

Applicant / PHCR:	Pharmaco Distribution (Pty) Ltd, South Africa	MODULE 1
Proprietary Name:	XENICAL®	1.3.2
Dosage Form / Strength:	Each capsule contains 120,0 mg Orlistat	
Registration Number:	32/11.3.1/0475	

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

XENICAL® 120 mg 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 your 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 XENICAL CONTAINS

- The active substance is 120 mg orlistat.
- The other ingredients 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 IS USED FOR

XENICAL is an anti-obesity agent. It does not suppress your appetite.

XENICAL is indicated in the treatment of obesity in conjunction with a mildly hypocaloric diet.

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BEFORE YOU TAKE XENICAL

Do not take XENICAL:

- If you are allergic (hypersensitive) to orlistat or any of the other ingredients of XENICAL.
- If you have chronic malabsorption syndrome (insufficient absorption of nutrients from the alimentary tract).
- If you have cholestasis (liver disorder).
- If you are breast feeding.

Take special care with XENICAL

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.

Pregnancy and breastfeeding

Taking XENICAL during pregnancy is not recommended.

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

If you are pregnant or breast feeding your baby please consult your doctor, pharmacist or other

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healthcare professional for advice before taking XENICAL.

Driving and using machinery

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

Taking other medicines with XENICAL

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, even those not prescribed.

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.
- Amiodarone: You may ask your doctor for advice.

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.

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines).

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HOW TO TAKE XENICAL

Always take XENICAL exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. The usual dose of XENICAL is one 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 XENICAL is too strong or too weak, talk to 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

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you take more capsules than you have been told to take, or if someone else accidentally

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takes your medicine, contact your doctor, pharmacist or nearest hospital as you may need medical attention.

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.

Effects when treatment with XENICAL is stopped

There are no suspected adverse reactions when you stop taking XENICAL.

POSSIBLE SIDE-EFFECTS

XENICAL can cause 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 XENICAL, consult your doctor, pharmacist or other healthcare professional 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 commonly include: urgent or increased need to go to the toilet, flatulence (wind) and discharge, oily discharge and oily or fatty stools.

These symptoms are particularly experienced after meals containing high levels of fat.

Rare cases of allergic reactions have occurred with XENICAL. The main symptoms are itching, rash, wheals (slightly elevated, itchy skin patches that are paler or redder than the surrounding skin), severe difficulty in breathing, nausea, vomiting and feeling unwell.

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Very rarely increases in liver enzyme levels, diverticulitis, and gallstones have been reported.

Rarely cases, generally of mild intensity, of rectal bleeding have been reported.

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

Convulsions could occur if you take antiepileptic medicines together with XENICAL.

If you have type 2 diabetes you could experience low blood sugar levels and bloating.

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.

STORING AND DISPOSING OF 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).

PRESENTATION OF XENICAL

Blister packs of 42 or 84 capsules.

IDENTIFICATION OF XENICAL

Gelatine capsules with a turquoise cap and turquoise body containing white to off white pellets.

Black imprint XENICAL 120.

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NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

Pharmaco Distribution (Pty) Ltd.

3 Sandown Valley Crescent,

South Tower, 1st Floor,

Sandton, 2196,

South Africa

DATE OF PUBLICATION OF THE PACKAGE INSERT

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