Package leaflet: Information for the user

Orlistat 60 mg capsules, hard
orlistat

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.
- Keep this leaflet. You may need to read it again.
- Ask your doctor or pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to your doctor or pharmacist if you do not lose weight after taking Orlistat 60 mg Capsules for 12 weeks. You may need to stop taking Orlistat 60 mg Capsules.

What is in this leaflet
1. What Orlistat 60 mg Capsules are and what they are used for
2. What you need to know before you take Orlistat 60 mg Capsules
3. How to take Orlistat 60 mg Capsules
4. Possible side effects
5. How to store Orlistat 60 mg Capsules
6. Contents of the pack and other information

1. What Orlistat 60 mg Capsules are and what they are used for

Orlistat Capsules (orlistat) is a peripherally acting antiobesity product which is used for weight loss in adults aged 18 and over who are overweight, and have a body mass index (BMI) of 28 or above. Orlistat capsules should be used along with a reduced calorie, lower-fat diet.
BMI is a way to find out if you have a healthy weight, or are overweight, for your height. The chart below will help you find out whether you are overweight and whether Orlistat 60 mg Capsules is right for you.
Find your height on the chart. If you weigh less than the weight shown for your height, do not take Orlistat Capsules**.**

Height	**Weight**		**Height**	**Weight**
1.50 m	63 kg		4' 10"	9st 8lbs
1.55 m	67.25 kg		5' 0"	10st 3lbs
1.60 m	71.75 kg		5' 2"	10st 13lbs
1.65 m	76.25 kg		5' 4"	11st 9lbs
1.70 m	81 kg		5' 6"	12st 5lbs
1.75 m	85.75 kg		5' 8"	13st 2lbs
1.80 m	90.75 kg		5' 10"	13st 13lbs
1.85 m	95.75 kg		6' 0"	14st 10lbs
1.90 m	101 kg		6' 2"	15st 8lbs

Risk of being overweight
Being overweight increases your risk of developing several serious health problems such as diabetes and heart disease. These conditions may not cause you to feel unwell so you should see your doctor for a general health check.

How Orlistat 60 mg capsules works
The active substance (orlistat) in Orlistat 60 mg Capsules is designed to target fat in your digestive system. It stops about a quarter of the fat in your meals from being absorbed. This fat will pass out of the body in your

stools (see section 4). It is therefore important that you commit to a lower-fat diet to manage these effects. If you do, the action of the capsules will assist your efforts by helping you to lose more weight compared to dieting alone. For every 2 kg (4 lb) you lose from dieting alone, Orlistat Capsules might help you lose up to 1 kg (2 lb) more.

2. What you need to know before you take Orlistat 60 mg Capsules

Do not take Orlistat 60 mg Capsules

- if you are allergic to orlistat or any of the other ingredients of this medicine (listed in section 6)
- if you are pregnant or breast-feeding
- if you are taking ciclosporin, used after organ transplants, for severe rheumatoid arthritis and some severe skin conditions
- if you are taking warfarin or other medicines used to thin the blood
- if you have cholestasis (condition where the flow of bile from the liver is blocked)
- if you have problems absorbing food (chronic malabsorption syndrome) diagnosed by a doctor.

Warnings and precautions

Talk to your doctor or pharmacist before taking Orlistat 60 mg Capsules

- If you have diabetes. Tell your doctor who may need to adjust your anti-diabetic medicine.
- If you have kidney disease. Talk to your doctor before taking Orlistat Capsules if you have problems with your kidneys. The use of orlistat may be associated with kidney stones in patients suffering from chronic kidney disease.

Children and adolescents

This medicine must not be taken by children and adolescents under 18 years old.

Other medicines and Orlistat Capsules

Orlistat Capsules may affect some medicines you have to take.
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

<u>Do not take Orlistat 60 mg Capsules with these medicines</u>

- ciclosporin: ciclosporin is used after organ transplants, for severe rheumatoid arthritis and some severe skin conditions.
- warfarin or other medicines used to thin the blood.

<u>The oral contraceptive pill and Orlistat 60 mg Capsules</u>

The oral contraceptive pill may be less effective if you get severe diarrhoea. Use an extra method of contraception if you get severe diarrhoea.

<u>Take a multivitamin every day if you are taking Orlistat Capsules</u>

Orlistat Capsules can lower the levels of some vitamins absorbed by your body. The multivitamin should contain vitamins A, D, E and K. You should take the multivitamin at bedtime, when you will not be taking Orlistat Capsules, to help ensure that the vitamins are absorbed.

<u>Talk to your doctor before taking Orlistat 60 mg Capsules if you are taking</u>

- amiodarone, used for heart rhythm problems
- acarbose (an anti-diabetic medicine used to treat type 2 diabetes mellitus). Orlistat 60 mg Capsules is not recommended for people taking acarbose
- a thyroid medicine (levothyroxine) as it may be necessary to adjust your dose and take your medicines at different times of the day
- a medicine for epilepsy as any changes in the frequency and severity of your convulsions should be discussed with your doctor
- medicines to treat HIV. It is important that you consult your doctor before taking Orlistat 60 mg Capsules if you are receiving treatment for HIV.

- medicines for depression, psychiatric disorders or anxiousness.

Talk to your doctor or pharmacist when taking Orlistat 60 mg Capsules
- if you are taking a medicine for high blood pressure as it may be necessary to adjust your dose
- if you are taking a medicine for high cholesterol as it may be necessary to adjust your dose.

Orlistat 60 mg Capsules with food and drink
Orlistat Capsules should be used along with a reduced calorie, lower-fat diet. Try to start this diet before beginning treatment. For information on how to set your calorie and fat targets, see *Further helpful information* in section 6.
Orlistat Capsules can be taken immediately before, during a meal or up to one hour after a meal. The capsule should be swallowed with water. This usually means one capsule at breakfast, lunch and dinner. If you miss a meal, or your meal contains no fat, do not take a capsule. Orlistat Capsules does not work unless there is some fat in the meal.
If you eat a high-fat meal, do not take more than the recommended dose. Taking the capsule with a meal containing too much fat may increase your chance of getting diet-related treatment effects (see section 4). Make every effort to avoid any high-fat meals while taking Orlistat Capsules.

Pregnancy and breast-feeding
Do not take Orlistat Capsules if you are pregnant or breast-feeding.

Driving and using machines
Orlistat Capsules is unlikely to affect your ability to drive and use machines.

Orlistat 60 mg Capsules contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per hard capsule, that is to say essentially 'sodium-free'.

3. How to take Orlistat 60 mg Capsules

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Preparing to lose weight
1. Choose your start date
Choose the day you will start taking the capsules ahead of time. Before you start taking the capsules, begin your reduced calorie, lower-fat diet and give your body a few days to adjust to your new eating habits. Keep a record of what you are eating in a food diary. Food diaries are effective, because they make you aware of what you are eating, how much you eat, and give you the basis to make changes.

2. Decide on your weight loss goal
Think about how much weight you want to lose and then set a target weight. A realistic goal is to lose between 5% to 10% of your starting weight. The amount of weight you lose may vary from week to week. You should aim to lose weight at a gradual, steady pace of about 0.5 kg (1 lb) per week.

3. Set your calorie and fat targets
To help you reach your weight-loss goal you need to set two daily targets, one for calories and one for fat. For further advice see *Further helpful information* in section 6.

Taking Orlistat 60 mg Capsules
Adults 18 and over
- Take one capsule, three times a day.

- Take Orlistat Capsules just before, during or up to one hour after meals. This usually means one capsule at breakfast, lunch and dinner. Make sure your three main meals are well balanced, reduced calorie, and lower-fat.
- If you miss a meal, or your meal contains no fat, do not take a capsule. Orlistat Capsules does not work unless there is some fat in the meal.
- Swallow the capsule whole with water.
- Do not take more than 3 capsules a day.
- Eat lower-fat meals to reduce the chance of diet-related treatment effects (see section 4).
- Try to be more physically active before you start taking the capsules. Physical activity is an important part of a weight loss programme. Remember to check with your doctor first if you have not exercised before.
- Continue to be active while taking Orlistat Capsules and after you stop taking it.

How long should be taken Orlistat 60 mg Capsules for?

- Orlistat Capsules should not be taken for more than six months.
- If you do not lose weight after taking Orlistat Capsules for 12 weeks, see your doctor or pharmacist for advice.
  You may need to stop taking Orlistat Capsules.
- Successful weight loss is not just about eating differently for a short period of time before reverting to your old habits. People who lose weight and maintain the loss make lifestyle changes, which include changes to what they eat and how active they are.

If you take more Orlistat 60 mg Capsules than you should

Do not take more than 3 capsules a day.

➢ If you have taken too many capsules, contact a doctor as soon as possible.

If you forget to take Orlistat 60 mg Capsules

If you miss taking a capsule:

- If it is less than an hour since your last main meal, take the missed capsule.
- If it is more than an hour since your last main meal, do not take the missed capsule. Wait and take the next capsule around your next main meal as usual.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.
Most of the common side effects related to Orlistat Capsules (for example, wind with or without oily spotting, sudden or more frequent bowel motions and soft stools) are caused by the way it works (see section 1). Eat lower-fat meals to help manage these diet-related treatment effects.

Serious side effects (it is not known how frequently these side effects occur)
Severe allergic reactions

- signs of a severe allergic reaction include: severe breathing difficulties, sweating, rash, itching, swollen face, rapid heart beat, collapse.

➢ Stop taking the capsules. Get medical help immediately.

Other serious side effects

- bleeding from the back passage (rectum)
- diverticulitis (inflammation of the large intestine). Symptoms may include lower stomach (abdominal) pain, particularly on the left side, possibly with fever and constipation.
- pancreatitis (inflammation of the pancreas). Symptoms may include severe abdominal pain sometimes radiating towards the back, possibly with fever, nausea and vomiting.

- skin blistering (including blisters that burst)
- severe stomach pain caused by gallstones
- hepatitis (inflammation of the liver). Symptoms can include yellowing skin and eyes, itching, dark coloured urine, stomach pain and liver tenderness (indicated by pain under the front of the rib cage on your right hand side), sometimes with loss of appetite.
- oxalate nephropathy (build up of calcium oxalate which may lead to kidney stones). See section 2, Warnings and precautions.

➢ Stop taking the capsules. Tell your doctor if you get any of these.

Very common side effects (may affect more than 1 in 10 people)

- wind (flatulence), with or without discharge/oily spotting
- sudden bowel motions
- fatty or oily stools
- oily discharge
- soft stools.

➢ Tell your doctor or pharmacist if any of these side effects gets severe or troublesome.

Common side effects (may affect up to 1 in 10 people)

- stomach (abdominal) pain
- incontinence (stools)
- runny/liquid stools
- more frequent bowel motions
- anxiety

➢ Tell your doctor or pharmacist if any of these side effects gets severe or troublesome.

Effects seen in blood tests (it is not known how frequently these effects occur: frequency cannot be estimated from the available data)

- increases in the levels of some liver enzymes
- effects on blood clotting in people taking warfarin or other blood-thinning (anti-coagulant) medicines.

➢ Tell your doctor that you are taking Orlistat Capsules when you have a blood test.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at:
www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.
By reporting side effects you can help provide more information on the safety of this medicine.

Learn to deal with Orlistat Capsules effects related to your diet or fat intake
The most common side effects are caused by the way the capsules work and result from some of the fat being passed out of your body. Such effects typically occur within the first few weeks of using the capsules, before you may have learnt to limit the amount of fat in your diet. Such diet-related treatment effects may be a signal that you have eaten more fat than you should have done.

You can learn to minimise the impact of diet-related treatment effects by following these guidelines:

- Start your lower-fat diet a few days, or even a week, before you begin taking the capsules.
- Find out more about how much fat your favourite foods typically contain, and the size of your portions. By familiarising yourself with portions you will be less likely to accidentally exceed your fat target.
- Distribute your fat allowance evenly across your meals for the day. Do not “save up” fat and calorie allowances and then splurge on a high-fat meal or dessert, as you may have done on other weight loss programmes.
- Most users who experience these effects find that they can manage and control them by adjusting their diet.

Do not be concerned if you do not experience any of these problems. This does not mean that the capsules are not working.

5. How to store Orlistat 60 mg Capsules

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the packaging after EXP. The expiry date refers to the last day of that month.

Capsules packed in bottles should be used within 6 months from the day of opening the bottle.

Do not store above 25°C.
Store in original package in order to protect from light and moisture.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Orlistat 60 mg Capsules contain

- The active substance is orlistat. Each hard capsule contains 60 mg orlistat.
- The other ingredients are:
  capsule filling: microcrystalline cellulose, sodium starch glycolate (type A), silica hydrophobic colloidal, sodium laurilsulfate;
  capsule shell: gelatin, titanium dioxide (E171), indigo carmine (E132).

What Orlistat 60 mg Capsules looks like and contents of the pack
Orlistat 60 mg Capsules capsules have a light blue cap and body.
Orlistat 60 mg Capsules is available in pack sizes of 42, 60, 84, 90 and 120 capsules. Not all pack sizes may be marketed.

Marketing authorisation holder
Teva UK Limited, Ridings Point, Whistler Drive, Castleford, WF10 5HX, United Kingdom.

Manufacturer
Pharmaceutical Works Polpharma SA, 19, Pelplińska Street, 83-200 Starogard Gdański, Poland

OR*

Merckle GmbH, Ludwig-Merckle-Strasse 3, 89143 Blaubeuren, Germany

OR*

Rontis Hellas Medical and Pharmaceutical Products S.A., P.O. BOX 3012 Larisa Industrial Area, Larisa 41004, Greece.

This leaflet was last revised in July 2024.

PL 00289/1679

FURTHER HELPFUL INFORMATION

Risk of being overweight
Being overweight will affect your health and increase your risk of developing serious health problems such as:

- High blood pressure
- Diabetes
- Heart disease
- Stroke
- Certain forms of cancer
- Osteoarthritis

Talk to your doctor about your risk of developing these conditions.

Importance of losing weight
Losing weight and maintaining weight loss, for example by improving your diet and increasing your physical activity, can help reduce the risk of serious health problems and help improve your health.

Helpful tips on your diet and your calorie and fat targets while taking Orlistat 60 mg Capsules
Orlistat 60 mg Capsules should be used along with a reduced calorie, lower-fat diet. The capsules work by preventing some of the fat you eat from being absorbed but you can still eat foods from all the main food groups.

Although you should focus on the calories and fat that you eat, it is important to eat a balanced diet.
You should choose meals which contain a range of different nutrients and learn to eat healthily for the long term.

Understanding the importance of calorie and fat targets
Calories are a measurement of the energy your body needs. They are sometimes called kilocalories or kcal. Energy may also be measured in kilojoules, which you may also see on food labels.

- The calorie target is the maximum number of calories you'll eat each day. See the chart further on in this section.
- Your fat gram target is the maximum number of grams of fat you'll eat in each meal. The fat gram target chart follows the information below on setting your calorie target.
- Controlling your fat target is essential because of the way the capsules work. Taking Orlistat 60 mg Capsules means your body will pass more fat through, and therefore may struggle to cope with eating as much fat as before. So by meeting your fat target, you'll maximise weight loss results while minimising the risk of diet-related treatment effects.
- You should aim to lose weight gradually and steadily. Losing around 0.5 kg (1 lb) per week is ideal.

How to set your calorie target
The following table has been worked out so that it gives you a calorie target that is about 500 calories fewer per day than your body needs to maintain your current weight. That adds up to 3500 fewer calories per week, about the number of calories in 0.5 kg (1 lb) of fat.

Your calorie target alone should allow you to lose weight at a gradual, steady pace of about 0.5 kg (1 lb) per week, without feeling frustrated or deprived.

Eating fewer than 1200 calories per day is not recommended.

You will need to know your activity level to set your calorie targets. The more active you are, the higher your calorie target.

- "Low activity" means you do little or no walking, climbing stairs, gardening, or other physical activity on a daily basis.
- "Moderate activity" means you burn around 150 calories per day in physical activity, for example, walking three kilometres (2 miles), gardening for 30 to 45 minutes, or running two kilometres (1.25

miles) in 15 minutes. Choose the level that most closely fits your daily routine. If you are unsure which level you are, choose "Low activity".

Women

Low activity	Below 68.1 kg	Below 10 st 10 lb	1200 calories
	68.1 kg to 74.7 kg	10 st 10 lb to 11 st 11 lb	1400 calories
	74.8 kg to 83.9 kg	11 st 12 lb to 13 st 2 lb	1600 calories
	84.0 kg and over	13 st 3 lb and over	1800 calories
Moderate activity	Below 61.2 kg	Below 9 st 9 lb	1400 calories
	61.3 kg to 65.7 kg	9 st 9 lb to 10 st 4 lb	1600 calories
	65.8 kg and over	10 st 5 lb and over	1800 calories

Men

Low activity	Below 65.7 kg	Below 10 st 4 lb	1400 calories
	65.8 kg to 70.2 kg	10 st 5 lb to 11 st	1600 calories
	70.3 kg and over	11 st 1 lb and over	1800 calories
Moderate activity	59.0 kg and over	9 st 4 lb and over	1800 calories

How to set your fat target
The following chart shows how to set your fat target based on the amount of calories you are allowed per day. You should plan to have three meals per day. If you have set a target of 1400 calories per day, for example, the maximum amount of fat allowed per meal would be 15 g. To stay within your daily allowance for fat, snacks should contain no more than 3 g of fat.

Amount of calories you can eat per day	**Maximum amount of fat allowed per meal**	**Maximum amount of fat allowed from snacks per day**
1200	12 g	3 g
1400	15 g	3 g
1600	17 g	3 g
1800	19 g	3 g

Remember:
- Stick to realistic calorie and fat targets as this is a good way of maintaining your weight loss achievements in the long-term.
- Write down what you eat in a food diary, including the calorie and fat content.
- Try to be more physically active before you start taking the capsules. Physical activity is an important part of a weight loss programme. Remember to check with your doctor first if you have not exercised before.
- Continue to be active while taking Orlistat 60 mg Capsules and after you stop taking it.

The Orlistat 60 mg Capsules weight loss programme combines the capsules with an eating plan and a wide range of resources to help you understand how to eat a reduced calorie, lower-fat diet and guidelines for becoming more active.