

Go with SYMPROIC®

Symproic®
(naldemedine) tablets
0.2 mg




















GO WITH IT

Your OIC treatment shouldn't define your every move

Only the one that matters. Go with SYMPROIC

Opioid-induced constipation (OIC) may interfere with your daily routine, but your treatment does not have to. SYMPROIC has been proven to provide relief from OIC with a simple dosing regimen.^{1,2} Unlike other prescription treatments, SYMPROIC can be taken once daily, any time of day, with or without food or laxatives.² With SYMPROIC, your OIC treatment does not have to define your every move. Just go with it!

Not all prescription OIC treatments are created equal

OIC treatment	 Is it taken once daily? ²⁻⁴	 Can you take it any time of day? ²⁻⁴	 Can you take it with or without food? ²⁻⁴	 Can you keep taking laxatives when starting therapy? ²⁻⁴
 Symproic® (naldemedine) tablets 0.2 mg	 Yes	 Yes	 Yes	 Yes
 movantik® (naloxegol) 25 mg tablets	 Yes	 No	 No	 No
 RELISTOR® methylnaltrexone bromide Tablets	 Yes	 No	 No	 No

SYMPROIC is a RECOMMENDED OIC therapy

SYMPROIC is the only drug in its class with both a **strong recommendation** and a **high quality of evidence** from the American Gastroenterological Association.⁵

Please see Medication Guide on page 2 and full Prescribing Information at SYMPROIC.com.

MEDICATION GUIDE

What is the most important information I should know about SYMPROIC?

SYMPROIC may cause serious side effects, including:

- **Tear in your stomach or intestinal wall (perforation).** Stomach pain that is severe can be a sign of a serious medical condition. If you get stomach pain that does not go away, stop taking SYMPROIC and get emergency medical help right away.
- **Opioid withdrawal.** You may have symptoms of opioid withdrawal during treatment with SYMPROIC including sweating, chills, tearing, warm or hot feeling to your face (flush), sneezing, fever, feeling cold, abdominal pain, diarrhea, nausea, and vomiting. Tell your healthcare provider if you have any of these symptoms.

What is SYMPROIC?

SYMPROIC is a prescription medicine used to treat constipation that is caused by prescription pain medicines called opioids, in adults with long-lasting (chronic) pain that is not caused by active cancer. It is not known if SYMPROIC is safe and effective in children.

Do not take SYMPROIC if you:

- have a bowel blockage (intestinal obstruction) or have a history of bowel blockage.
- Are allergic to SYMPROIC or any of the ingredients in SYMPROIC. See the end of this Medication Guide for a complete list of ingredients in SYMPROIC. Tell your healthcare provider or pharmacist before you start or stop any medicines during treatment with SYMPROIC.

Before you take SYMPROIC, tell your healthcare provider about all of your medical conditions, including if you:

- have any stomach or bowel (intestines) problems, including stomach ulcer, Crohn's disease, diverticulitis, cancer of the stomach or bowel, or Ogilvie's syndrome.
- have liver problems.
- are pregnant or plan to become pregnant. Taking SYMPROIC during pregnancy may cause opioid withdrawal symptoms in your unborn baby. Tell your healthcare provider right away if you become pregnant during treatment with SYMPROIC.
- are breastfeeding or plan to breastfeed. It is not known if SYMPROIC passes into your breast milk. You should not breastfeed during treatment with SYMPROIC and for 3 days after your last dose. Taking SYMPROIC while you are breastfeeding may cause opioid withdrawal symptoms in your baby. You and your healthcare provider should decide if you will take SYMPROIC or breastfeed. You should not do both.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Other medicines may affect the way SYMPROIC works.

How should I take SYMPROIC?

- Take SYMPROIC exactly as your healthcare provider tells you to take it.
- Take your prescribed dose of SYMPROIC 1 time each day.
- SYMPROIC can be taken with or without food.

- SYMPROIC has been shown to be effective in people who have taken opioid pain medicines for at least 4 weeks.
- Tell your healthcare provider if you stop taking your opioid pain medicine. If you stop taking your opioid pain medicine, you should also stop taking SYMPROIC.

What are the possible side effects of SYMPROIC?

See "**What is the most important information I should know about SYMPROIC?**"

The most common side effects of SYMPROIC include stomach (abdomen) pain, diarrhea, nausea and vomiting (gastroenteritis).

Tell your healthcare provider if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of SYMPROIC. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store SYMPROIC?

- Store SYMPROIC at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep SYMPROIC in the bottle that it comes in.

Keep SYMPROIC and all medicines out of the reach of children.

General information about the safe and effective use of SYMPROIC.

Medicines are sometimes prescribed for purposes other than those in a Medication Guide. Do not take SYMPROIC for a condition for which it was not prescribed. Do not give SYMPROIC to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about SYMPROIC that is written for health professionals.

What are the ingredients in SYMPROIC?

Active Ingredient: naldemedine tosylate

Inactive ingredients: D-mannitol, croscarmellose sodium, magnesium stearate, hypromellose, talc, and yellow ferric oxide

Manufactured for: BioDelivery Sciences International, Inc. Raleigh, NC 27612

Please see [Important Safety Information](#) and full [Prescribing Information](#) for SYMPROIC.

To report SUSPECTED ADVERSE REACTIONS, contact BioDelivery Sciences International, Inc. at 1-800-469-0261 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

References

1. Hale M, Wild J, Reddy J, Yamada T, Arjona Ferreira JC. Naldemedine versus placebo for opioid-induced constipation (COMPOSE-1 and COMPOSE-2): two multicentre, phase 3, double-blind, randomised, parallel-group trials. *Lancet Gastroenterol Hepatol*. 2017;2(8):555-564.
2. SYMPROIC [package insert]. Raleigh, NC: BioDelivery Sciences International, Inc.; 2020.
3. MOVANTIK [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; 2020.
4. RELISTOR [package insert]. Bridgewater, NJ: Salix Pharmaceuticals, Inc.
5. Crockett SD, Greer KB, Heidelbaugh JJ, Falck-Ytter, Hanson BJ, Sultan S, American Gastroenterological Association Institute Clinical Guidelines Committee. American Gastroenterological Association Institute guideline on the medical management of opioid-induced constipation. *Gastroenterology*. 2019;156(1): 218-226.

