

PACKAGE LEAFLET: INFORMATION FOR THE USER

Xenical 120 mg hard capsules
Orlistat

Read the entire leaflet carefully before you start using this medicine because it contains important information for you.

Keep this leaflet. You may need to read it again.

Do you have any further questions? Please contact your doctor or pharmacist.

Do not pass this medicine on to others, as it has been prescribed for you only. It may harm them, even if their symptoms are the same as yours.

Do you experience any side effects listed in section 4? Or do you experience a side effect not listed in this leaflet? Then contact your doctor or pharmacist.

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1. What is Xenical and what is it used for?

Xenical is an anti-obesity drug. It works in your digestive system to prevent about one-third of the fat present in the food you eat from being digested. Xenical binds to the enzymes in your digestive system (lipases) and blocks them from breaking down some of the fats you have eaten during your meal. The undigested fat cannot be absorbed and is eliminated from your body.

Xenical is used in the treatment of obesity in conjunction with a diet that contains a low amount of calories.

2. When should you not use this medicine or be extra careful with it?

When should you not use this medicine?

You are allergic to any of the ingredients in this medicine. You can find these ingredients in section 6.

You suffer from chronic malabsorption syndrome (insufficient absorption of food from the digestive tract).

You suffer from cholestasis (a liver disorder).

You are breastfeeding.

When should you be extra careful with this medicine?

Weight loss can also affect the dosage of medications for other conditions (e.g., high cholesterol or diabetes). Therefore, you should discuss these and other medications you may be using with your doctor. Weight loss may mean that adjustment of the dosage of those medications is necessary.

To maximize the effect of Xenical, you should adhere to the dietary plan as recommended by your doctor. As with any weight control program, overconsumption of fat and calories can reduce any effect on weight loss.

This medicine can cause a harmless change in your bowel habits, such as fatty or oily stools due to the excretion of undigested fat in the stool. The likelihood of this happening may increase if Xenical is taken with a high-fat diet. Furthermore, the daily intake of fat should be evenly distributed over three meals, as the likelihood of stomach and/or intestinal disturbances increases if Xenical is used with a very high-fat meal.

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

The use of orlistat may be associated with kidney stones in patients suffering from chronic kidney disease. Tell your doctor if you suffer from kidney problems.

This medicine contains less than 1 mmol sodium (23 mg) per capsule, which means it is essentially 'sodium-free'.

Children

Xenical is not intended for use in children.

Are you using any other medicines?

Are you using any other medicines besides Xenical or have you done so recently or is there a possibility that you will use other medicines in the near future? Then tell your doctor or pharmacist.

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

Xenical can alter the effects of the following medicines:

Anticoagulants (e.g., warfarin). Your doctor may need to monitor your blood clotting.

Ciclosporin (a medicine that can suppress the immune system). Concurrent administration with ciclosporin is not recommended. Your doctor may need to check your ciclosporin blood levels more frequently than usual.

Iodine salts and/or levothyroxine. Cases of hypothyroidism (reduced thyroid function) and/or reduced control of hypothyroidism may occur.

Amiodarone (a medicine used to treat an irregular heartbeat). Ask your doctor for advice about this.

Medicines to treat HIV.

Medicines for treating depression, psychiatric disorders, or anxiety.

Xenical reduces the absorption of some fat-soluble nutrients, particularly beta-carotene (pro-vitamin A) and vitamin E. Therefore, you should follow your doctor's advice to use a well-

balanced diet rich in fruits and vegetables. The doctor may advise you to take a multivitamin supplement.

Orlistat may interfere with the treatment of convulsions (seizures) by reducing the absorption of antiepileptic drugs, which can lead to seizures. Therefore, contact your doctor if you believe the frequency and/or severity of the seizures has changed while using Xenical with antiepileptic drugs.

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

What should you pay attention to with food and drink?

Xenical can be taken before, during a meal, or up to an hour after the meal. The capsule should be swallowed with water.

Pregnancy and breastfeeding

Use of Xenical during pregnancy is not recommended.

It is not known whether Xenical passes into breast milk. Therefore, you should not breastfeed while using Xenical.

Driving and using machines

Xenical has no known effect on the ability to drive and use machines.

3. How to use this medicine?

Follow your doctor's advice closely when taking Xenical. If in doubt, consult your doctor or pharmacist. The usual dosage of Xenical is one 120 mg capsule with each of the three daily meals. The capsule can be taken immediately before, during, or up to one hour after a meal. The capsule should be swallowed with water.

Xenical should be combined with a well-balanced, calorie-restricted diet rich in fruits and vegetables, with approximately 30% of the calories coming from fat. Your daily intake of fat, carbohydrates, and protein should be distributed over three meals. This means that you generally take one capsule at breakfast, one capsule at lunch, and one capsule at dinner. To achieve optimal results, you should avoid consuming foods containing fat, such as cookies, chocolate, and snacks, between meals.

Xenical only works if fat is present. Therefore, it is not necessary to take Xenical if you skip a meal or have a meal without fat.

If, for any reason, you have not taken your medication exactly as prescribed, inform your doctor. Otherwise, your doctor might think the medication is not working well or is not well tolerated and might wrongly change the treatment.

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

Xenical has been studied in long-term clinical studies lasting up to 4 years.

Have you used too much of this medicine?

If you have taken more capsules than prescribed or if someone else has accidentally taken capsules, contact a doctor, pharmacist, or hospital immediately as medical help may be needed.

Have you forgotten to use this medicine?

If you have forgotten to take the medicine once, take it as soon as you remember, provided it is within one hour after the meal, and then continue the treatment at the usual times. Do not take a double dose. If you have forgotten to take the medicine multiple times, contact your doctor and follow his/her advice.

Do not change the prescribed dosage yourself without consulting your doctor.

Do you have any other questions about the use of this medicine? Then contact your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can have side effects, although not everyone gets them.

Tell your doctor or pharmacist as soon as possible if you do not feel well during treatment with Xenical.

The majority of side effects associated with Xenical use arise from its local action on the digestive system. These symptoms are generally mild, occur at the start of treatment, and are mainly observed after meals with a high fat content. In general, these symptoms disappear with continued treatment and if you adhere to the prescribed diet.

Very common side effects (these may occur in more than 1 in 10 patients)

Headache, abdominal pain/discomfort, urgent or increased need to defecate, flatulence (gas) with discharge, oily discharge from the rectum, fatty or oily stools, liquid stools, low blood sugar levels (occurs in some individuals with type 2 diabetes).

Common side effects (these may occur in 1 to 10 out of 100 patients)

Rectal pain/discomfort, soft stools, fecal incontinence, bloating (occurs in some individuals with type 2 diabetes), dental/gum disorders, irregular menstruation, fatigue.

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

Allergic reactions. The main symptoms are itching, rash, hives (slightly raised, itchy areas of skin that are paler or redder than the surrounding skin), severe difficulty breathing, nausea, vomiting, and feeling unwell. Blistering (including bursting blisters). Diverticulitis (inflammation of pouches in the intestinal wall). Rectal bleeding. Increases in the levels of certain liver enzymes may be detected in blood tests. Hepatitis (liver inflammation). Symptoms may include yellowing of the skin and eyes, itching, dark-colored urine, stomach pain, and liver tenderness (manifesting as pain at the lower front of the rib cage on your right side), sometimes accompanied by loss of appetite. Stop using Xenical if such symptoms occur and inform your doctor. Gallstones. Pancreatitis (inflammation of the pancreas). Oxalate nephropathy (kidney disease with oxalate accumulation which can lead to kidney stones). See

section 2, Take special care with XENICAL. Effect on blood clotting when using anticoagulants.

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

Reporting side effects

If you experience side effects, contact your doctor or pharmacist. This also applies to possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system as listed in Appendix V. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store this medicine?

Keep out of the sight and reach of children.

Blister pack

Do not use Xenical after the expiry date stated on the box.

Store below 25 °C.

Store in the original package and keep the strip in the outer packaging to protect from light and moisture.

Glass bottles

Do not use Xenical after the expiry date stated on the bottle.

Store below 30 °C.

Keep the container tightly closed to protect against moisture.

Medicines should not be disposed of via wastewater or with household waste. Ask your pharmacist what to do with medicines you no longer need. These measures will help protect the environment.

6. Contents of the package and other information

What substances are in this medicine?

The active substance in this medicine is orlistat. Each capsule contains 120 mg of orlistat.

The other substances in this medicine are microcrystalline cellulose (E460), sodium starch glycolate (type A), povidone (E1201), sodium lauryl sulfate, and talc. The capsule shell consists of gelatin, indigotine (E132), titanium dioxide (E171), and edible printing ink.

What does Xenical look like and how much is in a package?

Xenical capsules are turquoise and printed with "XENICAL 120" and are supplied in blister packs and glass bottles, with 21, 42, and 84 capsules.

Not all pack sizes may be marketed.

Marketing authorization holder

CHEPLAPHARM Arzneimittel GmbH

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17489 Greifswald
Germany

Manufacturer
CHEPLAPHARM Arzneimittel GmbH
Bahnhofstr. 1a
17498 Mesekenhagen
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or

CHEPLAPHARM Arzneimittel GmbH
Ziegelhof 23-24
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This leaflet was last approved in {month YYYY}

More information about this medicine is available on the European Medicines Agency website: <http://www.ema.europa.eu>.