Abbreviated Prescribing Information

AMITIZA® ▼ (lubiprostone)

Before prescribing AMITIZA please consult the full Summary of Product Characteristics (SmPC) (http://www.medicines.org.uk/emc/). **Presentation:** Soft capsule 24 µg lubiprostone. **Indication:** Treatment of chronic idiopathic constipation in adults (>18years of age), when response to diet and other non-pharmacological measures (e.g., educational measures, physical activity) are inappropriate. **Dosage and administration:** One 24 µg capsule should be taken twice daily orally with food. A course of treatment is 2 to 4 weeks. No dosage changes are required based on age. No dose adjustment is required in patients with renal impairment or mild hepatic impairment. For patients with moderate to severe hepatic impairment (Child-Pugh classification B or C), the initial dosage should be decreased to 24 µg (1 capsule once a day after breakfast or supper). If the initial dose is tolerated and an adequate response has not been obtained after an appropriate interval, the dose can be increased to full dosing (1 capsule twice daily) with appropriate monitoring of patient response. **Contraindications:** Should not be used in patients with known or suspected mechanical gastrointestinal obstructions or with hypersensitivity to the active ingredient or to any of the excipients. **Warnings and Precautions:** Patients may experience nausea. If this occurs, concomitant consumption of food may reduce symptoms of nausea. AMITIZA should not be prescribed to patients that have severe diarrhoea. Patients should be aware of the possible occurrence of diarrhoea during treatment and inform their physician if severe diarrhoea occurs. Patients may experience dyspnoea or chest discomfort/pain shortly after taking AMITIZA. These symptoms generally resolve within a few hours, but recurrence has been reported with subsequent doses. If these symptoms occur, patients should seek medical advice. Due to the use of sorbitol as an excipient, patients with rare hereditary problems of fructose intolerance should not take this medicine. **Interactions:** It is unlikely that AMITIZA will cause interactions with other medications. **Pregnancy and lactation:** AMITIZA should not be used during pregnancy. In case of pregnancy, the risks and benefits of continued AMITIZA therapy should be considered. If breastfeeding, a decision must be made whether to discontinue breastfeeding or to discontinue/abstain from Amitiza therapy. **Side effects:** Most common adverse drug reaction from clinical trials and post marketing experience (≥ 1/10) was nausea. Other common adverse drug reactions (≥ 1/100 to < 1/10) were palpitations, diarrhoea, abdominal distension, flatulence, abdominal discomfort, abdominal pain, dyspepsia, oedema, chest discomfort, headache, dizziness, dyspnoea, hyperhidrosis and hot flush. For a full list of adverse drug reactions reported in clinical studies and post-marketing surveillance, please consult the SmPC. **Presentation and basic NHS price:** Bottles containing 28 and 56 soft capsules of 24 µg lubiprostone: £29.68 and £53.48, respectively. **Legal classification:** POM. **Marketing authorisation number:** PL 16189/0030. Further information is available from Takeda UK Ltd, Building 3, Glory Park, Glory Park Avenue, Wooburn Green, Bucks, HP10 0DF Tel: 01628 537900. Fax: 01628 526617. **Date of preparation:** March 2016. **Job code:** AMI/UK/160309

Adverse drug events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Takeda UK Ltd. on 01628 537900 or email DSO-UK@takeda.com