

XENICAL(R)

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. Your doctor has weighed the risks of you taking XENICAL capsules against the benefits they expect it will have for you.

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 to treat people who are overweight or obese.

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.

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

Your doctor, however, may have prescribed XENICAL for another purpose.

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

XENICAL is not addictive.

This medicine is available only with a doctor's prescription.

Before you take XENICAL

When you must not take it

Do not take XENICAL if:

- 1. you have had an allergic reaction to XENICAL or any ingredients listed at the end of this leaflet**
- 2. your doctor has diagnosed that your uptake of essential nutrients is lower than it should be**

This is called chronic malabsorption syndrome. This may occur with conditions such as tropical sprue and idiopathic steatorrhoea.

- 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**
- 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 doctor.

Do not give XENICAL to children.

The safety and effectiveness in children have not been established.

Before you start to take it

Tell your 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 breastfeeding or intend to breastfeed**
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 any other health problems.**

If you have not told your 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 doctor. Losing weight may mean you need adjustments to these medications.

Tell your 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 (Neoral(r))
- * other weight-loss medicines
- * some vitamin supplements.

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

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

Ask your doctor or pharmacist 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 doctor and pharmacist carefully.

They may differ from the information contained in this leaflet.

Take XENICAL exactly as your doctor has prescribed.

Your doctor will tell you how many XENICAL capsules to take each day.

The recommended dose of XENICAL is one 120 mg capsule taken three times a day.

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.

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.

XENICAL should be taken with a well-balanced 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.

How long to take XENICAL

XENICAL should be taken long term and must be taken every day.

Continue taking XENICAL for as long as your doctor prescribes.

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.

If you have missed several doses, please inform your doctor and follow the advice given to you.

In case of an overdose

Immediately telephone your 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 doctor or pharmacist.

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 doctor if you become pregnant while taking 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 the capsules are not helping your condition.

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

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

To gain the most benefit from XENICAL you should follow the nutrition program recommended to you by your doctor. 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 stop taking XENICAL or change the dose without first checking with your doctor. Do not let yourself run out of medicine 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 tells you 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

People on a weight reduction diet may become deficient in some vitamins and minerals. To avoid this, you should follow your doctor'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, your doctor may advise taking a vitamin supplement. If so, 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 the removal 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 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 may increase.

Side Effects

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

Tell your 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.

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 not listed above may also occur in some patients.

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

Ask your doctor or pharmacist 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.

If you take the capsules out of the packaging they will not keep well.

Keep the blister pack in a cool dry place where the temperature stays below 25 degrees 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 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
- * industrial methylated spirits
- * purified water
- * lecithin [322]
- * 2-ethoxyethanol
- * dimethicone
- * iron oxide black [172].

XENICAL capsules is available in blister packs containing 84 capsules.

Distributor

XENICAL is distributed by:
Roche Products Pty Limited
ABN 70 000 132 865
4 - 10 Inman Road
Dee Why NSW 2099

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- * AUST R 61598

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