ENTEREG® (alvimopan) | E.A.S.E.®

ENTEREG Access Support & Education Program

VA MEDICAL CENTER REGISTRATION FORM

Enrollment in the E.A.S.E. Program permits hospitals performing bowel resection surgeries to receive ENTEREG for short-term, in-hospital use.

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, including Boxed Warning on the reverse side.**

This hospital acknowledges that:

1. 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
2. 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
3. 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

*Hospital Name _____

*Hospital DEA# _____

*Authorized Signatory: First Name _____ *Last Name _____

*Title ☐ Hospital Pharmacist
☐ Representative of P&T Committee _____
(must check one) (insert title)

*E-mail Address _____

*Pharmacy Phone _____ *Pharmacy Fax _____

*Hospital Ship-to Address _____

*City _____ *State _____ *ZIP Code _____

Please check one: ☐ New Registration ☐ Update to Existing Registration

*Denotes mandatory fields to complete.

I confirm that the information above is correct.

I understand that this information will be used to enable Cubist to identify hospitals at which bowel resections are performed that are eligible to receive shipments of ENTEREG. I also understand that this information may be shared with others working with Cubist, other hospitals enrolled in the E.A.S.E. Program, and may be shared with government agencies.

Signature _____ Date _____

To submit via fax: Sign and fax to 1-800-278-1365
After verification of eligibility, a confirmation will be provided to you, **via fax and e-mail**.

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

NOTE: If you have multiple shipping sites, please complete a separate E.A.S.E. registration for each ship site with an accompanying DEA number.

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® (alvimopan) 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.

ENTEREG should be administered with caution to patients receiving more than 3 doses of an opioid within the week prior to surgery. These patients may be more sensitive to ENTEREG and may experience GI side effects (eg, abdominal pain, nausea and vomiting, diarrhea).

ENTEREG is not recommended for use in patients with severe hepatic impairment, endstage renal disease or undergoing surgery for correction of complete bowel obstruction.

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.

Please see the complete Prescribing Information, including Boxed Warning.

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www.cubist.com

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