XENICAL® (orlistat), Capsules, for oral use

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use XENICAL safely and effectively. See full prescribing information for details.

INDICATIONS AND USAGE

- XENICAL is a reversible inhibitor of pancreatic lipase that delays absorption of dietary fat.
- XENICAL is indicated for obesity management including weight loss and weight maintenance when used in conjunction with a reduced-calorie diet.

CONTRAINDICATIONS

- XENICAL is contraindicated in patients who have hypersensitivity to orlistat or to any component of this product.

WARNINGS

- XENICAL is a GI enzyme inhibitor and may be associated with GI symptoms such as oily stools, loose stools, and flatulence.
- Patients may have increased risk of adverse events such as gastrointestinal symptoms, including oily stools, flatulence, and loose stools, when taken with other treatments such as antacids, iron supplements, and aspirin.

PRECAUTIONS

- XENICAL should be used with caution in patients with concomitant alcohol and/or tobacco use, as it can increase the risk of liver injury.

ADVERSE REACTIONS

- The most common adverse events reported with XENICAL use are gastrointestinal events.

DRUG INTERACTIONS

- XENICAL is not known to interact with other medications. However, patients should be monitored for changes in coagulation parameters.

DOSE AND ADMINISTRATION

- XENICAL should be taken 3 times a day with each main meal.

HOW SUPPLIED/STORAGE AND HANDLING

- XENICAL is supplied in blisters of 30 capsules.

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FULL PRESCRIBING INFORMATION

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12.2 Pharmacodynamics

The effects of XENICAL on body mass index (BMI) and weight loss were assessed in a 54-week multicenter, double-blind, parallel-group study in 1,084 patients randomized to receive XENICAL 120 mg three times a day or placebo plus diet. The study was conducted in a diet-controlled setting. Each patient received a meal plan designed to meet individual energy requirements. The mean change in weight from baseline at 54 weeks was 9.2% in the XENICAL group and 2.4% in the placebo group. The mean change in BMI was 7.3% in the XENICAL group and 3.3% in the placebo group. The effects of XENICAL on body mass index (BMI) and weight loss were assessed in a 54-week multicenter, double-blind, parallel-group study in 1,084 patients randomized to receive XENICAL 120 mg three times a day or placebo plus diet. The study was conducted in a diet-controlled setting. Each patient received a meal plan designed to meet individual energy requirements. The mean change in weight from baseline at 54 weeks was 9.2% in the XENICAL group and 2.4% in the placebo group. The mean change in BMI was 7.3% in the XENICAL group and 3.3% in the placebo group.

12.3 Dose-Response Relationship

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12.4 Pharmacokinetics

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13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

The relative differences in risk factors between treatment with XENICAL and placebo were similar to the results observed in the year one studies. The mean change in weight from baseline at 54 weeks was 9.2% in the XENICAL group and 2.4% in the placebo group. The mean change in BMI was 7.3% in the XENICAL group and 3.3% in the placebo group.

14.2 Onset of Type 2 Diabetes in Obese Patients

The treatment effects of XENICAL were examined for 2 years in four of the five 1-year weight management clinical studies, 14119C and 14185). The diet utilized during the 1-year weight regain portion of the studies was a weight-maintenance diet. The relative differences in risk factors between treatment with XENICAL and placebo were similar to the results observed in the year one studies. The mean change in weight from baseline at 54 weeks was 9.2% in the XENICAL group and 2.4% in the placebo group. The mean change in BMI was 7.3% in the XENICAL group and 3.3% in the placebo group.

14.3 Clinical Trials

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14.4 Other Believable Explanations

The treatment effects of XENICAL were examined for 2 years in four of the five 1-year weight management clinical studies, 14119C and 14185). The diet utilized during the 1-year weight regain portion of the studies was a weight-maintenance diet. The relative differences in risk factors between treatment with XENICAL and placebo were similar to the results observed in the year one studies. The mean change in weight from baseline at 54 weeks was 9.2% in the XENICAL group and 2.4% in the placebo group. The mean change in BMI was 7.3% in the XENICAL group and 3.3% in the placebo group.

14.5 Adverse Events

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14.6 Interactions

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14.7 Other Information

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