



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/307667/2012
EMA/H/C/000854

EPAR summary for the public

Alli¹

orlistat

This is a summary of the European public assessment report (EPAR) for Alli. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Alli.

What is Alli?

Alli is a medicine that contains the active substance orlistat. It is available as capsules (60 mg) and as chewable tablets (27 mg).

What is Alli used for?

Alli is used to help patients lose weight. It is used in adults who are overweight with a body mass index (BMI) greater than or equal to 28 kg per square metre, in combination with a low calorie diet with reduced fat levels.

The medicine can be obtained without a prescription.

How is Alli used?

One Alli capsule or chewable tablet is taken just before, during, or up to one hour after each main meal, three times a day. If a meal is missed or contains no fat, Alli should not be taken. The patient should be on a diet in which about 30% of the calories come from fat. The food in the diet should be spread over three main meals. Alli should not be taken for more than six months.

Patients taking Alli should start a diet and exercise regime before beginning treatment. If patients taking Alli have been unable to lose weight after 12 weeks, they should speak to their doctor or pharmacist. It may be necessary to stop treatment.

¹ Previously known as Orlistat GSK.



How does Alli work?

The active substance in Alli, 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 a quarter of the fat eaten in the meal to be passed out in the stools undigested. The body does not absorb this fat and this helps the patient reduce their weight.

How has Alli been studied?

Because Alli is based on another medicine containing the same active substance already authorised in the EU (Xenical 120 mg capsules), some of the studies involved patients who took Xenical.

Alli capsules have been studied in three main studies. Two of the studies involving a total of 1,353 overweight or obese patients with a BMI of 28 kg/m² or more and lasted from one to two years, comparing Alli given at different doses 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. The third study compared Alli with placebo in 391 overweight patients with a BMI between 25 and 28 kg/m². The study lasted four months.

In all of the studies, the main measure of effectiveness was the change in weight.

The company also carried out studies to show that Alli 27 mg chewable tablets have the same effect on fat absorption as Alli 60 mg capsules.

What benefit has Alli shown during the studies?

Alli was more effective than placebo in reducing weight in patients with a BMI of 28 kg/m² or more. In the two studies of patients with a BMI of 28 kg/m² or more, patients taking Alli 60 mg capsules had lost an average of 4.8 kg after a year, compared with 2.3 kg in those taking placebo.

The study of Alli in patients with a BMI between 25 and 28 kg/m² failed to show a degree of weight loss that would be relevant for patients.

The studies comparing the chewable tablets with the capsules showed that the amount of undigested fat passed out in patients' stools was the same after taking either formulation.

What is the risk associated with Alli?

Most of the side effects with Alli affect the digestive system and are less likely to occur with a low fat diet. In general, they are mild, and occur at the beginning of treatment, going away after some time. The most common side effects with Alli (seen in more than 1 patient in 10) are oily spotting, flatus (gas) with discharge, faecal urgency (urgent need to open the bowels), fatty oily stool, oily evacuation (bowel movements of just oil, without stool), flatulence (gas) and soft stools. For the full list of all side effects reported with Alli, see the package leaflet.

Alli must not be used in people who are hypersensitive (allergic) to orlistat or any of the other ingredients. It must not be used in people who are being treated with ciclosporin (used to prevent organ rejection in transplant patients) or with medicines used to prevent blood clots such as warfarin. It must also not be used in people with chronic malabsorption syndrome (a long-term disease where nutrients from food are not easily absorbed during digestion) or cholestasis (a liver disorder), or in women who are pregnant or breast-feeding.

Why has Alli been approved?

The CHMP decided that the benefits of Alli are greater than its risks and recommended that it be given marketing authorisation.

Other information about Alli

The European Commission granted a marketing authorisation valid throughout the EU for Orlistat GSK on 23 July 2007. This authorisation was based on the authorisation already granted in 1998 to Xenical capsules. The name of the medicine was changed to Alli on 12 September 2008.

The full EPAR for Alli can be searched for on the Agency's website ema.europa.eu/Find/medicine/Human_medicines/European_Public_Assessment_Reports. For more information about treatment with Alli, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 05-2012.