

WARNING: FOR SHORT TERM HOSPITAL USE ONLY

ENTEREG is available only for short-term (15 doses) use in hospitalized patients. Only hospitals that have registered in and met all of the requirements for the ENTEREG Access Support and Education (E.A.S.E.®) Program may use ENTEREG.

ENTEREG Capsules are contraindicated in patients who have taken therapeutic doses of opioids for greater than 7 consecutive days immediately prior to taking ENTEREG.

There were more reports of myocardial infarctions in patients treated with alvimopan 0.5 mg twice daily compared with placebo-treated patients in a 12-month study of patients treated with opioids for chronic pain. In this study, the majority of myocardial infarctions occurred between 1 and 4 months after initiation of treatment. This imbalance has not been observed in other studies of alvimopan, including studies of patients undergoing bowel resection surgery who received alvimopan 12 mg twice daily for up to 7 days. A causal relationship with alvimopan has not been established.

Overall, the incidence of adverse reactions in short-term surgical clinical trials was similar between patients receiving either ENTEREG or placebo. Most common adverse reactions (incidence ≥3% and ≥1% placebo) in patients undergoing bowel resection were anemia, dyspepsia, hypokalemia, back pain, and urinary retention.

Adverse Event Reporting

Healthcare professionals should report all suspected adverse events associated with the use of ENTEREG. Please contact Cubist Pharmaceuticals at 1-877-CUBIST-6 (1-877-282-4786).

Alternatively, this information may be reported to the FDA MedWatch Reporting System by phone at 1-800-FDA-1088 (1-800-332-1088) or by mail using Form 3500 at www.fda.gov/medwatch.

If you have any questions, please contact Cubist Pharmaceuticals at 1-877-CUBIST-6 (1-877-282-4786) or visit www.entereg.com.

Please see accompanying complete Prescribing Information, including Boxed Warning.

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