

XENICAL®

Orlistat (120 mg capsules)

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What Xenical is used for

Xenical contains the active ingredient orlistat.

Xenical is indicated in the treatment of obesity in conjunction with a low calorie intake diet.

Xenical is effective in weight loss, weight maintenance and prevention of weight regains.

Ask your doctor if you have any questions about why Xenical has been prescribed for you.

How Xenical works

XENICAL belongs to a group of medicines called lipase inhibitors.

Xenical is a medicine used to treat obesity. It works in your digestive system to block about one-third of the fat in the food you eat from being digested.

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.

Before you use Xenical

- When you must not use it

Do not take or receive XENICAL if:

- you have had an allergic reaction to Xenical (orlistat) or any ingredients listed at the end of this leaflet
- you have chronic malabsorption syndrome (insufficient absorption of nutrients from alimentary tract)
- you have cholestasis (liver disorder)
- you are breast-feeding
- the package is torn or shows signs of tampering

- the expiry date (EXP) 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 you should be taking Xenical, talk to your doctor.

- Before you start to use it

Tell your doctor if:

- you are pregnant or plan to become pregnant. Xenical is not recommended for use during pregnancy.
- you are breast feeding or intend to breast feed. It is not known whether Xenical passes into breast milk and whether it affects your baby.
- you have or have had any health problems, especially the following:
 - chronic malabsorption syndrome (insufficient absorption of nutrients from the gut)
 - cholestasis (liver disorder)
- you have kidney-related problems
- if you are allergic to any other medicines, foods, dyes or preservatives.

If you have not told your doctor about any of the above, do so before you start taking Xenical.

- Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with Xenical. These include:

- anticoagulant medicines used for blood thinning, such as warfarin. Your doctor may need to monitor your blood coagulation.
- ciclosporin, a medicine used to treat rheumatoid arthritis and in organ transplants. It is not recommended to take ciclosporin while taking Xenical. Your doctor may need to monitor your ciclosporin blood levels more frequently than usual.
- iodine salts and/or levothyroxine, used in treatment of thyroid disorders. Cases of hypothyroidism and/or reduced control of hypothyroidism may occur
- amiodarone, used to correct irregular heartbeat.
- Medicines to treat HIV.

- Medicines for depression, psychiatric disorders or anxiousness.
- fat-soluble nutrient supplements, such as beta-carotene and vitamin E.
- medicines used to treat fits, seizures or convulsions (epilepsy) such as carbamazepine, phenobarbital and phenytoin.

Xenical is not recommended for people taking acarbose (an anti-diabetic drug used to treat type 2 diabetes mellitus).

These medicines may be affected by Xenical, or may affect how well Xenical works. You may need to take different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

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

How to use Xenical

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet.

- How much to use

Take Xenical exactly as your doctor has prescribed.

Your doctor will tell you how many Xenical capsules to take for each dose and how often to take them. The usual dose of Xenical is one 120mg capsule taken with each of the three main meals per day.

Children: Xenical is not intended for use in children.

- When to use it

Xenical can be taken immediately before, during a meal or up to one hour after a meal. Swallow capsules whole with a full glass of water.

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 doctor may suggest you take a multivitamin supplement. Your daily intake of fat, carbohydrate and protein should be distributed over three meals. 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.

- How long to use it

Continue taking Xenical for as long as your doctor tells you to. 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 forget to use it

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 to take it at the usual times. Do not take a double dose.

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.

- If you use too much (overdose)

If you take more capsules than you have been told to take, or if someone else accidentally takes your medicine, contact your doctor, pharmacist or nearest hospital as you may need medical attention.

While you are using it

- Things you must do

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

Tell your doctor immediately if you become pregnant while taking Xenical. Women of child-bearing potential should use effective contraception while taking Xenical. The use of an additional contraceptive method with oral contraceptives is recommended while using Xenical.

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 and change your treatment unnecessarily.

Tell your doctor if you feel Xenical is not helping your condition.

Be sure to keep all of your appointments with your doctor so that your progress can be checked.

- Things you must not do

- Do not stop taking Xenical or change the dose without first checking with your doctor.
- Do not let yourself run out of Xenical over the weekend or on holidays.
- Do not give Xenical to anyone else even if they have the same condition as you.
- Do not use Xenical to treat other complaints unless your doctor says to.
- Do not take any other medicines whether they require a prescription or not without first telling your doctor or consulting a pharmacist.

- Things to be careful of

Be careful driving or operating machinery until you know how Xenical affects you.

It is not known whether Xenical affects your ability to drive a car or operate machinery.

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.

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

This medicine can cause harmless 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.

Side effects

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

All medicines can have side effects. Xenical may have unwanted side effects in a few people, though not everyone will have them. 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 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.

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

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

- headache
- flatulence (wind) with discharge or oily discharge
- oily or fatty stools
- stomach upset including nausea (feeling sick), vomiting
- diarrhoea, urgent or increased need to pass motion
- pain in the stomach and/or anus
- low blood sugar levels in patients with type 2 diabetes
- involuntary excretion of bowel contents
- tiredness
- anxiety
- menstrual irregularities

These side effects are generally mild and may decrease with continued use of Xenical.

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you experience any of the following:

- itching and rashes
- difficulty breathing, shortness of breath, chest tightness, coughing or wheezing
- severe nausea and vomiting
- bleeding from the anus
- blisters on skin
- unusually prolonged bleeding
- frequency and/or severity of convulsions changes when taking Xenical together with anti-epileptic (anti-convulsive) drugs
- yellowing of the skin and eyes and dark coloured urine

These are 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 doctor if you notice anything else that is making you feel unwell, even if it is not on this list.

Ask your doctor or pharmacist if you do not understand anything in this list.

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

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npa.gov.my [*Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)*].

Storage and disposal of Xenical

- Storage

Keep Xenical where children cannot reach it.

Do not store above 25°C.

Keep the blister in the outer carton box in order to protect from light and moisture.

Keep your capsules in the blister pack until it is time to take them. If you take the capsules out of the blister pack they will not keep well.

- Disposal

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

Product Description

Xenical comes in one capsule strength, 120 mg.

Xenical comes in blister packs containing, 21, 42 or 84 capsules.

- What it looks like

The capsules are turquoise with the imprint "XENICAL 120".

- Ingredients

Active ingredient(s)

- orlistat (120 mg)

- Inactive ingredients

- microcrystalline cellulose (E460)
- sodium starch glycollate
- povidone (E1201)
- sodium lauryl sulphate
- talc
- capsule shell consists of gelatin, indigo carmine (E132), titanium dioxide (E171) and edible printing ink.

- MAL number

MAL05032548ACRZ

Manufacturer:

Made for CHEPLAPHARM
Arzneimittel GmbH, Ziegelhof 24,
17489 Greifswald, Germany, by
Delpharm Milano S.r.l., Via
Carnevale 1, 20054 Segrate (MI),
Italy

Product Registration Holder

DKSH Malaysia Sdn Bhd
B-11-01, The Ascent, Paradigm,
No.1 Jalan SS 7/26A, Kelana Jaya
47301 Petaling Jaya, Selangor, Malaysia

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