

EUROPEAN PUBLIC ASSESSMENT REPORT (EPAR)**XENICAL****EPAR summary for the public**

This document is a summary of the European Public Assessment Report (EPAR). It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the studies performed, to reach their recommendations on how to use the medicine.

If you need more information about your medical condition or your treatment, read the Package Leaflet (also part of the EPAR) or contact your doctor or pharmacist. If you want more information on the basis of the CHMP recommendations, read the Scientific Discussion (also part of the EPAR).

What is Xenical?

Xenical is a medicine containing the active substance orlistat. It is available as turquoise capsules (120 mg).

What is Xenical used for?

Xenical is used together with dieting for the treatment of obese (very overweight) patients with a body mass index (BMI) greater than or equal to 30 kg per square metre, or overweight patients (BMI greater than or equal to 28 kg/m²) who are at risk of illness because of their weight.

The medicine can only be obtained with a prescription.

How is Xenical used?

Xenical is given as one capsule taken with water just before, during, or up to one hour after each main meal. If a meal is missed or contains no fat, Xenical should not be taken. The patient should be on a diet in which about 30% of the calories come from fat, and which is rich in fruit and vegetables. The food in the diet should be spread over three main meals.

Treatment with Xenical should be stopped after 12 weeks if patients have been unable to lose at least 5% of their body weight since the start of treatment.

How does Xenical work?

The active ingredient in Xenical, orlistat, is an anti-obesity medicine, which does not affect appetite. Orlistat blocks gastrointestinal lipases (enzymes that digest fat). When these enzymes are blocked, they cannot digest some fats in the diet, and this allows about 30% of the fat eaten in the meal to pass through the gut undigested. The body cannot use this dietary fat for energy or convert it into fat tissue. This helps weight reduction.

How has Xenical been studied?

The effects of Xenical were first tested in experimental models before being studied in humans. Xenical has been studied in seven main studies involving over 3,000 overweight or obese patients. The studies lasted from one to two years and compared three different doses of Xenical with placebo (a dummy treatment), in combination with dieting. Neither the patients nor the doctors knew which treatment each patient was taking until the end of the study. An additional longer study in over 3,000

obese patients compared the effects of Xenical and placebo over four years, in combination with diet and exercise. In all studies, the main measure of effectiveness was the change in weight.

What benefit has Xenical shown during the studies?

Xenical was more effective than placebo in producing a reduction in weight. When the results from all seven shorter studies were taken together, patients taking 120 mg Xenical three times a day had an average fall of 6.1 kg in body weight after a year, compared with 2.6 kg in those taking placebo. The proportion of patients losing 10% or more of their body weight was 20% in the patients taking this dose of Xenical and 8% in those taking placebo. At the end of the four-year study, 21% of the patients treated with Xenical had lost more than 10% of their body weight, compared with 10% of the patients who received placebo.

What is the risk associated with Xenical?

The most common side effects with Xenical (seen in more than 1 patient in 10) are influenza (flu), hypoglycaemia (low blood sugar levels), headache, upper respiratory infection (colds), oily spotting from the rectum, abdominal (tummy) pain or discomfort, flatus (gas) with discharge, faecal urgency (urgent need to open the bowels), fatty or oily stools, flatulence (gas), liquid stools, oily evacuation (faeces) and increased defecation. These symptoms generally occur at the beginning of treatment, and go away after some time. For the full description of all side effects reported with Xenical, see the Package Leaflet.

Xenical should not be used in people who may be hypersensitive (allergic) to orlistat or any of the other ingredients. It should also not be used in people with a long-term malabsorption disease (where nutrients from the food are not easily absorbed during digestion), with cholestasis (a liver disorder) or who are breast-feeding.

Why has Xenical been approved?

The Committee for Medicinal Products for Human Use (CHMP) decided that Xenical's benefits are greater than its risks in conjunction with a mildly hypocaloric diet for the treatment of obese patients with a BMI greater or equal to 30 kg/m², or overweight patients (BMI ≥ 28 kg/m²) with associated risk factors. The Committee recommended that Xenical be given marketing authorisation.

Other information about Xenical:

The European Commission granted a marketing authorisation valid throughout the European Union for Xenical to Roche Registration Limited on 29 July 1998. The marketing authorisation was renewed on 29 July 2003 and on 29 July 2008.

The full EPAR for Xenical can be found [here](#).

This summary was last updated in 06-2008.