I. GOAL
To reduce the risk of myocardial infarction observed with longer use, Entereg (alvimopan) will be used only for short-term use (not to exceed 15 doses) in inpatient settings.

II. REMS ELEMENTS

A. Communication Plan
Adolor will implement a communication plan to healthcare providers to support implementation of this REMS.

Adolor will provide educational materials for distribution to healthcare professionals involved in the prescribing, dispensing, or administration of Entereg. This includes surgeons who perform bowel resection surgery, hospitalists, anesthesiologists, nurse anesthetists, pharmacists, nurses, and physicians assistants.

Healthcare Professional Education

• Dear Hospital Pharmacist Letter
The Dear Hospital Pharmacist Letter, to be distributed on product launch, will state that Entereg can be used for no more than 15 doses in inpatients, and that Entereg is not available for outpatient use. Additionally, the letter will provide a description of and directions on how to enroll in the E.A.S.E. program, the program that incorporates elements for safe use as shown in the appended Dear Hospital Pharmacist Letter.

• Entereg Access Support and Education (E.A.S.E.) educational materials
Adolor will use the E.A.S.E. educational materials (available in printed form as part of the E.A.S.E. Program Kit Folder [a print-based registration package], and on-line as part of the web-based registration system), to educate all hospital-based healthcare professionals that are involved in the prescribing, dispensing, or administration of Entereg.

The E.A.S.E. printed materials include:

• E.A.S.E. Program Overview
• E.A.S.E. Hospital Brochure
• E.A.S.E. Kit Folder
• Program Overview
Additional educational materials include:

- Dear Hospital Pharmacist Letter
- Professional Labeling

The educational materials will prominently feature the safety-related message that because of the risk of myocardial infarction observed with longer use, Entereg can be used for no more than 15 doses in inpatients, and Entereg cannot be prescribed for outpatients as shown in the appended printed material and web shots.

B. Elements to Assure Safe Use

1. Drug Dispensed Only in Hospitals

Entereg will be dispensed to patients only in hospitals. The hospital will not dispense Entereg for outpatient use.

2. Drug Dispensed in Specially Certified Hospitals

Entereg will be dispensed only in hospitals that perform bowel resection surgery and that are specially certified by enrollment in the E.A.S.E. program. The specially certified hospital will not transfer Entereg to any hospital not registered with the E.A.S.E. Program. To register in the E.A.S.E. program, responsible hospital personnel must attest that:

- E.A.S.E. educational materials have been received by the hospital and distributed to healthcare professionals who are responsible for the ordering, prescribing, dispensing, or administering of Entereg;
- The hospital has systems, order sets, protocols, or other measures in place to ensure that Entereg is dispensed only to patients with evidence of safe use conditions. Please see the appended Hospital Registration form.

Entereg will be distributed to registered hospitals via a drop-ship program through which Adolor retains direct control over who purchases Entereg. Hospitals that are registered in the E.A.S.E. Program may purchase Entereg utilizing the drop-ship program. The registered hospitals may order Entereg through their usual wholesalers; the wholesalers transmit the order through Adolor’s distributor. This distributor sends Entereg only to registered hospitals. Please see the appended Drop Shipment Procedure.
3. Drug Dispensed Only to Patients with Evidence of Safe-Use Conditions

Entereg will be dispensed only to patients in hospitals performing bowel resections; each patient will receive no more than 15 doses of the drug.

C. Implementation System

The Implementation System includes the following:

- Adolor will maintain a database of all specially certified hospitals;
- Adolor will monitor distribution to determine whether the drug is only drop-shipped to certified hospitals and will conduct audits to verify;
- Adolor will monitor dispensing of Entereg to ensure that it is dispensed only for inpatient use;
- Adolor will monitor the duration of therapy to determine whether Entereg is being dispensed to patients with evidence that the patient is hospitalized for bowel resection surgery and has received no more than 15 doses;
- Based on monitoring and evaluation of the elements to assure safe use, Adolor will take reasonable steps to work to improve implementation of these elements.

D. Timetable for Submissions of Assessments

REMS Assessments (see III below for content) will be submitted to FDA quarterly for the first 18 months following approval, then annually (from approval date) thereafter.

III. INFORMATION NEEDED FOR ASSESSMENTS

REMS Assessments will include the following:

- An assessment of use data establishing the circumstances of use of Entereg:
  - the extent of outpatient use;
  - the extent of inpatient use;
  - the extent of use > 15 doses within hospitals;
  - the extent of use in bowel resection procedures;
  - the extent of use in non-bowel resection procedures;
  - the extent of use for other (not associated with bowel resection or non-bowel resection procedures) reasons;
  - the extent of use by specially certified hospitals; and
  - the extent of use by hospitals that are not specially certified.
- A description of the investigation of use deviations and corrective actions taken.
• An assessment of healthcare professional understanding regarding the safe use of Entereg; i.e., the results of surveys administered to hospital pharmacists and surgeons 12 and 18 months following the launch of Entereg, and every 12 months thereafter if sufficient understanding is not displayed. Please see the appended Survey Program.

• A narrative summary and analysis of myocardial infarctions reported with use of Entereg.

• Based on the information provided, an assessment and conclusion of whether the REMS is meeting its goals, and whether modifications to the REMS are needed.
Dear Hospital Pharmacist:

Adolor and GlaxoSmithKline are pleased to introduce you to ENTEREG® (alvimopan) and the ENTEREG Access Support & Education (E.A.S.E.) Program. 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. 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.

Efficacy in clinical trials in the management of postoperative ileus following bowel resection:
- Accelerated time to upper and lower GI recovery
- Reduced the length of hospital stay

In clinical trials, ENTEREG did not reverse opioid analgesia.

Enrollment 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.

ENTEREG is available only to hospitals that perform bowel resections and are enrolled in the E.A.S.E. Program. This program is designed to ensure that ENTEREG is used in accordance with the FDA-approved label and requires:
- 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.

For more information on the program, contact your Adolor/GlaxoSmithKline account manager or visit www.entereg.com.

Ordering Information

After hospitals have enrolled in the E.A.S.E. Program, ENTEREG can be ordered from wholesalers and will be shipped directly to your inpatient hospital pharmacy by the distributor. ENTEREG cannot be transferred from an enrolled to a non-enrolled hospital.
Dosing With ENTEREG

ENTEREG® is for hospital use only. The recommended adult dose of ENTEREG® is 12 mg administered 30 minutes to 5 hours prior to surgery, followed by 12 mg twice daily beginning the day after surgery for a maximum of 7 days or until discharge. Patients should not receive more than 15 doses of ENTEREG®.

Important Safety Information

ENTEREG® (alvimopan) is contraindicated in patients who have taken therapeutic doses of opioids for more 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, hyperkalemia, back pain, and urinary retention.

Adverse Event Reporting

Healthcare professionals should report all suspected adverse events associated with the use of ENTEREG®. Please contact Adolor Corporation at 700 Pennsylvania Drive, Exton, PA 19341 or 1-866-4ADOLOR (1-866-423-6657), or the GSK Response Center at 1-888-625-5249. 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 Adolor Corporation at 1-866-4ADOLOR (1-866-423-6657) or visit www.enterg.com.

Please see accompanying complete Prescribing Information.

Sincerely,

[Signature]                             [Signature]

Eric Mortensen, MD, PhD               David Jeckson, MD
Group Director, Gastroenterology     Senior Vice President and
and Urology                           Chief Medical Officer
GskSmithKline                          Adolor Corporation
2001 Renaissance Blvd.               700 Pennsylvania Drive
King of Prussia, PA 19406             Exton, PA 19341

Sources: ENTEREG (prescribing information), Exton, PA: Adolor Corporation; 2008.
E.A.S.E. is a trademark of Adolor Corporation. © Copyright 2008 Adolor Corporation. All rights reserved. Printed in USA 10/2008.
E.A.S.E. Program Kit Folder
Welcome to the
ENTEREG Access Support & Education Program

Adolor and GlaxoSmithKline are pleased to introduce you to ENTEREG and the E.A.S.E. Program. Enroll in the E.A.S.E. Program allows 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 Adolor/GlaxoSmithKline account manager. It can also be downloaded in PDF format 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)

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

**Important Safety Information**

ENTEREG is contraindicated in patients who have taken therapeutic doses of opioids for more 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 Adolor Corporation at 700 Pennsylvania Drive, Easton, PA 19042 or 1-866-4ADOLOR (1-866-423-6567), or the GSK Response Center at 1-888-825-5245. 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.

Please see enclosed complete Prescribing Information.

If you have any questions, please contact Adolor Corporation at 1-866-4ADOLOR (1-866-423-6567) or visit www.entereg.com.
Hospital Registration Form

Approved for hospital use only

HOSPITAL 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.

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

DEA 

Hospital Identification Number

First Name ___________________ Middle Name ___________ Last Name ____________________

Title ___________________________

Email Address ____________________

Office Phone ____________________ Fax ____________________

Hospital Ship-to Address ____________________________

City ___________________________ State ___________ ZIP Code __________

I confirm that the information above is correct.

I understand that this information will be used to enable Adolor to identify hospitals at which bowel ressections are performed that are eligible to receive shipments of ENTEREG. I also understand that this information may be shared with others working with Adolor, 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 1-800-270-1555

After verification of eligibility, a confirmation will be provided to you.

If you have any questions, please contact Adolor Corporation at 1-866-4ADOLOR (1-866-423-6567) or visit www.entereg.com.

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ENTEREG®, now available to enrolled hospitals

ENTEREG is a peripherally acting  σ-opioid receptor antagonist 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.

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.

Enrollment in the E.A.S.E. Program

ENTEREG is available only to hospitals that perform bowel resections and are enrolled in the E.A.S.E. Program. This program is designed to ensure that ENTEREG is used in accordance with the FDA-approved label and 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

For more information on the program, contact your Adolor/GlaxoSmithKline account manager or visit www.entereg.com.

How to Order

In order to receive ENTEREG, your hospital must enroll in the E.A.S.E. Program. Upon enrollment:

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

<table>
<thead>
<tr>
<th>How supplied</th>
<th>Product code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>NDC 112827-010-30</td>
<td>Blue, hard gelatin capsule printed with “ADO 8499” on both the body and the cap of the capsule</td>
</tr>
</tbody>
</table>

Store at 25°C (77°F); excursions permitted to 15°C-30°C (59°F-86°F) [see USP Controlled Room Temperature].
Prescribing Information Brochure
FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

ENTEREG is indicated in adults to prevent and shorten postoperative ileus following partial large or small bowel resection surgery with parenteral nutrition.

2 DOSAGE AND ADMINISTRATION

2.1 Usual Dosage in Adults

For hospital use only. The recommended initial dose of ENTEREG is 12 mg, administered 12 minutes to 1 hour prior to surgery. Enterally, 12 mg (tablet) administered the day after surgery for a minimum of 7 days or until discharge. Patients discharged from the hospital within 1 day of ENTEREG.

2.2 Special Populations

- In patients undergoing emergent, urgent, or semi-urgent laparotomy, the recommended initial dose is 12 mg administered 12 minutes to 1 hour prior to surgery. Enterally, 12 mg (tablet) administered the day after surgery for a minimum of 7 days or until discharge. Patients discharged from the hospital within 1 day of ENTEREG.

- CDK-11: In patients undergoing emergent, urgent, or semi-urgent laparotomy, the recommended initial dose is 12 mg administered 12 minutes to 1 hour prior to surgery. Enterally, 12 mg (tablet) administered the day after surgery for a minimum of 7 days or until discharge. Patients discharged from the hospital within 1 day of ENTEREG.

3 DOSAGE FORMS AND STRENGTHS

- Powder for oral suspension (tablet) with talc and the cap of the capsule.
Web Site Sample Screens

![Web Site Sample Screens](image-url)
Important Safety Information

ENTEREG is contraindicated in patients who have taken therapeutic doses of opioids for more 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 with opioids for chronic pain. In this study, the majority of myocardial infarctions occurred between 1 and 4 months after initiation of treatment. This increase 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. More common adverse reactions (moderate to severe) 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 Adolor Corporation at 700 Pennsylvania Drive, Exton, PA 19341 or 1-866-4ADOLOR (1-866-423-6657).

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 Adolor Corporation at 1-866-4ADOLOR (1-866-423-6657).

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E.A.S.E.™ (ENTEREG Access Support & Education) PROGRAM

Educational Materials

Adolor and GlaxoSmithKline are pleased to offer you the following educational materials and resources. Please check back as we continue to add new materials to the E.A.S.E. program.

- Welcome to E.A.S.E. program (PDF)
- Hospital Brochure (PDF)
- Prescribing Information Brochure (PDF)

The E.A.S.E. Program is a trademark of Adolor Corporation.

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Welcome to the E.A.S.E.™ [ENTELEG Access Support and Education] Program

Adolor and GlaxoSmithKline are pleased to introduce you to ENTELEG and the E.A.S.E. Program. Enrollment in the E.A.S.E. Program permits hospitals performing bowel resection surgeries to receive ENTELEG. It is important that you understand this program in order to help your pharmacy order, stock and dispense ENTELEG.

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

In a large (12-month) clinical study of ENTELEG 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 ENTELEG is administered only short-term in inpatient, hospital settings, and for no more than 15 doses. See Important Safety Information.

This program requires 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 administering of ENTELEG.

2. The hospital has a system, order set, protocol, or other measures in place to limit the use of ENTELEG to no more than 15 doses per patient for administration in the hospital only.

3. The hospital will not dispense ENTELEG for outpatients and will not transfer ENTELEG to any hospital not registered with the E.A.S.E. Program.

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

- Registration Form
- Ordering Information
- Hospital Brochure

Important Safety Information

Enteleg is contraindicated in patients who have taken nephrotoxic doses of opioids for more than 7 consecutive days immediately prior to taking ENTEREG. These were more reports of angioedema infections in patients treated with enteleg 1.5 mg twice daily compared with placebo-treated patients in a 12-month study of patients with opioids for chronic pain. In the study, the majority of angioedema infections occurred between 1 and 6 months after initiation of treatment. The incidence has not been observed in other studies of enteleg, including studies of patients undergoing bowel resection surgery who received enteron 12 mg twice daily for up to 7 days. A causal relationship with enteleg has not been established.

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

Adverse event reporting

Healthcare professionals should report all suspected adverse events associated with the use of ENTEREG. Please contact Adolor Corporation at 720 Pennsylvania Drive, Eatontown, NJ 07724 or 1-866-4ADOLOR (1-866-423-6657). 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 3520 at www.fda.gov/medwatch.

Please see complete prescribing information.

If you have any questions, please contact Adolor Corporation at 1-866-4ADOLOR (1-866-423-6657).

Home | Prescribing Information | Important Safety Information | The E.A.S.E. Program

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EASE™ ENTEREG Access Support & Education Program
Online Hospital Registration

Enrollment in the EASE Program permits hospitals performing bowel resection surgeries to receive ENTEREG for interim in-hospital use. In one long-term (12-month) clinical study of alvimopan in patients treated with opioids for chronic pain, a sudden increase in serial cardiovascular events was noted. As such, the EASE Program was developed to ensure that ENTEREG is administered only short term in inpatient hospital settings, and for no more than 15 days. See Important Safety Information.

This hospital acknowledges that:
1. The EASE Program Educational Materials have been reviewed by the hospital and provided to the healthcare professionals who are responsible for the ordering, dispensing, or administering ENTEREG.
2. The hospital has reviewed, understood, and agrees to the following instructions and limitations to limit the use of ENTEREG to no more than 15 doses per patient for administration in the hospital only.
3. This hospital will not dispense ENTEREG for outpatient use and will not transfer ENTEREG to any hospital not registered with the EASE Program.

Required fields are indicated with an asterisk (*).

*Hospital name: [ ]
*Institution Number: [ ]
*First Name: [ ]
*Last Name: [ ]
*Title: [ ]
*E-mail Address: [ ]
*Telephone: [ ]
*Fax: [ ]
*Hospital Site Address: [ ]
*City: [ ]
*State: [ ]
*Zip Code: [ ]

I confirm that the information above is correct.

Understanding that this information will be used by Adolor to identify hospitals, at which bowel resection surgery is performed, that are eligible to receive ENTEREG. I also understand that this information may be shared with others working with Adolor.

*Your Signature: [ ]
*Date: [ ]

For electronic submission: Your signature and date of signing are required to complete your hospital registration. Please type your name and date in the spaces provided. Your signature certifies that you have read and agree with the Hospital Registration Form. A confirmation will be e-mailed to you after verification of eligibility.

Submit

To submit fax: Simply print out this form, sign, and fax to 1-800-279-1386. After verification of eligibility, a confirmation will be provided to you.

If you have any questions, please contact Adolor Corporation at 1-866-4ADOLOR (1-866-423-6567).

Approved for hospital use only.

EASE ENTEREG Access Support & Education Program

The EASE Program is a trademark of Adolor Corporation.

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Drop Shipment Procedure

ENTEREG® (alvimopan)
RiskMAP
PROCEDURE FOR DIRECT SHIPMENT TO REGISTERED HOSPITALS

1.0 Objective
To describe the procedure utilized to restrict distribution of Entereg® (alvimopan) to hospitals that are registered with Adolor in accordance with the hospital registration procedure as set forth in the Procedure for Registration of Hospitals (Registered Hospital).

2.0 Action
2.1 Adolor maintains and updates a list of Registered Hospitals eligible to receive and dispense Entereg® based on the registration of these hospitals in accordance with the Procedure for Registration of Hospitals.
2.2 The Adolor’s Contracted Distribution Designee (Distributor) updates their order management system to block shipments of Entereg® to wholesalers and any other customer.
2.3 Adolor provides the list of Registered Hospitals to the Distributor.
2.4 Hospitals place orders for Entereg® through their normal procurement channels (i.e. Wholesalers).
2.5 Wholesalers transmit the hospital orders to the Distributor either electronically or manually. Wholesalers are not eligible to carry inventory of or distribute Entereg®.
2.6 The Distributor receives the order and verifies ordering hospital against the current list of Registered Hospitals.
   2.6.1 Orders from Registered Hospitals are transferred to the distributor’s warehouse for fulfillment pursuant to section 2.7.
   2.6.2 Orders from ineligible hospitals are rejected and reported to Adolor for notification of rejection to the wholesaler and the hospital.
2.7 Orders from Registered Hospitals that are transmitted to the Distributor’s warehouse for fulfillment are prepared for direct shipment to the eligible recipient as follows:
   2.7.1 The number of units ordered are picked from the Distributor’s inventory of Entereg®.
   2.7.2 The units are packaged in an appropriate shipping container addressed to the Registered Hospital’s name and address (and pharmacy as appropriate).
   2.7.3 The shipping container is sealed and staged to the outbound staging area for pick up by an authorized delivery service for delivery per customer request.
2.8 Via the invoice, the Distributor notifies the Wholesaler through which, the order was placed, that the shipment to the Registered Hospital has been made.
Survey Program

Survey instrument to Assess the Risk Management Plan Education

Objective

To assess the effectiveness of the communication of the Key RiskMAP Messages to HCPs who are critical to the proper utilization of the Product in accordance with the goal of the RiskMAP as follows:

Overview

Sponsor commits to assessing the effectiveness of the communication of the Key RiskMAP messages and educational efforts through an unbiased survey. This survey will assess the level of understanding of the Key RiskMAP Messages. Respondents will include a representative sample of HCPs responsible for the ordering and/or dispensing of the Product in the Registered Hospitals.

Key elements of the research are as follows:

1. In administering the surveys, Sponsor will engage a third-party market research provider (Surveyor), such as National Analysis Worldwide, to conduct the surveys.

2. The representative sample will include general and colorectal surgeons and hospital pharmacists potentially engaged in the ordering and/or dispensing of the Product in Registered Hospitals.

3. The representative sample will be achieved through a random sampling of:
   a. Surgeons who practice at Registered Hospitals that have either:
      i. used the Product, or
      ii. probably / definitely will use, but have not yet used the Product
   b. Hospital pharmacists who practice at Registered Hospitals that have either:
      i. stocked and dispensed the Product, or
      ii. probably / definitely will dispense, but have not yet dispensed the Product

4. Sample sizes will result in data that is statistically significant.

5. Surveys will be administered at 12 and 18 months post-launch, with a target of achieving 80% participant accuracy rate on pre-selected questions related to the Key RiskMAP Messages. Sponsor will continue surveys at 12 month intervals thereafter should the 80% accuracy rate not be achieved.
   a. The survey will also contain questions not related to the Key RiskMAP Messages. Only those questions directly related to the Key RiskMAP Messages will be used to calculate the accuracy rate.
      i. These non-RiskMAP questions are provided to strengthen the survey in providing a frame of reference for the survey participants for the questions that follow. In particular, question 1 is a filter question to determine if a survey participant has heard of the Product. If the participant has not heard of the Product, the survey terminates and in all other cases it continues. Question 2 is meant to provide additional information regarding intended usage / dispensing of the Product. In addition, the information from questions 1 and 2 will be helpful in performing additional analysis of the core RiskMAP message questions, as they provide essential information in understanding the profile of the participants as related to the Product, as well as to provide an understanding of awareness of (question 1), usage / dispensing of (question 1), and intended usage / dispensing of the Product (question 2).
     b. The accuracy rate can be calculated in any one of several ways for various diagnostic purposes. The Sponsor proposes it be based upon the percentage of surgeons and pharmacists who correctly answer all pre-selected Key RiskMAP Message-related questions.
      i. The Sponsor will tally the 80% success score by all respondents combined (surgeons, pharmacists); 80% of all respondents to the surgeon survey (General and Colorectal); 80% of all respondents to the pharmacists survey (hospital pharmacists involved in ordering product) and 80% of respondents from Wave 1 and 90% of respondents from Wave 2.
6. To maximize response rate, the surveys will be conducted via internet and/or telephone, with proper controls in place to ensure a uniform survey experience for both venues of participation.

7. To minimize sampling bias:
   a. All general and colorectal surgeons and hospital pharmacists potentially engaged in the ordering and/or dispensing of the Product in Registered Hospitals will be eligible for participation. This includes surgeons performing a high or low volume of bowel resection surgeries or pharmacists representing hospitals where a high or low volume of bowel resection surgeries occur.
   b. Multiple efforts will be made to re-contact potential respondents to minimize non-response bias.

8. Prior to the first wave of the research, the third-party market research vendor will conduct pretests. The pretest will serve to hone the questions to be utilized in the quantitative study, and to ensure that none of the questions induce bias. The Sponsor will submit the data collected via these survey pretests prior to the first wave of research.

9. Sponsor has submitted concise specialty-specific surveys which include screening questions, questions that will measure the knowledge of the Key RiskMAP messages, and other questions not directly related to Key RiskMAP messages, but deemed relevant for tracking.

**Study Design & Methodology**

The Sponsor has submitted Study Design and Methodology for surveying HCPs in Registered Hospitals to evaluate the success of the education program for the Product.

The survey will be comprised of:

A limited number of screening questions to assess whether a respondent is qualified to participate based on:
- Physician specialty
- Awareness of the Product
- Experience prescribing (surgeons), or dispensing (pharmacists)
- A participant's intent to prescribe (surgeons), or dispense (pharmacists) in the future

Survey questions designed to assess the knowledge of Key RiskMAP Messages:
- Entereg® (alvimopan) 12-mg Capsules are to be administered for a maximum of 15 doses.
- Entereg® (alvimopan) 12-mg Capsules are only to be administered within the registered acute-care hospital setting (not to be prescribed at discharge).
- The proper utilization of Entereg® (alvimopan) 12-mg Capsules is for short-term use (not to exceed 15 doses), due to results from one long-term (12-month) clinical study of alvimopan in patients treated with opioids for chronic pain, where a numeric imbalance was seen in the incidence of ischemic cardiovascular events.

The surgeon and pharmacist respondents will be recruited by third-party vendors using contact information maintained in representative market research lists. These lists will be used to create target lists that will include contact information for surgeons and pharmacists who practice at Registered Hospitals. These target lists will include high and low volume Product users (as well as potential users), and high and low volume
bowel resection performers. All will be given the opportunity to participate. Multiple efforts will be made to re-
contact potential respondents to minimize non-response bias.

How the surveys will be administered

A third-party vendor will send blinded (as to Sponsor) invitations via phone, fax, and/or email to surgeons and
pharmacists who reside at Registered Hospitals. They will be invited to participate via telephone or in an
online web based application. This dual approach is the most effective way to reach the target audience,
maximizing the rate of participation in this study, and ensuring that the most robust and defensible sample is
obtained.

Frequency

The Sponsor recommends two waves of research, fielded at 12 and 18 months post-launch and then annually
thereafter if education is deemed not successful (i.e., <80% accuracy rate based upon pre-selected questions
related to the Key RiskMAP Messages).

Sample Designs & Size

The Sponsor is proposing the following sample sizes per wave:

### PROJECTED SAMPLE SIZES PER WAVE

<table>
<thead>
<tr>
<th>Time Period</th>
<th>Colorectal Surgeons &amp; General Surgeons performing Bowel Resection surgeries</th>
<th>Hospital Pharmacists at hospitals that perform Bowel Resection surgeries</th>
</tr>
</thead>
<tbody>
<tr>
<td>12 months post-launch</td>
<td>150</td>
<td>150</td>
</tr>
<tr>
<td>18 months post-launch</td>
<td>150</td>
<td>150</td>
</tr>
</tbody>
</table>

These sample sizes are based on the confidence intervals in the following table:

### TABLE OF CONFIDENCE INTERVALS BY SAMPLE SIZE AND % ANSWERED CORRECTLY

- 95% Confidence Level -

<table>
<thead>
<tr>
<th>Sample Size</th>
<th>50%</th>
<th>60%</th>
<th>70%</th>
<th>80%</th>
<th>90%</th>
</tr>
</thead>
<tbody>
<tr>
<td>50</td>
<td>14%</td>
<td>14%</td>
<td>13%</td>
<td>11%</td>
<td>8%</td>
</tr>
<tr>
<td>75</td>
<td>11%</td>
<td>11%</td>
<td>10%</td>
<td>9%</td>
<td>7%</td>
</tr>
<tr>
<td>100</td>
<td>10%</td>
<td>10%</td>
<td>9%</td>
<td>8%</td>
<td>6%</td>
</tr>
<tr>
<td>125</td>
<td>9%</td>
<td>9%</td>
<td>8%</td>
<td>7%</td>
<td>5%</td>
</tr>
<tr>
<td>150</td>
<td>8%</td>
<td>8%</td>
<td>7%</td>
<td>6%</td>
<td>5%</td>
</tr>
</tbody>
</table>

**Confidence with Selected Sample Sizes**

The recommended sample size of 150 establishes a confidence interval of ±8 percentage points at the 95%
confidence level if 80% of the respondents answered correctly. It is important to note that this confidence
interval should be applied to the accuracy rate on a per question basis.
A respondent will be considered to have adequate knowledge of the Key RiskMAP messages if they accurately answer the two pre-selected survey questions correctly (Knowledgeable Respondents). The response rate will be calculated based on the number of Knowledgeable Respondents divided by the total number of Respondents.

Assumptions

The ability to meet the aforementioned sample sizes is dependant upon assumptions, including but not limited to, the number of Registered Hospitals and the HCPs affiliated therewith, overall response rate for participation, and completion rate which will depend upon pre-determined survey eligibility (awareness of the Product and potential to use or dispense the Product).

The above sample sizes assume a total universe of approximately 2500 hospitals and 15,000 surgeons (general and colorectal) that perform bowel resections. The sample sizes are based upon the rationale that all surgeons who perform bowel resections and pharmacists at Registered Hospitals where bowel resections are performed will be invited to participate. For the purposes of this sampling design exercise, it is estimated that 50% of hospitals will have registered during the twelve months post launch, a 5% response rate can be achieved with these specialties, and a subset of this sample will be eligible to complete the survey based upon pre-determined survey requirements. It is important to note that a different frequency of reporting requires reevaluation of sample size.

Regarding participation eligibility, the Sponsor proposes:

1. Every qualifying surgeon and pharmacist affiliated with the Registered Hospitals who perform bowel resections will be invited to participate, since these surgeons and pharmacists all have potential responsibility for using or dispensing the Product.
2. Respondents who answered the RiskMAP questions in Wave 1 will not be eligible to participate in Wave 2.
3. Upon conclusion of the survey, a reinforcement of the RiskMAP information will be provided to participants who answered the questions correctly and a redirection will be provided to physicians who answered incorrectly. In this manner, the survey itself can be used as a means of education reinforcement for the Key RiskMAP messages.

Survey Controls for Bias

Sampling Bias

Surveyor will be instructed to randomly sample the participants in each universe (of surgeons and pharmacists) which, based upon the projected sample sizes, is expected to engage an appropriate cross-section of HCPs from both recently enrolled and tenured registrant hospitals. Screening questions will be designed to encourage participation by all levels of the Product users/dispensers, including surgeons that have not used but probably / definitely will use the Product in the future, and Pharmacists who have not dispensed but probably / definitely will dispense in the future.

The survey will include as participants any surgeon who has ever used the Product without reference to volume of the Product use or number of bowel procedures performed. Likewise, any pharmacist employed in a pharmacy at a Registered Hospital that stocks the Product or who has dispensed the Product will be included as an eligible participant.
Individual Target HCPs may be affiliated with more than one Registered Hospital and in such cases, will only be included once in the universe. If a Target HCP is affiliated with multiple hospitals, they will be included in the universe so long as at least one of the hospitals is a Registered Hospital.

Also, multiple attempts will be made to recruit respondents from each of the Registered Hospitals, thus minimizing non-response bias.

**Questionnaire Bias**

Surveyor will ensure that survey bias is minimized through the application of careful research methods, including but not limited to, randomization of questions and response lists within questions, carefully constructed non-leading questions, and a pretest which will serve to hone the questions to be utilized in the quantitative study, and to ensure that none of the questions induce bias.

**Survey Pretests**

Prior to the first wave of the research, the third-party market research vendor will conduct pre-tests. In these pretests, approximately 8 qualifying physicians will be interviewed by a trained moderator, employing the appropriate use information and questioning sequences to be employed in the quantitative study. The pretest will serve to hone the questions to be utilized in the quantitative study, and to ensure that none of the questions induce bias. The Sponsor will submit the data collected via these survey pretests prior to the first wave of research.
**Survey Instruments**

**Surgeon Survey**

- Screen for General & Colorectal Surgeons at Registered Hospitals. Record physician specialty.
- Questions shaded in **GREEN** indicate pre-selected questions to evaluate awareness of the Key RiskMAP Messages (involved in calculation of accuracy rate).
- Appropriate programming language will be enabled and thoroughly tested.
- Respondents will be prevented from altering their previous responses.
- Response lists will be randomized.

**Screener**

1. Which of the following products have you heard of and/or ever used?

   [NOTE: Multiple products used by bowel resection surgeons will be provided in question response lists to reduce the tendency of respondents to falsely indicate they have heard of or used any one product in order to collect honoraria for participation.]

<table>
<thead>
<tr>
<th>Product</th>
<th>Yes (heard of)</th>
<th>No (haven’t heard of)</th>
<th>Unsure if I have ever heard of</th>
<th>I have used this product at least once</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amitiza (tubiprostone)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acactan (aztreonam)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Enemd (aperiplant)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Enterog (alvimopan)</td>
<td>[If selected, terminate and tally]</td>
<td>[If selected, terminate and tally]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Retistor (methylodrroxone)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reglan (meclorplamide)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Zofran (ondanestron)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

[SHOW QUESTION 2 FOR THOSE WHO HAVE NOT USED SELECT PRODUCTS]

2. For each of the products you have not yet used, what are you likely to do in the future?

   [Show all products from question above for which the respondent did not select “I have used this product at least once”]

<table>
<thead>
<tr>
<th>Product</th>
<th>Definitely will use</th>
<th>Probably will use</th>
<th>Don’t know / Unsure</th>
<th>Probably will not use</th>
<th>Definitely will not use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product 1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product 2</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Product 3</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Enterog (alvimopan)</td>
<td>If selected, continue</td>
<td>If selected, continue</td>
<td>If selected, terminate and tally</td>
<td>If selected, terminate and tally</td>
<td>If selected, terminate and tally</td>
</tr>
<tr>
<td>Product 4</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
For the next several questions you will be asked about the product Enterog® (alvimopan).

3. What is the indication for the use of Enterog? Please be as specific as possible.

4. What is the maximum number of doses of Enterog that should be administered to a patient? (Record one response)

**Randomize List**

- [ ] Maximum of 15 doses (1 pre-op dose, then post surgery BID for a maximum of 7 days) ............... 1
- [ ] Maximum of 29 doses (1 pre-op dose, then post surgery BID for a maximum of 14 days) .......... 2
- [ ] Maximum of 5 doses (1 pre-op dose, then post surgery BID for a maximum of 2 days) .......... 3
- [ ] There is no limit to number of doses ............... 4
- [ ] Don't know / unsure ................................... 5

5. Where should Enterog be administered? (Record one response)

**Randomize List**

- [ ] Only in the inpatient setting ......................... 1
- [ ] Only in the outpatient setting ...................... 2
- [ ] In both inpatient and outpatient settings ........ 3
- [ ] Don't know / unsure ................................... 4

6. The reason Enterog should be limited to short term in-patient administration is: In a long-term (12-month) clinical study for another indication, a numeric imbalance was seen in the incidence of ....

(Record one response)

**Randomize List**

- [ ] Ischemic colitis ...................................... 1
- [ ] Ischemic cardiovascular adverse events ........ 2
- [ ] Abnormal liver function test results .......... 3
- [ ] Don't know / unsure ................................... 4
[SHOW TO PHYSICIANS WHO ANSWERED Q4 AND OR Q5 INCORRECTLY]

Thank you for participating in this study. Please note that you answered incorrectly to the following question(s). The correct information regarding appropriate use of the Product as presented in the Product labeling is as follows. Please be mindful of this information when using this medication:

[INSERT QUESTION(S) HIGHLIGHTING CORRECTED RESPONSE]

[SHOW TO PHYSICIANS WHO ANSWERED Q4 AND Q5 CORRECTLY]

Thank you for participating in this study. Please note that you answered correctly to the following questions regarding appropriate use of the Product as presented in the Product labeling. Please continue to be mindful of this information:

[INSERT QUESTION(S) HIGHLIGHTING CORRECT RESPONSE]

END
Hospital Pharmacist Survey

- Screen for Hospital Pharmacists at Registered Hospitals who have a role in the dispensing of medication.
- Questions shaded in GREEN indicate pre-selected questions to evaluate awareness of the Key RiskMAP Messages (involved in calculation of accuracy rate).
- Appropriate programming language will be enabled and thoroughly tested.
- Respondents will be prevented from altering their previous responses.
- Response lists will be randomized.

1. Which of the following products have you heard of and/or ever dispensed?

   [NOTE: Multiple products used by bowel resection surgeons will be provided in question response lists to reduce the tendency of respondents to falsely indicate they have heard of or used any one product in order to collect honoraria for participation].

<table>
<thead>
<tr>
<th>Product</th>
<th>Randomize list</th>
<th>Yes (heard of)</th>
<th>No (haven’t heard of)</th>
<th>Unsure if I have ever heard of</th>
<th>I have dispensed this product at least once</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amitiza (lipigorstone)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Azactam (aztreonam)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Enterog (alvimopan)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Emend (aprepitant)</td>
<td>[If selected, terminate and tally]</td>
<td>[If selected, terminate and tally]</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EnteroG (alvimopan)</td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Ralston (methylnefropine)</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Replant (ofloclorapamido)</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Zofran (ondansetron)</td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
</tbody>
</table>

[SHOW QUESTION 2 FOR THOSE WHO HAVE NOT DISPENSED SELECT PRODUCTS]

2. For each of the products you have not yet dispensed, what are you likely to do in the future?

[Show all products from question above for which the respondents did not select “I have dispensed this product at least once”]

<table>
<thead>
<tr>
<th>Product</th>
<th>Randomize list</th>
<th>Definitely will dispense</th>
<th>Probably will dispense</th>
<th>Don’t know / Unsure</th>
<th>Probably will not dispense</th>
<th>Definitely will not dispense</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product 1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product 2</td>
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<td></td>
</tr>
<tr>
<td>Product 3</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Enterog (alvimopan)</td>
<td></td>
<td>If selected, continue</td>
<td>If selected, continue</td>
<td>If selected, terminate and talty</td>
<td>If selected, terminate and talty</td>
<td>If selected, terminate and talty</td>
</tr>
<tr>
<td>Product 4</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
For the next several questions you will be asked about the product Entereg® (alvimopan).

3. What is the indication for the use of Entereg? Please be as specific as possible.

4. What is the maximum number of doses of Entereg that should be administered to a patient? *(Record one response)*

Randomize List

- [ ] Maximum of 15 doses (1 pre-op dose, then post surgery BID for a maximum of 7 days) ............... 1
- [ ] Maximum of 20 doses (1 pre-op dose, then post surgery BID for a maximum of 14 days) ............... 2
- [ ] Maximum of 5 doses (1 pre-op dose, then post surgery BID for a maximum of 2 days) ............... 3
- [ ] There is no limit to number of doses ......................... 4
- [ ] Don’t know / unsure ................................................. 5

5. Where should Entereg be administered? *(Record one response)*

Randomize List

- [ ] Only in the inpatient setting ........................................... 1
- [ ] Only in the outpatient setting ........................................... 2
- [ ] In both inpatient and outpatient settings ..................... 3
- [ ] Don’t know / unsure ....................................................... 4

6. The reason Entereg should be limited to short term in-patient administration is: In a long-term (12-month) clinical study for another indication, a numeric imbalance was seen in the incidence of ...

*(Record one response)*

Randomize List

- [ ] Ischemic colitis ................................................. 1
- [ ] Ischemic cardiovascular adverse events .................... 2
- [ ] Abnormal liver function test results ....................... 3
- [ ] Don’t know / unsure ....................................................... 4
[SHOW TO PHARMACISTS WHO ANSWERED Q4 AND OR Q5 INCORRECTLY]

Thank you for participating in this study. Please note that you answered incorrectly to the following question(s). The correct information regarding appropriate use of the Product as presented in the Product labeling is as follows. Please be mindful of this information when using this medication:

[INSERT QUESTION(S) HIGHLIGHTING CORRECTED RESPONSE]

[SHOW TO PHARMACISTS WHO ANSWERED Q4 AND Q5 CORRECTLY]

Thank you for participating in this study. Please note that you answered correctly to the following questions regarding appropriate use of the Product as presented in the Product labeling. Please continue to be mindful of this information:

[INSERT QUESTION(S) HIGHLIGHTING CORRECT RESPONSE]

END