

▼ RIZMOIC®

NALDEMEDINE FOR OPIOID-INDUCED CONSTIPATION

Low-cost oral alternative

PRODUCT INFORMATION



IMPORTANT THERAPEUTIC INNOVATION



MODEST THERAPEUTIC INNOVATION



SOME ADDED VALUE IN SPECIFIC SITUATIONS



NO THERAPEUTIC INNOVATION



INSUFFICIENT EVIDENCE

WHAT IS IT?

Peripheral opioid receptor antagonist.

INDICATION

Opioid-induced constipation in adults who have previously been treated with a laxative. In Spain, it is only funded in oncology patients.

POSODOLOGY AND METHOD OF ADMINISTRATION

A 200 mcg tablet once-a-day. It may be used with or without laxatives. Stop treatment if opioid pain medication is discontinued. **Special populations:** No dose adjustment is required in >65 years of age, or in mild or moderate renal or hepatic impairment. Use with caution in >75 years of age. Avoid in severe hepatic impairment. Clinical monitoring is needed when initiating therapy in severe renal impairment.

EFFICACY

Compared to placebo: Response was defined as ≥ 3 spontaneous bowel movements per week and an increase from baseline of ≥ 1 spontaneous bowel movement per week. In cancer patients, response increased by 36.8%, and in two studies in patients with chronic non-cancer pain (CNC) 13.0% and 18.9%. A third study in CNC showed an increase in 1.28 spontaneous bowel movements per week at 12 weeks and 1.00 at 52 weeks.

RISKS

The most frequently reported adverse reactions in CNC patients were abdominal pain (7.8%), diarrhoea (5.9%), nausea (3.6%) and vomiting (1.1%); while in cancer patients, they were diarrhoea (24.5%) and abdominal pain (3.9%). The majority of these adverse events were of mild to moderate severity. Serious cases of intestinal perforation were reported in high-risk patients. **Contraindications:**

gastrointestinal obstruction or perforation; concomitant use with CYP3A inhibitors/inducers and P-glycoprotein inhibitors. **Caution:** naldemedine may precipitate symptoms of opioid withdrawal. It hasn't been studied in patients with myocardial infarction, stroke or transient ischaemic attack.

PLACE IN THERAPEUTICS

Alternative in CNC adult patients (non-financed) or cancer patients (financed) with opioid-induced constipation who do not respond to laxatives. Although it has not been directly compared with other drugs, it has advantages over methylnaltrexone related to administration route (oral vs. subcutaneous administration) and over naloxegol for having efficacy studies in oncology patients. It has a similar safety profile than available therapeutic alternatives and lower cost.

PRESENTATIONS

Rizmoic® 200 mcg 28 film-coated tablets (80.8 €).

Daily cost treatment (euros)

NALDEMEDINE (200 mcg) **2.86**

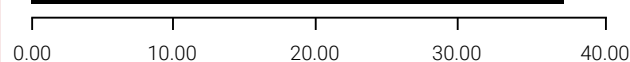
NALOXEGOL (12.5 mg) **3.42**

METILNALTREXONE (12 mg) **21.21**

Minimum dose: 4 times/week

METILNALTREXONE (12 mg) **37.12**

Maximum dose: once-a-day



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