



Is chronic constipation keeping you stuck in the bathroom?

Ask your doctor if AMITIZA can help your chronic constipation symptoms

Individual results may vary.

[Talk About AMITIZA.com](http://TalkAboutAMITIZA.com)

Make the conversation with your doctor easier

Create a discussion guide at TalkAboutAMITIZA.com

If your doctor determines you have chronic constipation, and laxatives haven't helped enough, ask if you can start with a free sample of AMITIZA.

Indication

AMITIZA (lubiprostone) 24 mcg capsules twice daily is approved to treat Chronic Idiopathic Constipation (CIC) in adults. "Idiopathic" means the cause of the constipation is unknown and not due to an underlying illness or medication.

Important Safety Information

AMITIZA (lubiprostone) is not for everyone. If you know or suspect you have a bowel blockage, do not take AMITIZA. If you are unsure, your healthcare provider (HCP) should evaluate your condition before starting AMITIZA.

Some patients taking AMITIZA may experience nausea. Take AMITIZA with food and water to reduce the occurrence of nausea.

Do not take AMITIZA if you have severe diarrhea. Some patients taking AMITIZA may experience diarrhea. If your diarrhea becomes severe, stop taking AMITIZA and tell your HCP.

Patients may experience fainting and low blood pressure after taking the first dose or repeated doses of AMITIZA. Stop taking AMITIZA and tell your HCP if these reactions occur. Symptoms usually go away before the next dose but may recur with repeated use. Tell your HCP if you are taking any medications to lower blood pressure. Other side effects such as diarrhea or vomiting may increase the risk of fainting and low blood pressure.

Important Safety Information (cont.)

Within an hour of taking AMITIZA, a sensation of chest tightness and shortness of breath may occur. These symptoms usually go away within three hours, but may recur with repeated use. Tell your HCP if you experience these symptoms.

The most common side effects of taking AMITIZA 24 mcg twice daily for CIC are nausea, diarrhea, headache, abdominal pain, abdominal distension, and gas. These are not all the side effects associated with AMITIZA.

Tell your HCP if you are taking a diphenylheptane opioid (e.g., methadone).

AMITIZA has not been studied in pregnant women. Based on animal studies, AMITIZA may cause fetal harm. AMITIZA should only be used during pregnancy if the potential benefits justify the potential risk to the fetus. If you are pregnant or become pregnant while being treated with AMITIZA, talk to your HCP to evaluate the risks to the fetus. Tell your HCP if you are nursing and monitor infants for diarrhea.

Tell your HCP if you have liver problems.

Please see accompanying Important Patient Information for AMITIZA on reverse side.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.



IMPORTANT PATIENT INFORMATION

AMITIZA® [ah-mah-TEE-zah]
(lubiprostone)
soft gelatin capsules



Rx Only

Please read this consumer brief summary carefully before you start taking AMITIZA. Read it again each time you refill your prescription, in case there is any new information. This information does not take the place of talking to your healthcare professional about your medical condition or treatment. Ask your healthcare professional if you do not understand any of this information or if you want to learn more about AMITIZA.

What is AMITIZA?

AMITIZA is a prescription medicine formulated as a soft gelatin capsule and available in two dosages used to treat the following conditions:

- Chronic Idiopathic Constipation (orange capsules, 24 mcg, twice daily) in adults. Idiopathic means the cause of the constipation is unknown and not due to underlying illness or medication.
- Constipation caused by opioids, a type of prescription pain medicine, in adults with chronic pain that is not caused by active cancer (orange capsules, 24 mcg, twice daily). The effectiveness of AMITIZA has not been established if you are taking a diphenylheptane opioid (e.g., methadone).
- Irritable Bowel Syndrome with Constipation in adult women (pink capsules, 8 mcg, twice daily).

It is not known if AMITIZA is safe and effective in children under 18 years of age.

Who should not take AMITIZA?

Do not take AMITIZA if:

- You know or suspect you have a bowel blockage. If you are unsure, your healthcare professional should check your condition before starting AMITIZA.
- You have severe diarrhea.
- You are pregnant or become pregnant, unless you have discussed this with your healthcare professional. Based on animal studies, AMITIZA may cause fetal harm. AMITIZA should only be used in pregnancy if the potential benefit justifies the potential risks to the fetus. If you are pregnant or become pregnant while being treated with AMITIZA, talk to your healthcare professional to evaluate the risks to the fetus. Tell your healthcare professional if you are breast-feeding, and monitor infants for diarrhea.
- You are allergic to AMITIZA or any of its ingredients. See the end of this brief summary of important patient information for a complete list of ingredients.

What should I tell my healthcare professional before and while taking AMITIZA?

Before you take AMITIZA, tell your healthcare professional if you:

- are pregnant or plan to become pregnant. AMITIZA has not been studied in pregnant women and should only be used during pregnancy if the potential benefits justify the potential risk to the fetus. If you are pregnant or become pregnant while being treated with AMITIZA, talk to your healthcare professional to evaluate the risks to the fetus.
- are breastfeeding or planning to breastfeed. If breastfeeding while taking AMITIZA, you should monitor the breastfed infant for diarrhea.
- have liver problems.
- cannot swallow a capsule.

Tell your healthcare professional about all the medicines you take or plan to take, including prescription and nonprescription medicines, vitamins and herbal supplements. AMITIZA may affect how other medicines work, and other medicines may affect how AMITIZA works. Especially tell your doctor if you are taking a diphenylheptane opioid (e.g., methadone). Tell your doctor if you are taking any medications to lower blood pressure.

How should I take AMITIZA?

AMITIZA should be taken with food and water twice a day or as prescribed by your healthcare professional. Swallow the gelatin capsule whole. Capsules should not be broken apart or chewed.

If you miss a dose of AMITIZA, just skip that dose. Do not take two capsules to make up for the missed dose. Instead, just wait until the next time you are supposed to take it, and then take your normal dose.

What are the possible side effects of AMITIZA?

The most common side effects reported by patients taking AMITIZA 24 mcg twice daily included:

Chronic Idiopathic Constipation

- nausea
- abdominal pain
- diarrhea
- abdominal distention (bloating)
- headache
- gas

Opioid-Induced Constipation

- nausea
- diarrhea

The most common side effects reported by patients taking AMITIZA 8 mcg twice daily included:

Irritable Bowel Syndrome with Constipation

- nausea
- diarrhea
- abdominal pain

Patients taking AMITIZA may experience nausea; taking AMITIZA with food and water may reduce symptoms of nausea.

If you experience severe diarrhea, stop taking AMITIZA and tell your healthcare professional.

Patients may experience fainting and low blood pressure after taking the first dose or repeated doses of AMITIZA. Stop taking AMITIZA and tell your HCP if these reactions occur. Symptoms usually go away before the next dose but may recur with repeated use. Other side effects such as diarrhea or vomiting may increase the risk of fainting and low blood pressure.

Within an hour of taking AMITIZA, a sensation of chest tightness and shortness of breath may occur; these symptoms usually go away within three hours, but may recur with repeated use. Tell your healthcare professional if you experience any of these symptoms.

These are not all the possible side effects of AMITIZA. Tell your doctor if you have any side effects that bother you or that do not go away. For more information, ask your healthcare professional or pharmacist. Call your healthcare professional for medical advice about side effects. You may report side effects to the U.S. Food and Drug Administration (FDA) at 1-800-FDA-1088.

How should I store AMITIZA?

Store AMITIZA at room temperature and protect from light and extreme temperatures. AMITIZA should be stored in a tightly closed, child-proof container and kept out of the reach of children. Do not use AMITIZA past the expiration date shown on the package.

General information about AMITIZA

Do not use AMITIZA for a disease or condition for which it was not prescribed. Do not give AMITIZA to others, even if they have the same symptoms you have. It may harm them.

If you would like more information, talk with your healthcare professional. You can ask your pharmacist or healthcare professional for information that is written for healthcare professionals. For more information about AMITIZA, you can visit the AMITIZA website at www.amitiza.com or call toll-free at 1-877-825-3327.

What are the ingredients in AMITIZA?

Active ingredient: lubiprostone, 24 mcg or 8 mcg

Inactive ingredients: medium-chain triglycerides, gelatin, sorbitol and purified water. The 24 mcg (orange) capsules also contain the dyes FD&C Red #40 and D&C Yellow #10. The 8 mcg (pink) capsules also contain the dyes ferric oxide and titanium dioxide.

Marketed by:

Sucampo Pharma Americas, LLC., Rockville, MD 20850 and
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