

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S3

XENICAL® capsules

Orlistat

Read all of this leaflet carefully before you start taking XENICAL

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- XENICAL has been prescribed for you personally and you should not pass it on to others.

It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

- What XENICAL is and what it is used for
- What you need to know before you start taking XENICAL
- How to take XENICAL
- Possible side effects
- How to store XENICAL
- Contents of the pack and other information

1. What XENICAL is and what it is used for



XENICAL contains the active substance orlistat. XENICAL is indicated in the treatment of obesity in conjunction with a mildly hypocaloric diet.

XENICAL attaches to the enzymes in your digestive system (lipases) and blocks them from breaking down some of the fat you have eaten during your meal. The undigested fat cannot be absorbed and is eliminated by your body.

2. What you need to know before you take XENICAL

Do not take XENICAL:

- if you are hypersensitive (allergic) to orlistat or any of the other ingredients of XENICAL (listed in section 6);
- if you have chronic malabsorption syndrome (insufficient absorption of nutrients from the alimentary tract);
- if you have cholestasis (liver disorder);
- if you are breastfeeding;
- if you have an eating disorder other than obesity (bulimia);
- if you are younger than 12 years of age.

Do not take XENICAL if any of the above apply to you. If you are not sure, talk to your doctor, pharmacist or nurse before taking XENICAL.

Warnings and precautions

Weight loss may also affect the dose of medicines taken for other conditions (e.g. high cholesterol or diabetes). Be sure to discuss these and other medicines you may be taking, with your doctor. Losing weight may mean you need adjustments to the dose of these medicines.



To gain maximum benefit from XENICAL you should follow the nutrition program recommended to you by your doctor. Over-consumption of fat and calories may reduce any weight loss effect.

XENICAL can cause changes in your bowel habits, such as fatty or oily stools, due to the elimination 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 evenly over three main meals because if XENICAL is taken with a meal very high in fat, the possibility of gastrointestinal effects may increase.

The use of an additional contraceptive method is recommended to prevent possible failure of oral contraception that could occur in case of severe diarrhoea.

The use of XENICAL may be associated with renal stones in patients suffering from chronic kidney disease. Inform your doctor whether you suffer from problems with your kidney.

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

Children

XENICAL is not intended to be used in children under the age of 12.

Other medicines and XENICAL

Always tell your healthcare provider if you are taking any other medicines (this includes all complementary or traditional medicines).

This is important as using more than one medicine at the same time can strengthen or weaken the effects of the medicines.

XENICAL can modify the activity of:

- Anticoagulant medicines (e.g. warfarin): Your doctor may need to monitor your blood coagulation.
- Ciclosporin: Co-administration with ciclosporin is not recommended. Your doctor may need to monitor your ciclosporin blood levels more frequently than usual.
- Iodine salts and/or levothyroxine. Cases of hypothyroidism and/or reduced control of hypothyroidism may occur.
- Amiodarone: You may ask your doctor for advice.
- Medicines to treat HIV.
- Medicines for depression, psychiatric disorders or anxiousness.

XENICAL reduces the absorption of supplements of some fat-soluble nutrients, particularly beta-carotene and vitamin E. You should therefore follow your doctor's advice in taking a well-balanced diet rich in fruit and vegetables. Your doctor may suggest you take a multivitamin supplement.

XENICAL may upset your stabilised anticonvulsant treatment, by decreasing the absorption of your antiepileptic medicines, thus leading to convulsions. Please contact your doctor if you think that the frequency and/or severity of your convulsions have increased or changed when taking XENICAL together with antiepileptic medicines.

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking XENICAL.

XENICAL with food and drink

XENICAL can be taken immediately before, during a meal or up to one hour after a meal. The capsule should be swallowed with water.

Pregnancy and breastfeeding

Pregnancy

Taking XENICAL during pregnancy is not recommended.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking XENICAL.

Breastfeeding

You should not breastfeed your infant during treatment with XENICAL as it is not known whether XENICAL passes into human milk.

Driving and using machines

XENICAL has no known effect on your ability to drive a car or operate machinery.

3. How to take XENICAL

Do not share medicines prescribed for you with another person.

Always take XENICAL exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Using this medicine

The usual dose of XENICAL is one 120 mg capsule taken with each of the three meals per day. It can be taken immediately before, during a meal or up to one hour after a meal.

XENICAL should be taken with a well-balanced, calorie-controlled diet that is rich in fruit and vegetables and contains an average of 30 % of the calories from fat. Your daily intake of fat, carbohydrate and protein should be distributed over three meals. This means you will usually take one capsule at breakfast time, one capsule at lunch time and one capsule at dinner time. To gain optimal benefit, avoid the intake of food containing fat between meals, such as biscuits, chocolate and savoury snacks.

XENICAL only works in the presence of dietary fat. Therefore, if you miss a main meal or if you have a meal containing no fat, XENICAL need not be taken.

Tell your doctor, if for any reason, you have not taken your medicine exactly as prescribed, otherwise, your doctor may think that it was not effective or well tolerated and may change your treatment unnecessarily.

If you have the impression that the effect of XENICAL is too strong or too weak, tell your doctor or pharmacist.

Your doctor will discontinue the treatment with XENICAL after 12 weeks if you have not lost at least 5 % of your body weight as measured at the start of treatment with XENICAL.

If you take more XENICAL than you should

If you take more than the prescribed dose (an overdose), you should contact a doctor immediately or go to the nearest hospital casualty department.

If you forget to take XENICAL

If you forget to take your medicine at any time, take it as soon as you remember provided this is within one hour of your last meal, then continue taking it at the usual times. Do not take a double dose to make up for any forgotten individual doses. If you have missed several doses, please inform your doctor and follow the advice given to you. Do not change the prescribed dose yourself unless your doctor tells you to.

4. Possible side-effects

XENICAL can have side effects.

Not all side effects reported for XENICAL are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your health care provider for advice.

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

The majority of unwanted effects related to the use of XENICAL result from its local action in your digestive system. These symptoms are generally mild, occur at the beginning of treatment and are particularly experienced after meals containing high levels of fat. Normally, these symptoms disappear if you continue treatment and keep to your recommended diet.

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Very common side effects (affects more than 1 user in 10)

Headache, abdominal pain/discomfort, urgent or increased need to open the bowels, flatulence (wind) with discharge, oily discharge, oily or fatty stools, liquid stools, low blood sugar levels (experienced by some people with type 2 diabetes).

Common side effects (affects 1 to 10 users in 100)

Rectal pain/discomfort, soft stools, incontinence (stools), bloating (experienced by some people with type 2 diabetes), tooth/gum disorder, irregularity of menstrual cycle, tiredness.

The following side effects have also been reported but their frequency cannot be estimated from the available data:

Allergic reactions. The main symptoms are itching, rash, wheals (slightly elevated, itchy skin patches that are paler or redder than surrounding skin), severe difficulty in breathing, nausea, vomiting and feeling unwell. Skin blistering (including blisters that burst). Diverticulitis. Bleeding from the back passage (rectum). Increases in the levels of some liver enzymes may be found in blood tests. 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. Stop Xenical if such symptoms occur and tell your doctor. Gallstones. Pancreatitis (inflammation of the pancreas). Oxalate nephropathy (build-up of calcium oxalate which may lead to kidney stones). See Chapter 2, take special care with XENICAL. Effects on clotting with anti-coagulants.

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

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (whoumc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of XENICAL.

5. How to store XENICAL

Store at or below 25 °C. Store in original package and keep blister in outer carton in order to protect from light and from moisture.

XENICAL should not be used after the expiry date shown on the container.

Keep out of reach and sight of children.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What XENICAL contains

Each hard capsule contains 120 mg orlistat as the active substance.

The excipients are microcrystalline cellulose, sodium starch glycollate, povidone, sodium lauryl sulphate and talc. The capsule shell consists of gelatine, indigo carmine (E132), titanium dioxide (E171) and edible printing ink.

What XENICAL looks like and contents of the pack

Gelatine hard capsules with a turquoise cap and turquoise body containing white to off white pellets. Black imprint XENICAL 120. Capsules are packed in a PVC/Al blister. Packs containing 42 or 84 capsules.

Not all pack sizes are marketed.

Holder of Certificate of Registration

Pharmaco Distribution (Pty) Ltd.

3 Sandown Valley Crescent,

South Tower, 1st Floor,

Sandton 2196,

South Africa.

Ethical assistance Line: +27 (0)11 784 0077

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