

## FIRST TIME GENERIC APPROVAL

<b>Brand Name</b>	Entereg®
<b>Generic Name</b>	alvimopan
<b>Drug Manufacturer</b>	Cubist Pharmaceuticals

### New Drug Approval

#### TYPE OF CLINICAL UPDATE

First time generic approval

#### FDA APPROVAL DATE

November 17, 2020

#### LAUNCH DATE

NA

#### REVIEW DESIGNATION

Standard

#### TYPE OF REVIEW

New Drug Application (NDA): 021775

#### DISPENSING RESTRICTIONS

The drug is available only to hospitals that enroll in a restricted program for short-term use called the Entereg® Access Support & Education (E.A.S.E.) Program.

### Overview

#### INDICATION FOR USE

Alvimopan capsules are indicated to accelerate the time to upper and lower gastrointestinal recovery following surgeries that include partial bowel resection with primary anastomosis.

#### MECHANISMS OF ACTION

It is a peripherally-selective, mu-opioid receptor antagonist that is restricted in activity to the GI tract. Postoperative ileus can affect all segments of the gastrointestinal tract and is characterized by abdominal distention and bloating, nausea, vomiting, pain, accumulation of gas and fluid in the bowel, and delayed passage of flatus and defecation, potentially prolonging gastrointestinal recover hospitalization after bowel surgery. Opioid agonists (e.g., morphine) are used universally and effectively for the treatment of postoperative pain; however, their use may result in inhibition of gastrointestinal motility and contribute to the development of postoperative ileus. Because alvimopan acts within the gastrointestinal tract, it antagonizes opioid-induced gastrointestinal dysfunction while maintaining the central analgesic effects of opioid agonists. In isolated guinea pig ileum, alvimopan competitively antagonizes the effects of morphine on contractility.

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### DOSE FORM AND STRENGTH

Capsules: 12 mg

### DOSE & ADMINISTRATION

- For hospital use only.
- The recommended dosage is 12 mg administered 30 minutes to 5 hours prior to surgery followed by 12 mg twice daily beginning the day after surgery until discharge for a maximum of 7 days. Patients should not receive more than 15 doses of alvimopan capsules.
- Alvimopan capsules can be taken with or without food.

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