

Consumer Medicine Information

XENICAL[®]

Orlistat
120 mg capsules

What is in this leaflet

This leaflet answers some common questions about XENICAL capsules.

It does not contain all the available information.

It does not take the place of talking to your pharmacist or doctor.

All medicines have risks and benefits. Your pharmacist or doctor will consider the risks of your taking XENICAL capsules against the benefits expected for you.

If you have any concerns about taking this medicine, talk to your pharmacist or doctor.

Keep this leaflet with the medicine.

You may need to read it again.

What XENICAL is used for

XENICAL contains the active ingredient orlistat.

XENICAL is used to assist with losing weight, maintaining a certain weight and preventing weight regain.

XENICAL is used to treat adults with an initial Body Mass Index (BMI) which measures 30 or more.

One way to measure if you are overweight, and how overweight you are, is to calculate your Body Mass Index (BMI). You can calculate your BMI by multiplying your height in metres by itself (squaring your height in metres), and then dividing your weight in kilograms by your squared height.

$$\text{BMI} = \frac{\text{weight (kg)}}{\text{height (m)} \times \text{height (m)}} = \frac{\text{weight (kg)}}{[\text{height (m)}]^2}$$

If your BMI is 25 or more you may be overweight, and if your BMI is 30 or more you may be very overweight. BMI may vary across different populations due, in part, to different body proportions. Talk to your pharmacist or doctor if you have any questions about your BMI.

XENICAL should be taken in conjunction with a low-fat, well-balanced, calorie-controlled diet and other appropriate measures such as exercise.

XENICAL belongs to a group of medicines called lipase inhibitors. These medicines work by preventing the absorption of dietary fat in your body rather than by suppressing your appetite.

Dietary fats are large molecules that need to be broken down before they can be absorbed into the body. They are broken down by enzymes called lipases. When taken with a meal, XENICAL interferes with the activity of these enzymes and allows about 30% of the fat eaten in the meal to pass through the gut undigested. Therefore, your body cannot store these excess calories as fatty tissue or use them as a source of energy. This helps you to reduce your weight by burning up fat that you are already carrying, maintain your weight loss and minimise any weight regain.

Losing even small amounts of weight and keeping it off can have additional health benefits for you, especially if you are at risk of other diseases such as heart disease and diabetes. XENICAL can also help to improve risk factors associated with being overweight, such as high blood pressure, high cholesterol and high blood sugar. If these are not treated, they may lead to other diseases such as heart disease or diabetes.

Ask your pharmacist or doctor if you have any questions about using XENICAL.

This medicine is available only from a pharmacist or doctor.

Before you take XENICAL

When you must not take it

Do not take XENICAL if:

- 1. you have had an allergic reaction to XENICAL or any ingredients listed at the end of this leaflet**
- 2. your body does not absorb essential nutrients as well as it should**
This is called chronic malabsorption syndrome.
- 3. you have a blockage of your bile duct (cholestasis)**
- 4. the package is torn or shows signs of tampering**
- 5. the expiry date printed on the pack has passed**
If you take this medicine after the expiry date has passed, it may not work as well.

If you are not sure if you should be taking XENICAL ask a pharmacist or doctor if XENICAL is right for you.

Use in children

The safety and effectiveness of XENICAL in children or adolescents under the age of 18 years has not been established.

Before you start to take it

Tell your pharmacist or doctor if:

- 1. you are pregnant or trying to become pregnant**
The effect of XENICAL on an unborn baby when taken by a pregnant woman is unknown. If you are pregnant, XENICAL is not recommended.
- 2. you are breastfeeding**
It is not known whether XENICAL passes into breast milk. If you are breastfeeding XENICAL is not recommended.
- 3. you have any other health problems, especially the following:**

- diabetes, as weight loss may improve the control of your diabetes and your diabetic medications may need to be adjusted.
- chronic kidney disease or a history of kidney stones.

4. you are allergic to any other medicines, foods, dyes or preservatives

If you are unsure about any of the above, talk to your pharmacist or doctor before you take XENICAL.

Taking other medicines

Some medicines and XENICAL may interfere with each other. These include:

- cyclosporin (Neoral[®], Sandimmun[®]), a transplant rejection medicine
- oral anticoagulant medicines such as warfarin (Marevan[®], Coumadin[®])
- amiodarone (Cordarone X[®], Aratac[®]), a medicine used to treat irregular heartbeat
- vitamin supplements containing vitamins D or E, or betacarotene – these should be taken at least 2 hours after you have taken XENICAL, or at bedtime.
- Anti epileptic medications (Epilim[®], Topamax[®])

These medicines may be affected by XENICAL, or may affect how well it works. You may need to use different amounts of your medicine, or you may need to take different medicines. Ask your pharmacist or doctor for advice if you are taking any of these medicines.

Because weight loss has many beneficial effects, it may also affect the dose of medication taken for conditions influenced by being overweight such as high cholesterol, high blood pressure or diabetes. Be sure to discuss these and other medicines you may be taking with your pharmacist or doctor. Losing weight may mean you need adjustments to other medicines you are taking.

Your pharmacist and doctor have more information on medicines to be careful with or avoid while taking XENICAL.

Ask your pharmacist or doctor if you are not sure about this list of medicines.

How to take XENICAL

How much to take

The usual dose is one 120 mg XENICAL capsule three times a day. Each XENICAL capsule should be taken with a main meal.

Taking more than the recommended dose will not provide additional benefit.

How to take it

Swallow capsules whole with a glass of water.

Do not open the capsules and do not take any capsules that are damaged.

XENICAL should be taken with a well-balanced diet that is rich in fruit and vegetables and contains an average of 30% calories from fat. Your daily intake of fat, carbohydrate and protein should be distributed over three main meals. To gain the most benefit, avoid eating food high in fat between meals, such as biscuits, chocolate or savoury snacks.

When to take it

One XENICAL capsule should be taken with each of the three main meals per day. Usually this is one XENICAL capsule at breakfast, lunch and dinner. The capsule can be taken during the meal or up to one hour after the meal is eaten.

XENICAL should be taken every day to be effective.

XENICAL only works in the presence of dietary fat in your body. You do not need to take a XENICAL capsule if you miss a meal or if you know that your meal contains no fat (however, most meals contain some fat).

How long to take XENICAL

XENICAL will usually be taken for several months depending on your individual needs, to help you to reduce your weight, maintain your weight loss and help prevent the weight being regained. For more information talk to your pharmacist or doctor.

If you forget to take XENICAL

Provided you remember within one hour of your last meal, take your XENICAL capsule and then go back to taking it as you would normally. If it is more than one hour after your last main meal, skip the dose you missed and take your next dose when you are meant to.

If you are not sure whether to skip the dose, talk to your pharmacist or doctor.

Do not double a dose to make up for one you have missed.

If you have missed several doses just go back to taking XENICAL as you would normally.

In case of an overdose

Immediately telephone your doctor or National Poisons Information Centre (telephone 0800 POISON or 0800 764 766) for advice or go to your nearest Accident and Emergency Centre if you think that you or anyone else may have taken too much XENICAL, even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Keep telephone numbers for these places handy.

If you are not sure what to do, contact your pharmacist or doctor.

While you are taking XENICAL

Things you must do

Tell all doctors, dentists and pharmacists who are treating you that you are taking XENICAL.

Tell your pharmacist or doctor if you become pregnant while taking XENICAL.

As with any weight-control programme, over-consumption of fat and calories may counteract any weight loss effect.

Thirteen Low Fat Tips

- Try to eat three regular meals each day – breakfast, lunch and dinner. This helps to prevent hunger and reduce unnecessary snacking.
- Eat more fruit, vegetables, grains and cereals.
- If you use butter or margarine, scrape it on thinly.
- Choose low-fat substitutes i.e. trim milk, low-fat cheese, low-fat yoghurts, etc.
- Become a label reader. Look for foods that have less than 5 g of fat per 100 g of product.
- Eat less high-fat snacks and takeaways (i.e. potato chips, sausage rolls, meat pies).
- Cut all visible fat off meat, remove skin from chicken.
- Aim for palm size servings of lean meat. Have skinless poultry and fish at least once or twice a week.

- Grill, bake, stir-fry, microwave – TRY NOT TO FRY.
- Use less creamy sauces, mayonnaise and dressings.
- Aim to eat less than 40 g – 50 g of fat per day.
- Watch portion sizes – try using a smaller plate.
- Be careful not to replace the fat in your diet with large quantities of other foods, such as sugar and alcohol.

and try to do some physical activity daily.

Start by walking for 10 minutes. Build up to 30-40 minutes per day.

Because increased exercise will help weight loss, it is advisable to follow a regular exercise programme eg; walking, swimming.

A realistic weight loss to aim for is 0.5 – 1 kg (1 – 2 lb) per week.

Talk to your pharmacist or doctor about what would be a healthy weight for you.

If you are concerned that XENICAL is not working, talk to your pharmacist or doctor.

Things you must not do

Do not give XENICAL to anyone else, even if they have the same condition as you.

Do not use XENICAL to treat other complaints. XENICAL is only for weight control.

Do not take any other medicines whether they require a prescription or not without first consulting a pharmacist or doctor.

Things to be careful of

People on a weight reduction diet may become deficient in some vitamins and minerals. To avoid this, you should eat a well-balanced diet rich in fruit and vegetables. Because XENICAL works by preventing the absorption of some of the fat from the diet, it may affect absorption of some fat soluble nutrients. Although most people taking XENICAL will still have normal vitamin levels, a vitamin supplement may be taken. If you do take a supplement, then it should be taken at least two hours after you have taken a XENICAL capsule, or at bedtime.

XENICAL can cause changes in your bowel habits, such as fatty or oily stools. This is due to the removal of undigested fat in your faeces. The possibility of this happening may increase if XENICAL is taken with a diet high in fat. In addition, your daily intake of fat should be distributed over three main meals. If XENICAL is taken with any one meal very high in fat, the possibility of unwanted effects on the digestive system may increase.

Side Effects

Tell your pharmacist or doctor as soon as possible if you do not feel well while you are taking XENICAL.

XENICAL helps most people who are very overweight but it may have unwanted side effects.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

The majority of unwanted effects related to XENICAL result from its local action in your digestive system.

Ask your pharmacist or doctor to answer any questions you may have.

Tell your pharmacist or doctor if you notice any of the following and they worry you:

- increased flatulence (wind) with or without discharge
- abdominal pain
- urgent need to open the bowels (defaecate)
- need to defaecate more often
- oily, fatty, soft or liquid stools
- oily discharge from anus
- rectal pain or discomfort
- tooth and gum problems

Tell your pharmacist or doctor if you have type II diabetes and you notice any of the following and they worry you:

- bloating
- hypoglycaemia - symptoms include: sweating, weakness, hunger, dizziness, trembling, headache, flushing or paleness, numbness, fast pounding heart.

These are the more common side effects of XENICAL. They normally occur at the beginning of treatment and usually go away if you continue treatment and keep to your recommended diet. These symptoms are generally mild and are usually experienced after meals containing high levels of fat.

Other less common side effects include:

- anxiety
- menstrual irregularities
- tiredness/fatigue
- headache
- signs of respiratory infection such as coughing, runny nose, shortness of breath, and/or fever
- signs of urinary tract infection such as going to the toilet more frequently, burning sensation when passing urine and/or lower back pain
- blistering of the skin
- back pain

Tell your doctor immediately, or go to your nearest Accident and Emergency Centre, if you notice any of the following:

- symptoms of liver disease (hepatitis) such as nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes and dark coloured urine
- sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing
- unexplained bleeding, bruising or blood in your urine

These may be serious side effects. You may need urgent medical attention. Serious side effects are rare.

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

Tell your pharmacist or doctor if you notice anything else that is making you feel unwell, even if it is not on this list.

Ask your pharmacist or doctor if you don't understand anything in this list.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After taking XENICAL

Storage

Keep your capsules in the blister pack until it is time to take them, and keep the blister pack inside the carton in order to protect from light.

If you take the capsules out of the packaging they will not keep well.

Keep XENICAL in a cool dry place where the temperature stays below 25°C.

Do not store XENICAL, or any other medicine, in a bathroom or near a sink.

Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep XENICAL where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If you stop taking XENICAL, or the capsules have passed their expiry date, ask your pharmacist what to do with any capsules that are left over.

Product Description

What XENICAL looks like

XENICAL 120 mg capsules have a turquoise cap and turquoise body with "XENICAL 120" printed in black ink.

Ingredients

Active ingredient - orlistat

- each XENICAL capsule contains 120 mg orlistat

Inactive ingredients –

The capsule also contains microcrystalline cellulose, sodium starch glycollate, povidone, sodium lauryl sulphate and talc. The capsule shell contains gelatine, indigo carmine, titanium dioxide and traces of black printing ink.

XENICAL does not contain sucrose, gluten, tartrazine or any other azo dyes.

Distributor

XENICAL is distributed by:
Pharmaco (NZ) Ltd
PO Box 4079
Auckland 1140

Under license of CHEPLAPHARM Arzneimittel GmbH.

Medical Enquiries: 0800 804 079

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