

FRONT

Package leaflet: Information for the user



Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your doctor or pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to your doctor or pharmacist if you do not lose weight after taking alli for 12 weeks. You may need to stop taking alli.

What is in this leaflet:

1. What alli is and what it is used for
2. What you need to know before you take alli
3. How to take alli
4. Possible side effects
5. How to store alli
6. Contents of the pack and other information

1. What alli is and what it is used for
alli 60 mg hard capsules (orlistat) is a peripherally acting antiobesity product which is used for weight loss in adults aged 18 and over who are overweight and have a body mass index (BMI) of 28 or above. alli should be used along with a reduced calorie, lower-fat diet. BMI is a way to find out if you have a healthy weight, or are overweight, for your height.

The active substance (orlistat) in alli is designed to target fat in your digestive system. It stops about a quarter of the fat in your meals from being absorbed. This fat will pass out of the body in your stools (see section 4). It is therefore important that you commit to a lower-fat diet to manage these effects. If you do, the action of the capsules will assist your efforts by helping you to lose more weight compared to dieting alone.

For every 2 kg (4 lb) you lose from dieting alone, alli might help you lose up to 1 kg (2 lb) more.

2. What you need to know before you take alli

Do not take alli

- **if you are allergic to orlistat or any of the other ingredients of this medicine (listed in section 6).**
- **if you are pregnant or breast-feeding.**
- **if you are taking ciclosporin.**
- **if you are taking warfarin** or other medicines used to thin the blood.
- **if you have cholestasis (liver disorder).**
- **if you have problems absorbing food** (chronic malabsorption syndrome) diagnosed by a doctor.

Warning and precautions

Talk to your doctor or pharmacist before taking 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.

Children and adolescents

This medicine must not be taken by children and adolescents under 18 years old.

Other medicines and alli

alli may affect some medicines you have to take.

→ **Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.**

Do not take alli with these medicines

- **Ciclosporin**
- **Warfarin** or other medicines used to thin the blood.

HALEON

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.**

Take a multivitamin every day if you are taking alli

- 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** (an anti-diabetic medicine used to treat type 2 diabetes mellitus). alli is not recommended for people taking acarbose.
- **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.
- **medicines to treat HIV.** It is important that you consult your doctor before taking alli if you are receiving treatment for HIV.
- **medicines for depression, psychiatric disorders or anxiousness.**

Talk to your doctor or pharmacist when taking alli

- if you are taking a medicine for high blood pressure.
- if you are taking a medicine for high cholesterol.

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.
- alli can be taken immediately before, during a meal or up to one hour after a meal. The capsule should be swallowed with water. If you miss a meal, or your meal contains no fat, do not take a capsule. alli does not work unless there is 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 section 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
alli is unlikely to affect your ability to drive and use machines.

alli contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially 'sodium-free'.

3. How to take alli

Adults 18 and over

- Take one capsule, three times a day.
- Take alli just before, during or up to one hour after meals. This usually means one capsule at breakfast, lunch and dinner. Make sure your three main meals are well balanced, reduced calorie, and lower-fat.
- If you miss a meal, or your meal contains no fat, do not take a capsule. alli does not work unless there is some fat in the meal.
- Swallow the capsule whole with water.
- Do not take more than 3 capsules a day.
- Eat lower-fat meals to reduce the chance of diet-related treatment effects (see section 4).
- Try to be more physically active before you start taking the capsules. Physical activity is an important part of a weight loss programme. Remember to check with your doctor first if you have not exercised before.
- Continue to be active while taking alli and after you stop taking it.

How long should I take alli for?

- **alli should not be taken for more than six months.**
- **If you do not lose weight after taking alli for 12 weeks**, see your doctor or pharmacist for advice. You may need to stop taking alli.

If you take more alli than you should

- Do not take more than 3 capsules a day.
- **If you have taken too many capsules, contact a doctor as soon as possible.**

If you forget to take alli

- If you miss taking a capsule:
 - If it is less than an hour since your last main meal, take the missed capsule.
 - If it is more than an hour since your last main meal, do not take the missed capsule. Wait and take the next capsule around your next main meal as usual.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine 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 section 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 yellowing skin and eyes, itching, dark coloured urine, stomach pain and liver tenderness (indicated by pain under the front of the rib cage on your right hand side), sometimes with loss of appetite.
- Oxalate nephropathy (build up of calcium oxalate which may lead to kidney stones). See section 2, warnings and precautions.

→ **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*
- 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.

Common side effects

- *These may affect up to 1 in 10 people*
- 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 (frequency cannot be estimated from the available data)

- 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.

Reporting of side effects

If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store alli

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the carton and bottle after "EXP". The expiry date refers to the last day of that month.
- Do not store above 25°C.
- Keep the container tightly closed to protect from moisture.
- The bottle contains two sealed canisters containing silica gel to keep the capsules dry. Keep the canisters in the bottle. Do not swallow them.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What alli contains

The active substance is orlistat. Each hard capsule contains 60 mg of orlistat.

The other ingredients are:

- **Capsule filling:** microcrystalline cellulose (E460), sodium starch glycolate, povidone (E1201), sodium laurilsulfate, talc.
- **Capsule shell:** gelatin, indigo carmine (E132), titanium dioxide (E171), sodium laurilsulfate, sorbitan monolaurate, black ink (shellac, iron oxide black (E172), propylene glycol).
- **Capsule band:** gelatin, polysorbate 80, indigo carmine (E132).

What alli looks like and contents of the pack

alli capsules have a turquoise cap and body, with a dark blue band round the middle, imprinted with "alli".

alli is available in pack sizes of 42, 60, 84, 90 and 120 capsules.

Not all pack sizes may be available.

Marketing Authorisation Holder:

Haleon UK Trading Limited, Weybridge, KT13 0NY, U.K.

Manufacturer:

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