

XENICAL®

orlistat

Consumer Medicine Information

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 doctor or pharmacist.

All medicines have risks and benefits.

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

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 treat people who are obese (BMI 30 or higher) or overweight (BMI 27 or higher) with other risk factors (eg high blood pressure, high cholesterol, high blood lipid profile).

Your Body Mass Index (BMI) is calculated by dividing your weight (in kg) by your height (in metres) squared.

XENICAL belongs to a group of medicines called lipase inhibitors.

These medicines work by targeting the absorption of dietary fat in your body rather than 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. That is, lipases play an important role in the digestion of dietary fat. When taken with a meal, XENICAL interferes with the activity of these enzymes. This 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 lower weight and minimise any weight regain.

Losing even small amounts of weight and keeping it off produces additional health benefits for you, especially when you are at risk for other diseases such as heart disease and diabetes. XENICAL can also help to improve risk factors, such as high blood pressure, high cholesterol and high blood sugar. If these are not treated, they could lead to other diseases such as hypertension and diabetes.

Ask your pharmacist or doctor if you have any questions about obesity related risk factors.

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

Ask your pharmacist or doctor if you have any questions or if you are not sure why XENICAL has been recommended for you.

XENICAL is not addictive.

Before you take XENICAL

When you must not take it

Do not take XENICAL if:

- 1. you have had an allergic reaction to XENICAL (orlistat) 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. T
- 3. you have certain pancreatic problems**
- 4. you have had recent major surgery to your stomach or intestines**
- 5. you have a blockage of your bile duct (gall stones)**
- 6. if the packaging is torn or shows signs of tampering or the capsules do not look quite right**
- 7. if 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 if you should be taking XENICAL, talk to your pharmacist or doctor.

Do not give XENICAL to children or adolescents under 18 years of age.

The safety and effectiveness in children have not been established.

Before you start to take it

Tell your pharmacist or doctor if:

1. you are pregnant or plan to become pregnant

It is not known whether XENICAL is harmful to an unborn baby when taken by a pregnant woman. It is not generally recommended for use in pregnant women unless the benefits of treatment outweigh the risk to the unborn baby.

2. you are breast-feeding or intend to breast-feed

It is not known whether XENICAL passes into breast milk. You should not breast-feed while taking XENICAL.

3. you have vitamin deficiencies

4. you have kidney stones

5. you have any allergies to any other substances, such as foods, preservatives or dyes

6. you have peptic (stomach) ulcer disease

7. you receive long term treatment for mental or nerve disorders

8. you have symptomatic cholelithiasis (painful gall stones)

9. you have post surgical adhesions

10. you have an eating disorder

11. you take large doses of laxatives

12. you have epilepsy or suffer from fits

13. you have significant heart, kidney, liver, gastrointestinal or endocrine disorders

14. you have any other health problems.

If you have not told your pharmacist or doctor about any of the above, tell them before you take any XENICAL.

Taking other medicines

Because weight loss has many beneficial effects, it may also affect the dose of medication taken for conditions such as high cholesterol or diabetes. Be sure to discuss these and other drugs you may be taking with

your pharmacist or doctor. Losing weight may mean you need adjustments to these medications.

Tell your pharmacist or doctor if you are taking any other medicines including any that you have bought from a pharmacy, supermarket or healthfood shop. Some medicines and XENICAL may interfere with each other. These include:

- cyclosporin, a transplant rejection drug
- amiodarone, a medicine used to treat irregular heart beat
- warfarin or other anticoagulants, medicines that prevent blood clots
- acarbose, a medicine used to treat diabetes
- medicines used to treat epilepsy or fits
- other weight-loss medicines
- some vitamin supplements.

These medicines may be affected by XENICAL. Your pharmacist or doctor will advise you.

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

Follow all directions given to you by your pharmacist and doctor carefully.

They may differ from the information contained in this leaflet.

Take XENICAL exactly as your pharmacist or doctor has prescribed.

The recommended dose of XENICAL for adults over 18 years of age is one 120 mg capsule taken three times a day.

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

It is also recommended that you take a daily multivitamin supplement containing vitamins A, D and E.

Use by people under 18 years of age is not recommended except on medical advice.

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 calorie - controlled 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 3 main meals. To gain the most benefit, avoid eating food containing fat between meals, such as biscuits, chocolate or savoury snacks.

Look out for fats in foods by reading all food labels. Your fat intake may also be reduced by removing all fat from meat, skin from chicken and using non fat or low fat milk.

Be careful not to replace the fat in your diet with large quantities of other foods, such as sugar and alcohol.

For further dietary advice, refer to the NH&MRC website at <http://www.nhmrc.gov.au>

Because increased exercise will help weight loss, it is advisable to follow a regular exercise program (eg walking, swimming). See your doctor before starting an exercise program.

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

When to take it

You will usually take 1 capsule with each of the 3 main meals per day. This means that you will usually take one capsule at breakfast, lunch and

dinner. It can be taken during the meal or up to 1 hour after the meal is consumed.

XENICAL only works in the presence of dietary fat in your body. Therefore, if you miss a main meal or if you know that the meal contains no fat, then XENICAL need not be taken.

How long to take XENICAL

Continue taking XENICAL for as long as your pharmacist or doctor prescribes, for up to four years.

XENICAL should be taken every day to be effective.

Weight loss normally starts within 2 weeks and continues for 6 to 12 months on XENICAL treatment. XENICAL will then help you to maintain this new lower weight and help to prevent weight being regained.

The improvement in risk factors (such as reduction in high blood pressure, normalising blood sugar levels and lowering cholesterol levels) is usually observed within 1 month of starting therapy and has been maintained during the course of XENICAL treatment.

If you forget to take XENICAL

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Otherwise, take it as soon as you remember provided this is within 1 hour of your last meal and then go back to taking it as you would normally.

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

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

In case of an overdose

Immediately telephone your pharmacist or doctor or Poisons Information Centre (telephone 13 11 26) for advice or go to Accident and Emergency at your nearest

hospital 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.

Tell your pharmacist or doctor if, for any reason, you have not taken your medicine exactly as prescribed.

Otherwise, your pharmacist or doctor may think that it was not effective and change your treatment unnecessarily.

Tell your pharmacist or doctor if you feel the capsules are not helping your condition.

If you have high blood sugar or cholesterol levels, your doctor may ask you to have regular blood tests to monitor your blood sugar or blood cholesterol levels.

If you are being treated for epilepsy and/or fits, please contact your doctor if you think that the frequency or severity of convulsions have changed while taking XENICAL.

To gain the most benefit from XENICAL you should follow the nutrition program recommended to you by your doctor or pharmacist. As with any weight-control program, over-consumption of fat and calories may counteract any weight loss effect.

Things you must not do

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

Do not take any other medicines whether they require a prescription or not without first telling your 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 follow your doctor's or pharmacist's advice in taking 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, you should take a multivitamin supplement containing fat-soluble vitamins. This supplement should be taken at least 2 hours before or after XENICAL, or at bedtime.

XENICAL can cause harmless 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 will increase if XENICAL is taken with a diet high in fat. In addition, your daily intake of fat should be distributed over 3 main meals. If XENICAL is taken with any one meal very high in fat, the possibility of unwanted effects on the digestive system will 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 overweight or obese but it may have unwanted side effects in a few.

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 use 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
- oily, fatty or liquid stools
- oily discharge from anus.
- rectal pain or discomfort

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.

Normally, these symptoms disappear if you continue treatment and keep to your recommended diet. These symptoms are generally mild, occur at the beginning of treatment, go away after a short period of time and are particularly experienced after meals containing high levels of fat.

Other side effects may also occur in some patients including:

- nausea (feeling sick)
- dyspepsia (indigestion)
- headache
- asthenia (unusual tiredness or weakness).

Tell your doctor as soon as possible if you notice any of the following:

- anxiety

- 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
- rash or blistering of the skin
- muscle or back pain

The above list includes serious side effects that may require medical attention.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- 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 face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing
- unexplained bleeding, bruising or blood in your urine

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare (if consistent with the frequencies in the PI).

Tell your pharmacist or doctor if you notice anything else that is making you feel unwell.

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 packs inside the original carton to protect from light and moisture.

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 or other places where it may get hot, even for a short period.

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 your pharmacist or doctor tells you to 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 body with "XENICAL Roche 120" printed in black ink.

Ingredients

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

Active ingredient - orlistat

- each XENICAL capsule contains 120 mg orlistat.

Inactive ingredients -

The capsule also contains:

- microcrystalline cellulose
- sodium starch glycollate
- povidone
- sodium lauryl sulfate
- talc [553].

The capsule shell contains:

- gelatin
- indigo carmine [132]
- titanium dioxide [171].

The printing ink contains:

- shellac
- lecithin [322]
- dimethicone 1510
- iron oxide black [172].

XENICAL capsules are available in blister packs containing 42 and 84 capsules.

Distributor

XENICAL is distributed by:

Roche Products Pty Limited

ABN 70 000 132 865

4 - 10 Inman Road

Dee Why NSW 2099

AUSTRALIA

Medical Enquiries 1800 233 950

Please check with your pharmacist for the latest Consumer Medicine Information.

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