PRODUCT MONOGRAPH

Pr XENICAL®

orlistat

Capsules 120 mg

Pharmaceutical Standard: Professed

Anti-Obesity Agent/Gastrointestinal Lipase Inhibitor

Hoffmann-La Roche Limited
7070 Mississauga Road
Mississauga, Ontario
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Submission Control No: 185765

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This leaflet is part III of a three-part "Product Monograph" published when XENICAL (pronounced Zen-e-cal) was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about XENICAL. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:
XENICAL is used along with a mildly reduced calorie diet to assist in weight loss and to maintain the weight loss in obese patients and overweight patients who have health risk factors such as type 2 diabetes, high blood pressure, and blood lipid problems. The weight loss will contribute to lowering the blood pressure and cholesterol and blood sugar levels.

Even a modest weight loss of 5-10% can lower your risk of developing health problems.

The weight loss achieved with XENICAL, along with a mildly reduced calorie diet, may also help reduce the risk of developing type 2 diabetes if you have impaired glucose tolerance.

XENICAL is recommended for:
• patients with a Body Mass Index (BMI*) greater than or equal to 30 kg/m², or
• patients with a BMI* greater than or equal to 27 kg/m² who have health problems, such as type 2 diabetes, high blood pressure, high cholesterol or a large waist measurement.

* BMI is a simple measurement to estimate how overweight a person is. See your doctor to have your BMI measured.

What it does:
• XENICAL is a prescription medicine when, combined with a mildly reduced calorie diet (average 20% decrease in daily calories, and no more than 30% of calories from fat), can help you lose weight and keep it off.
• XENICAL is a fat blocker. Fats from foods need to be broken down before they can be absorbed into the body. To break down fat, your body uses enzymes, called lipases. XENICAL, when taken with meals, prevents these enzymes from working. This blocks the absorption of about one third (30%) of the fat in food. The fat that is not absorbed passes out of the body in bowel movements, called stools. When you absorb less fat, you take in fewer calories, which leads to weight loss.
• XENICAL taken in combination with diabetes medications such as insulin, metformin and/or a sulfonylurea (like glyburide) may help you manage your type 2 diabetes by lowering your blood sugar.
• XENICAL does not suppress or change your appetite. It does not affect the brain like other medicines used for weight loss. Less than 1% of XENICAL is absorbed and the rest leaves the body in the stool.

When it should not be used:
XENICAL should not be used in patients with chronic malabsorption syndrome, cholestasis and in patients with known hypersensitivity with orlistat or to any component of XENICAL. (See “What the important non-medicinal ingredients are”)

Chronic malabsorption syndrome is when the body has trouble absorbing nutrients from the intestine into the bloodstream. Cholestasis is caused by an obstruction in the liver where bile, a fluid made in the liver, is not able to be eliminated from the body through the intestine normally.

XENICAL is not intended to be used in children under 12 years of age, as this medicine has not been studied in this age group.
What the medicinal ingredient is:
Each capsule contains 120 mg of the active ingredient, orlistat.

What the important non-medicinal ingredients are:
The capsules contain non-medicinal or inactive ingredients. These are:
- microcrystalline cellulose, povidone, sodium starch glycolate, sodium lauryl sulphate, talc.

The capsule shell contains:
- gelatin, indigo carmine, titanium dioxide, edible printing ink.

What dosage forms it comes in:
XENICAL is a turquoise capsule with “ROCHE XENICAL 120” printed in black ink.

WARNING AND PRECAUTIONS

BEFORE you use XENICAL talk to your doctor or pharmacist and make sure they know if:
- you have ever had a bad reaction to orlistat (XENICAL) or any of the inactive ingredients of XENICAL
- you are allergic to other medicines, foods and dyes
- you are taking cyclosporine
- you are taking diabetes medicines such as insulin, metformin and/or a sulfonylurea
- you are taking any other medicines including those not prescribed by your doctor
- you always have problems absorbing your food (chronic malabsorption syndrome)
- you have bowel or rectal problems
- you have gallbladder problems
- you have kidney problems. Kidney injury has been reported in patients treated with XENICAL.
- you are pregnant, plan on becoming pregnant, or are breastfeeding.
- you are taking birth control pills to prevent pregnancy. If you experience severe diarrhea, your birth control pills might not work as well and you might need to use an additional birth control method
- you are taking medicines to control seizures
- you are taking levothyroxine

Severe liver injury in patients taking XENICAL have been rarely reported. Promptly discontinue XENICAL and talk to your doctor if you have symptoms suggestive of liver impairment, such as loss of appetite, itching, yellowing of the skin, dark urine, light colored stools, or right upper quadrant pain that may be accompanied by nausea and vomiting.

This information will help your doctor and you decide whether you should use XENICAL, and what extra care may need to be taken while you are on the medicine.

INTERACTIONS WITH THIS MEDICATION

Drugs that may interact with XENICAL include cyclosporine, amiodarone, and levothyroxine.

If you experience severe diarrhea, your birth control pills might not work as well and you might need to use an additional birth control method.
**PROPER USE OF THIS MEDICATION**

**Usual dose:**

*Your doctor has prescribed XENICAL after carefully studying your case. Other people may not benefit from taking this medicine, even though their problems may seem similar to yours. Do not give your XENICAL to anyone else.*

**Weight Management:**
- Take one capsule (120 mg) during or just following each main meal (breakfast, lunch and dinner). Swallow the capsule whole along with some water. Take the capsule no later than 1 hour after the meal is eaten.
- For example, if you just finished eating lunch at 12:30 p.m., you should take your lunchtime dose before 1:30 p.m.
- XENICAL should be taken with a mildly reduced calorie diet that contains no more than 30% of calories from fat as recommended by your doctor, dietitian or other healthcare professional.
- XENICAL can reduce the absorption of fat-soluble vitamins and beta-carotene. In clinical studies, most people's vitamin and beta-carotene levels were within the normal range. However, your doctor may tell you to take a daily multivitamin supplement while taking XENICAL. If you are between the ages of 12 to 16, you should take a multivitamin while taking XENICAL. A multivitamin should be taken two hours before or after your XENICAL capsule, or at bedtime.
- If you occasionally miss a main meal or if your meal contains no fat, do not take your XENICAL capsule.
- Take this medicine only as directed by your doctor. Do not take more of it, do not take it more often, and do not take it for a longer time than your doctor ordered.
- You will not lose more weight or lose it more quickly if you take more XENICAL capsules than your doctor has instructed.

**If You Have Type 2 Diabetes:**
- Your reduced calorie diet should be consistent with the dietary recommendations of the Canadian Diabetes Association Guidelines for the Nutritional Management of Diabetes Mellitus in the New Millennium.
- You should talk with your doctor about diabetes medications you may be taking, as this dosage might need to be lowered.

Taking XENICAL can help you reach a healthier weight. This medicine works best when you take it as directed, eat less fat and become more physically active.

**What else should you remember while you are taking XENICAL?**
- As XENICAL works by partially blocking dietary fat absorption, the expected weight loss will not occur if you replace the fat calories with carbohydrates or protein.
- Eat foods from all food groups (for example, see "Canada's Food Guide to Healthy Eating").
- Divide your day's calories and fat over 3 meals.
- Choose foods that have a lower fat content.
- Add less fat (butter, margarine or oils) to the foods you prepare.
- Develop healthy eating habits, like eating more fruits and vegetables.
- Gradually increase your physical activity as recommended by your doctor.
- If you have to go to the hospital or if you are given a new prescription medicine, you should tell the doctor(s) that you are taking XENICAL.
- Losing weight can affect the dose of other medicines you need, such as those for diabetes, high blood pressure or high cholesterol. Your doctor may need to adjust the doses of your other medicines. He or she may ask you to have regular blood tests to check your blood sugar and/or cholesterol level.
- If you have type 2 diabetes, you should follow the dietary recommendations of the Canadian Diabetes Association and test blood sugar and HbA1c levels regularly.
Missed Dose:

- If you forget to take a dose, it can be taken up to one hour after a meal and still be effective. Do not take double the amount if you miss one dose. XENICAL cannot work properly if many doses are missed.

Overdose:

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Unwanted effects are possible with all medicines. Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking XENICAL.

Weight Management:
The most common possible side effects from XENICAL are directly related to the way XENICAL works. By blocking the absorption of some dietary fat, it is likely that you will experience some change in bowel habits. These effects are generally mild and transient (occur for a short period of time). They can increase if you eat high fat foods. In clinical studies, only 3% of people experienced one of these effects more than twice:

- oily spotting
- gas with discharge
- urgent need to have a bowel movement
- fatty/oily stools
- oily discharge
- increased number of bowel movements
- inability to control bowel movements.

Due to the presence of undigested fat, the oil in your bowel movement may be clear, orange or brown in colour. These bowel changes are a natural effect of blocking the fat from being absorbed and indicate that XENICAL is working.

How can you deal with these unwanted effects?

- Unwanted side effects are more likely to occur if you eat meals that contain large amounts of fat. Sticking to a diet that contains no more than 30% of calories from fat in each meal will reduce side effects.
- Try to avoid eating fatty foods.

Some unwanted side effects may go away during treatment as your body adjusts to the medicine.

Pancreatitis (inflammation of the pancreas) has been reported with the use of XENICAL.

Kidney problems, including kidney failure, have been reported with the use of XENICAL. Your doctor may do certain tests to check your kidney function while you are taking XENICAL.

If You Have Type 2 Diabetes:
Also, symptoms of hypoglycemia (low blood sugar) may occur, such as:

- sweating
- dizziness
- shakiness
- hunger
- confusion
Talk to your doctor for advice about how you can help avoid these symptoms and whether the dosage of the diabetes medications you may be taking might need to be lowered or discontinued.

### SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

<table>
<thead>
<tr>
<th>Symptom / effect**</th>
<th>Talk with your doctor or pharmacist</th>
<th>Stop taking drug and seek immediate medical help</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Only if severe</td>
<td>In all cases</td>
</tr>
<tr>
<td><strong>Allergic reaction</strong></td>
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<td></td>
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<tr>
<td>- Signs and symptoms include the following: wheezing, unexplained rash, difficulty swallowing or breathing, unexplained swelling, hives.</td>
<td></td>
<td>✓</td>
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<tr>
<td><strong>Formation of gallstones</strong></td>
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<tr>
<td>- Signs and symptoms include the pain in the upper right portion of the abdomen that may be accompanied by nausea and vomiting.</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td><strong>Bleeding from the back passage (rectum)</strong></td>
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<tr>
<td><strong>Kidney stones</strong></td>
<td></td>
<td></td>
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<tr>
<td>- Signs and symptoms include the following: back pain, blood in the urine.</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td><strong>Liver injury (including severe liver injury)</strong></td>
<td></td>
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<tr>
<td>- Signs and symptoms include the following: loss of appetite, itching, yellowing of the skin, dark urine, light colored stools, or right upper quadrant pain that may be accompanied by nausea and vomiting.</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td><strong>Pancreatitis (inflammation of the pancreas)</strong></td>
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<tr>
<td>- Signs and symptoms include the following: upper abdominal pain, abdominal pain that radiates to your back, abdominal pain that feels worse after eating, nausea, vomiting, tenderness when touching the abdomen.</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td><strong>Kidney problems (including kidney failure)</strong></td>
<td></td>
<td></td>
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<tr>
<td>- Signs and symptoms include decreased or no urination, nausea, vomiting, swelling (especially of the hands or feet), painful urination, blood in the urine, severe pain the back, belly or groin</td>
<td></td>
<td>✓</td>
</tr>
</tbody>
</table>

If you are concerned about these or any other unexpected effects while on XENICAL, talk with your doctor or pharmacist.

This is not a complete list of side effects. For any unexpected effects while taking XENICAL, contact your doctor or pharmacist.

### HOW TO STORE IT

**How should this product be stored?**

- Keep out of the reach and sight of children.
- Store XENICAL in its original labelled container at room temperature (between 15-25°C). Keep the blister package in the XENICAL outer carton, in order to protect it from light and moisture.
- Store away from heat.
  - Do not use this medicine after the expiry date on the package.
REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
  - Fax toll-free to 1-866-678-6789, or
  - Mail to: Canada Vigilance Program
    Health Canada
    Postal Locator 0701E
    Ottawa, ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (http://hc-sc.gc.ca/index-eng.php); the manufacturer’s website (www.rochecanada.com), or by calling 1-888-762-4388.

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