

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using XENICAL?

XENICAL contains the active ingredient orlistat. XENICAL is used to treat people who are obese (BMI \geq 30) or overweight (BMI \geq 27) with other risk factors (e.g. high blood pressure, high cholesterol, high blood lipid profile).

For more information, see Section [1. Why am I using XENICAL?](#) in the full CMI.

2. What should I know before I use XENICAL?

Do not use if you have ever had an allergic reaction to orlistat or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use XENICAL?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with XENICAL and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use XENICAL?

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

More instructions can be found in Section [4. How do I use XENICAL?](#) in the full CMI.

5. What should I know while using XENICAL?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using XENICAL.• Tell your pharmacist or doctor if, for any reason, you have not taken your medicine exactly as prescribed.• Tell your pharmacist or doctor if you feel the capsules are not helping your condition.
Things you should not do	<ul style="list-style-type: none">• 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.
Driving or using machines	<ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until you know how XENICAL affects you.• XENICAL may cause dizziness in some people.
Drinking alcohol	<ul style="list-style-type: none">• Tell your doctor or pharmacist if you drink alcohol.• Alcohol is not expected to interact with XENICAL.
Looking after your medicine	<ul style="list-style-type: none">• Keep your capsules in the blister pack until it is time to take them.• Keep the blister packs inside the original carton to protect from light and moisture.

For more information, see Section [5. What should I know while using XENICAL?](#) in the full CMI.

6. Are there any side effects?

Mild side effects include: Nausea (feeling sick), gum disease (swollen, painful bleeding gums), dyspepsia (indigestion), bloating, 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, Headache, asthenia (unusual tiredness or weakness). 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. **Serious side effects (Call your doctor straight away, or go straight to the Emergency Department)** include: Severe and continuous rectal bleeding, signs of urinary tract infection such as going to the toilet more frequently, burning sensation when passing urine and/or lower back pain, anxiety, signs of respiratory infection such as coughing, runny nose shortness of breath, and/or fever, rash or blistering of the skin, muscle or back pain, hypothyroidism (tiredness, lethargy, muscle weakness, cramps, feeling the cold, a slow heart rate, dry and flaky skin, hair loss, a deep and husky voice, weight gain). **Very serious side effects (Call your doctor straight away, or go straight to the Emergency Department)** include: 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, symptoms of inflammation of the pancreas (pancreatitis) such as severe upper stomach pain, often with nausea and vomiting.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

XENICAL[®]

Active ingredient(s): *orlistat*

Consumer Medicine Information (CMI)

This leaflet provides important information about using XENICAL capsules. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using XENICAL.**

Where to find information in this leaflet:

- [1. Why am I using XENICAL?](#)
- [2. What should I know before I use XENICAL?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use XENICAL?](#)
- [5. What should I know while using XENICAL?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using XENICAL?

XENICAL contains the active ingredient *orlistat*.

XENICAL is used to treat people who are obese (BMI \geq 30) or overweight (BMI \geq 27) with other risk factors (e.g. 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.

2. What should I know before I use XENICAL?

Warnings

Do not use XENICAL if:

- you are allergic to XENICAL (*orlistat*), or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- your body does not absorb essential nutrients as well as it should. This is called chronic malabsorption syndrome.
- you have certain pancreatic problems.
- you have had recent major surgery to your stomach or intestines.
- you have a blockage of your bile duct (gall stones).
- if the packaging is torn or shows signs of tampering or the capsules do not look quite right.
- 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.

Check with your doctor or pharmacist if you:

- are pregnant or plan to become pregnant.
- are breast-feeding or intend to breast-feed.
- are taking oral contraceptives.
- have vitamin deficiencies.
- have kidney stones.
- have any allergies to any other substances, such as foods, preservatives or dyes.
- have peptic (stomach) ulcer disease.
- receive long term treatment for mental or nerve disorders.
- have symptomatic cholelithiasis (painful gall stones).
- have post surgical adhesions.
- have an eating disorder.
- take large doses of laxatives.

- have epilepsy or suffer from fits.
- have significant heart, kidney, liver, gastrointestinal or endocrine disorders.
- are taking medicines for HIV.
- have a thyroid disorder.
- 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.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor or pharmacist if you are pregnant or intend to become pregnant.

It is not known whether XENICAL is harmful to an unborn baby when taken by a pregnant woman. It should not be used in pregnant women.

Talk to your doctor or pharmacist if 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.

If you are taking oral contraceptives, commonly known as birth control pills, the use of an additional method of contraception is recommended. This is because you might experience severe diarrhoea whilst taking XENICAL which may decrease the absorption of oral contraceptive into your body. It is recommended that you use an additional method of contraception to prevent pregnancy.

3. What if I am 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 doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with XENICAL and affect how it works.

- ciclosporin, 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 and any other medicine used for diabetes
- medicines used to treat epilepsy or fits
- medicines for HIV
- drugs to control hypothyroidism

- lithium and other medicines used for mental or sleep disorders
- 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.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect XENICAL.

4. How do I use 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 E and K.
- Use by people under 18 years of age is not recommended except on medical advice.
- Follow the instructions provided with the medicine.
- Do not exceed the recommended dosage.

When to take XENICAL

- 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.**

How to take XENICAL

- **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 <https://www.nhmrc.gov.au>

Because increased exercise will help weight loss, it is advisable to follow a regular exercise program (e.g. 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.

If you use too much XENICAL

If you think that you have used too much XENICAL, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your pharmacist or doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using XENICAL?

Things you should do

- **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.

Remind any doctor, dentist or pharmacist you visit that you are using XENICAL.

Things you should 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.**

Weight reduction diet

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.

Oral contraceptive use

If you are taking oral contraceptives, commonly known as birth control pills, the use of an additional method of contraception is recommended. This is because you might experience severe diarrhoea whilst taking XENICAL which may decrease the absorption of oral contraceptive into your body. It is recommended that you use an additional method of contraception to prevent pregnancy.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how XENICAL affects you.

XENICAL may cause dizziness in some people.

Drinking alcohol

Tell your doctor or pharmacist if you drink alcohol.

Alcohol is not expected to interact with XENICAL.

Looking after your medicine

- **Keep your capsules in the blister pack until it is time to take them.**
- **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.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat, or sunlight where the temperature stays below 25°C; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on windowsills.

Keep it where young children cannot reach it.

When to discard your medicine

If your doctor tells you to stop taking the capsules or the capsules have passed their expiry date.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

The majority of unwanted effects related to XENICAL use result from its local action in your digestive system.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">• Nausea (feeling sick)• Gum disease (swollen, painful bleeding gums)• Dyspepsia (indigestion)• Bloating, 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.• Headache, asthenia (unusual tiredness or weakness)	Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you.
<ul style="list-style-type: none">• Bloating• Hypoglycaemia - symptoms include: sweating, weakness, hunger, dizziness, trembling, headache, flushing or paleness, numbness, fast pounding heart. <p>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.</p>	Tell your pharmacist or doctor if you have type II diabetes and you notice any of the following and they worry you.

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">• Severe and continuous rectal bleeding• Signs of urinary tract infection such as going to the toilet more frequently, burning sensation when passing urine and/or lower back pain• Anxiety• Signs of respiratory infection such as coughing, runny nose shortness of breath, and/or fever• Rash or blistering of the skin• Muscle or back pain• Hypothyroidism (tiredness, lethargy, muscle weakness, cramps, feeling the cold, a slow heart rate, dry and flaky skin, hair loss, a deep and husky voice, weight gain).	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects. You may require medical attention.

Very serious side effects

Very serious side effects	What to do
<ul style="list-style-type: none">• 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• Symptoms of inflammation of the pancreas (pancreatitis) such as severe upper stomach pain, often with nausea and vomiting.	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p> <p>You may need urgent medical attention or hospitalisation.</p>

These very serious side effects are very rare.

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

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

7. Product details

This medicine is available from a pharmacist without a doctor's prescription.

What XENICAL contains

Active ingredient (main ingredient)	120 mg orlistat
Other ingredients (inactive ingredients)	<p>The capsule also contains:</p> <ul style="list-style-type: none">• microcrystalline cellulose• sodium starch glycollate• povidone• sodium lauryl sulfate• purified talc. <p>The capsule shell contains:</p> <ul style="list-style-type: none">• gelatin• indigo carmine• titanium dioxide. <p>The printing ink contains:</p> <ul style="list-style-type: none">• shellac

- | | |
|--|--|
| | <ul style="list-style-type: none">• lecithin• dimeticone 1510• iron oxide black. |
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XENICAL does not contain sucrose, gluten, tartrazine or any other azo dyes.

Do not take this medicine if you are allergic to any of these ingredients.

What XENICAL looks like

XENICAL 120 mg capsules (AUST R 61598) have a turquoise cap and body with "XENICAL 120" printed in black ink.

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

Who distributes XENICAL

Pharmaco (Australia) Ltd
Level 13, 465 Victoria Avenue
Chatswood NSW 2067
Australia

Phone: 1800 201 564

Under license of CHEPLAPHARM Arzneimittel GmbH

This leaflet was prepared in August 2022.