

Questions about opioid-induced constipation (OIC)

Q What is opioid-induced constipation?

OIC, also known as opioid constipation, is a common condition that affects many people taking long-term opioid treatments. Opioids work by binding to opioid receptors found throughout the central nervous system. This results in pain relief. However, the same receptors are also found in the intestinal tract. When opioids bind with receptors in the intestinal tract, it commonly results in constipation. Opioid constipation is different from other forms of constipation and may require a different kind of treatment.

Q Where is opioid constipation felt?

If you've experienced constipation, you know how uncomfortable it can feel. Some of the many common sensations or symptoms of OIC include:

- Constant bloating
- Feeling "full"
- Cramping in the gastrointestinal (GI) tract
- Stomach discomfort, pressure, or pain
- Rectal discomfort or pain
- Aching in the lower back

Q How is opioid constipation treated?

Because about 40% to 50% of patients receiving opioid therapy for chronic non-cancer pain report experiencing constipation, your healthcare provider may prescribe a laxative at the same time that your opioid medicine is prescribed. Laxatives may work temporarily, but if you are taking opioids long term, your healthcare provider may recommend a prescription treatment, like a PAMORA (peripherally acting mu-opioid receptor antagonist). PAMORAs, like SYMPROIC, work by addressing the underlying cause of OIC by blocking the effects of opioids in the gut.

Q Why do opioids cause constipation?

Opioid constipation is different from other kinds of constipation. When taking an opioid, the pain signals to your brain are reduced. However, because the same kind of receptors are found along your digestive tract, opioids can also cause constipation. This type of constipation is known as OIC—or opioid-induced constipation—and may require a prescription treatment.

Q How can I relieve constipation due to pain medicine?

Some degree of opioid constipation is felt by many people who take opioids. For some people with opioid constipation, over-the-counter treatments are not enough. If you are taking an opioid for chronic non-cancer pain and it causes constipation, your doctor may be able to prescribe a medicine that is specifically designed to target the source of opioid constipation.

Q How should I talk to my doctor about my opioid constipation symptoms?

OIC is different from regular constipation and may last as long as you take opioids. Use the [Doctor Discussion Guide](#) to help start an open and honest conversation with your healthcare provider about your symptoms of OIC.

Q Do all opioids cause constipation?

Although side effects vary from person to person, all opioids can potentially lead to opioid constipation. Pain medications that fall into the "opioid" category include:

- Morphine
- Codeine
- Hydrocodone
- Oxycodone/OxyContin

If your chronic pain is finally under control with an opioid, the last thing you want is the frustration and discomfort of constipation. Although not every person will experience opioid constipation, it is by far the most common and debilitating effect of long-term opioid therapy. Find out more by visiting our page [all about OIC](#).

Questions about SYMPROIC[®]

Q 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.

SYMPROIC is the only OIC therapy with a strong recommendation and high quality of evidence from the American Gastroenterological Association.

SYMPROIC can help you go:*,†

- More often
- More completely
- Without straining

*Results from clinical studies compared with placebo (sugar pill).

†Individual results may vary.

Q How does SYMPROIC work?

SYMPROIC works by helping to address the cause of OIC. It blocks the effects of opioids in your gut, giving your bowel a chance to work.

Q What are the most common side effects of SYMPROIC?

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

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.

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 the FDA at 1-800-FDA-1088.

Q How can SYMPROIC help improve OIC symptoms?

Symptoms of OIC include

- Going less often
- Pushing harder (straining more)
- Not going all the way
- Passing harder stools

Clinical studies in patients with chronic non-cancer pain have shown SYMPROIC can help with these OIC symptoms. SYMPROIC may help you go:*,†

- More often—Bowel movements occur more frequently
- More completely—Bowel movements feel complete
- Without straining—Bowel movements are easier to pass

*Results from clinical studies compared with placebo (sugar pill).

†Individual results may vary.

Learn more about SYMPROIC and OIC by visiting our page [What is SYMPROIC?](#)

Questions about SYMPROIC[®] cost and savings

Q How much does SYMPROIC cost?

The cost of SYMPROIC varies based on insurance and pharmacy. Check with your insurance provider and pharmacy to determine the cost.

Q Will my insurance cover SYMPROIC?

Every insurance plan is different. Check with your insurance provider to determine your coverage.

Q How do I save on my OIC medicine?

If eligible, you could pay as little as \$0 for each prescription of SYMPROIC. Maximum savings limits apply, and out-of-pocket expense may vary depending on your insurance provider. Find out if you're eligible [here](#).

Follow these simple steps to save on SYMPROIC:

1. If you're eligible, download the [SYMPROIC Savings Card](#).
2. Call 1-844-231-2396 to activate your SYMPROIC Savings Card.
3. Present your SYMPROIC Savings Card and your prescription to your pharmacist.

Q How do I activate my SYMPROIC Savings Card?

You must activate your SYMPROIC Savings Card before using it. Activate your card by calling [1-844-231-2396](tel:1-844-231-2396).

Q Are there any restrictions on the SYMPROIC Savings Card?

The card cannot be used if your prescriptions are covered by

- Any federal or state healthcare program, including a state medical or pharmaceutical assistance program (Medicare, Medicaid, Medigap, VA, DOD, TRICARE, etc.)
- Medicare's Prescription Drug Program (Part D Program)
- Insurance in states that have an "all payor" anti-kickback law or insurance that is paying the entire cost of the prescription

Cash-paying patients are not eligible. Click [here](#) to review all Terms and Conditions and Eligibility Requirements.

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.

