

**PACKAGE LEAFLET: INFORMATION FOR THE
USER AMITIZA 24 MICROGRAM SOFT CAPSULES**

Lubiprostone.

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What AMITIZA is and what it is used for?
2. Before you take AMITIZA
3. How to take AMITIZA
4. Possible side effects
5. How to store AMITIZA
6. Further information

1. WHAT AMITIZA IS AND WHAT IT IS USED FOR?

AMITIZA capsules work by increasing the amount of fluids into the bowels. This helps the passage of stool and reduces the feeling of uncomfortable and difficult bowel movements that occurs with constipation.

AMITIZA is used to treat chronic constipation.

2. BEFORE YOU TAKE AMITIZA

Do not take AMITIZA:

- If you are allergic (hypersensitive) to lubiprostone or any of the other ingredients of AMITIZA.
- If you have a blockage in your bowels (intestine).
- If you are less than 18 years of age. There is no information available on the use of AMITIZA in people under 18 years of age

This medicinal product contains the sugar sorbitol, if you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Do not take AMITIZA if you think any of these apply to you.

Take special care with AMITIZA:

- It is possible that you may feel like getting sick (nausea) whilst taking AMITIZA. Taking AMITIZA with food will help to reduce this feeling.

- If you have certain symptoms such as severe stomach pain or cramps your doctor may need to check if you have a blockage or inflammation in your bowels. If you have any of these problems AMITIZA may not be suitable for you.
- You should not take AMITIZA if you have severe diarrhoea. You may get diarrhoea while taking AMITIZA. If you get severe diarrhoea tell your doctor.
- It is possible that sometimes, shortly after taking AMITIZA that you may feel short of breath, or have a feeling of tightness in your chest. This usually stops within a few hours, but if you are worried please contact your doctor, who will help you, before taking any more AMITIZA.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. This includes treatments that you might buy in a pharmacy or in a supermarket.

Taking AMITIZA with food and drink

AMITIZA should be taken with food and the capsules should be swallowed whole with a sufficient amount of water. Taking AMITIZA with food may reduce symptoms of nausea.

Pregnancy and breast-feeding

AMITIZA has not been studied in pregnant women and should not be used during pregnancy and in women of childbearing potential not using contraception.

It is not known whether AMITIZA is excreted in human milk. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from AMITIZA, it should not be used whilst breastfeeding.

Ask your doctor or pharmacist for advice before taking any medication.

Driving and using machines

No studies on the effects on the ability to drive and use machines have been performed.

If you experience a side effect of AMITIZA that may affect your ability to drive or operate machinery, do not drive or operate machinery.

Important information about some of the ingredients of AMITIZA

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking AMITIZA, this is because AMITIZA contains sorbitol.

3. HOW TO TAKE AMITIZA

Always use AMITIZA exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

For adults only: The usual dose is one 24 microgram capsule twice a day. You should only take AMITIZA for 2 to 4 weeks. If you do not respond to Amitiza at least after 2 weeks talk to your doctor.

Take AMITIZA with water at mealtimes. AMITIZA may make you feel nauseous and taking it with food may help. The capsules should be swallowed whole and should not be broken apart or chewed.

Your doctor should regularly assess the need for you to continue treatment.

If you take more AMITIZA than you should

If you accidentally take too many capsules you are more likely to experience side effects. You should contact your doctor or pharmacist immediately. If possible, take your bottle of capsules with you to show the doctor or pharmacist.

If you forget to take AMITIZA

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.

If you stop taking AMITIZA

Take AMITIZA as prescribed by your doctor, if you stop taking AMITIZA your symptoms may return. If you think you are suffering from a side effect of AMITIZA, ask your doctor or pharmacist for advice. If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, AMITIZA can cause side effects, although not everybody gets them.

The most common (more than 1 in 10 patients) side effects reported by people taking AMITIZA was nausea, with diarrhoea and headache, also being commonly reported.

Tell your doctor if you experience severe nausea. Your doctor may be able to suggest other ways to manage your nausea. If you do get nausea, taking AMITIZA with food may reduce the symptoms.

If you get severe diarrhoea during treatment or your diarrhoea worsens, tell your doctor immediately.

Other common (greater than 1 in 100 patients) side effects reported by people taking AMITIZA included abdominal pain, abdominal swelling, flatulence, loose stools, dizziness, increased heart rate, oedema, tiredness, chest discomfort/pain, shortness of breath, abdominal discomfort, upset stomach, dry mouth, excessive sweating, hot flushes and stomach discomfort.

Rarely (greater than 1 in 1000 patients) the following have been reported: vomiting, occasional fainting and muscle spasms.

Also, some reports of flu-like symptoms, throat tightness, allergic reaction/rash, low blood pressure and insufficient blood supply to the large intestine causing inflammation (ischaemic colitis) have been received but it is not possible to accurately estimate their frequency.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly to HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel:

+353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE AMITIZA

Keep out of the reach and sight of children.

Keep the container tightly closed.

Store in the original container. Once opened, use within 4 weeks.

Do not store above 30°C. Do not freeze.

Do not use AMITIZA after the expiry date, which is stated on the bottle and carton as “EXP” followed by the date. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What AMITIZA contains

- The active substance is lubiprostone
- One soft capsule contains 24 micrograms of lubiprostone
- The other ingredients are medium-chain triglycerides, gelatin, sorbitol (E420), and purified water.
- The outside of each soft capsule has black ink printing. The black ink consists of propylene glycol, black iron oxide, polyvinyl acetate phthalate and polyethylene glycol.

What AMITIZA looks like and contents of the bottle

AMITIZA is available as an oval, soft gelatin capsule with an amber appearance with SPI printed on one side. Each capsule contains 24 micrograms of lubiprostone.

Each bottle contains 28 or 56 capsules of AMITIZA.

Marketing Authorisation Holder and Manufacturer

The marketing authorisation holder of AMITIZA is:

Takeda UK Limited
Building 3,
Glory Park,
Glory Park Avenue,
Wooburn Green,
BUCKS,
HP10 0DF,
UK

The manufacturer of AMITIZA is:

~~Catalent UK Packaging Ltd.~~
~~Lancaster Way~~
~~Wingates Industrial Estate~~

~~Westhoughton~~
~~Bolton~~
~~Lancashire~~
~~BL5 3XX~~
~~United Kingdom~~

~~and~~

Takeda GmbH (Plant Singen)
Robert Bosch Strasse 8
78224 Singen
Germany

For any information about this medicine, reporting an undesired effect or a product defect,
please contact the Marketing Authorisation Holder.

This leaflet was last approved in ~~April~~December 2016.