

Important new safety information

Please read this information carefully as it may be relevant to you and may need to discuss it with your doctor.

The new safety information affects Chapters 2 and 4 of the **alli** package leaflet. The updated sections are below.

2. Before you take **alli**

Do not take **alli**

- If you are under 18.
- If you are pregnant or breast-feeding.
- If you are taking ciclosporin, used after organ transplants, for severe rheumatoid arthritis and some severe skin conditions.
- If you are taking warfarin or other medicines used to thin the blood.
- If you are allergic (hypersensitive) to orlistat or any of the ingredients of **alli**: **see Chapter 6 for further information.**
- If you have cholestasis (condition where the flow of bile from the liver is blocked).
- If you have problems absorbing food (chronic malabsorption syndrome) diagnosed by a doctor.

Take special care with **alli**

If you have diabetes. Tell your doctor who may need to adjust your anti-diabetic medicine.

If you have kidney disease. Talk to your doctor before taking **alli** if you have problems with your kidneys. The use of orlistat may be associated with kidney stones in patients suffering from chronic kidney disease

Taking other medicines

alli may affect some medicines you have to take. Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Do not take **alli** with these medicines

- Ciclosporin: ciclosporin is used after organ transplants, for severe rheumatoid arthritis and some severe skin conditions.
- Warfarin or other medicines used to thin the blood.

The oral contraceptive pill and **alli**

- The oral contraceptive pill may be less effective if you get severe diarrhoea. Use an extra method of contraception if you get severe diarrhoea.

Multivitamins and **alli**

- You should take a multivitamin, every day. **alli** can lower the levels of some vitamins absorbed by your body. The multivitamin should contain vitamins A, D, E and K. You should take the multivitamin at bedtime, when you will not be taking **alli**, to help ensure that the vitamins are absorbed.

Talk to your doctor before taking **alli** if you are taking

- amiodarone, used for heart rhythm problems.
- acarbose, used for diabetes.
- a thyroid medicine (levothyroxine) as it may be necessary to adjust your dose and take your medicines at different times of the day.
- a medicine for epilepsy as any changes in the frequency and severity of your convulsions should be discussed with your doctor.

Talk to your doctor or pharmacist when taking **alli**

- If you are taking a medicine for high blood pressure as it may be necessary to adjust your dose.
- If you are taking a medicine for high cholesterol as it may be necessary to adjust your dose.

Taking **alli** with food and drink

alli should be used along with a reduced calorie, lower-fat diet. Try to start this diet before beginning treatment. For information on how to set your calorie and fat targets, see *Further helpful information* in the blue pages in Chapter 6.

Take **alli** at mealtimes. This usually means one capsule at breakfast, lunch and dinner. If you miss a meal, or your meal contains no fat, do not take a capsule. **alli** does not work unless there's some fat in the meal.

If you eat a high-fat meal, do not take more than the recommended dose. Taking the capsule with a meal containing too much fat may increase your chance of getting diet-related treatment effects (see Chapter 4). Make every effort to avoid any high-fat meals while taking **alli**.

Pregnancy and breast-feeding

Do not take **alli** if you are pregnant or breast-feeding.

Driving and using machines

No effect on ability to drive or use machines has been observed.

4. Possible side effects

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

Most of the common side effects related to **alli** (for example, wind with or without oily spotting, sudden or more frequent bowel motions and soft stools) are caused by the way it works (see Chapter 1). Eat lower-fat meals to help manage these diet-related treatment effects.

Serious side effects

It is not known how frequently these side effects occur

Severe allergic reactions

- Signs of a severe allergic reaction include: severe breathing difficulties, sweating, rash, itching, swollen face, rapid heart beat, collapse.
- ➔ **Stop taking the capsules. Get medical help immediately.**

Other serious side effects

- Bleeding from the back passage (rectum)
 - Diverticulitis (inflammation of the large intestine). Symptoms may include lower stomach (abdominal) pain, particularly on the left side, possibly with fever and constipation
 - Pancreatitis (inflammation of the pancreas). Symptoms may include severe abdominal pain sometimes radiating towards the back, possibly with fever, nausea and vomiting
 - Skin blistering (including blisters that burst)
 - Severe stomach pain caused by gallstones.
 - Hepatitis (inflammation of the liver). Symptoms can include yellow skin and eyes, itching, stomach pain and liver tenderness.
- ➔ **Stop taking the capsules. Tell your doctor if you get any of these.**

Very common side effects

*These may affect more than 1 in 10 people taking **alli***

- Wind (flatulence), with or without oily spotting
 - Sudden bowel motions
 - Fatty or oily stools
 - Soft stools
- ➔ **Tell your doctor or pharmacist if any of these side effects gets severe or troublesome.**

alli 60 mg hard capsules are a weight loss aid containing orlistat. For overweight adults with a BMI of 28 or over. Follow a reduced calorie, lower-fat diet. Always read the label.

Common side effects

*These may affect up to 1 in 10 people taking **alli***

- Stomach (abdominal) pain
 - Incontinence (stools)
 - Runny/liquid stools
 - More frequent bowel motions
 - Anxiety
- Tell your doctor or pharmacist if any of these side effects gets severe or troublesome.

Effects seen in blood tests

It is not known how frequently these effects occur

- Increases in the levels of some liver enzymes
 - Effects on blood clotting in people taking warfarin or other blood-thinning (anti-coagulant) medicines
- Tell your doctor that you are taking **alli** when you have a blood test.

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

Learn to deal with diet-related treatment effects

The most common side effects are caused by the way the capsules work and result from some of the fat being passed out of your body. Such effects typically occur within the first few weeks of using the capsules, before you may have learnt to limit the amount of fat in your diet. Such diet-related treatment effects may be a signal that you have eaten more fat than you should have done.

You can learn to minimise the impact of diet-related treatment effects by following these guidelines:

- Start your lower-fat diet a few days, or even a week, before you begin taking the capsules.
- Find out more about how much fat your favourite foods typically contain, and the size of your portions. By familiarising yourself with portions you will be less likely to accidentally exceed your fat target.
- Distribute your fat allowance evenly across your meals for the day. Do not “save up” fat and calorie allowances and then splurge on a high-fat meal or dessert, as you may have done on other weight loss programmes.
- Most users who experience these effects find that they can manage and control them by adjusting their diet.

Do not be concerned if you do not experience any of these problems. This does not mean that the capsules aren't working.