

Package leaflet: Information for the user

Orlistat HEXAL® 60 mg Hartkapseln [hard capsules]

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 pharmacist if you need more information or advice.
- If you experience any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet (see section 4).
- If you do not lose weight after taking Orlistat HEXAL 60 mg for 12 weeks, see your doctor or pharmacist for advice. You may need to stop taking Orlistat HEXAL 60 mg.

What is in this leaflet

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



1 What Orlistat HEXAL 60 mg is and what it is used for

Orlistat HEXAL 60 mg 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 HEXAL 60 mg 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 HEXAL 60 mg 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 HEXAL 60 mg.

Body height	Body weight
1.50 m	63 kg
1.55 m	67.25 kg
1.60 m	71.75 kg
1.65 m	76.25 kg
1.70 m	81 kg
1.75 m	85.75 kg
1.80 m	90.75 kg
1.85 m	95.75 kg
1.90 m	101 kg

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 HEXAL 60 mg works

The active ingredient (orlistat) in Orlistat HEXAL 60 mg 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. You may experience diet-related side effects (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 you lose from dieting alone, Orlistat HEXAL 60 mg can help you lose 1 kg more.

2 What you need to know before you take Orlistat HEXAL 60 mg

Do not take Orlistat HEXAL 60 mg if

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

Warnings and precautions

Talk to your doctor or pharmacist before taking Orlistat HEXAL 60 mg:

- 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 HEXAL 60 mg 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 is not intended to be taken by children and adolescents under 18 years old.

Other medicines and Orlistat HEXAL 60 mg

Orlistat HEXAL 60 mg may affect the efficacy of other medicines you have to take at the same time.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

Do not take Orlistat HEXAL 60 mg with the following medicines:

- 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.

Oral contraceptives and Orlistat HEXAL 60 mg

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

Multivitamins and Orlistat HEXAL 60 mg

- You should take a multivitamin, every day. Orlistat HEXAL 60 mg 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 HEXAL 60 mg to help ensure that the vitamins are absorbed.

Please talk to your doctor or pharmacist before taking Orlistat HEXAL 60 mg if you are taking:

- amiodarone, used for heart rhythm problems;
- acarbose (an anti-diabetic drug used to treat type 2 diabetes mellitus). Orlistat HEXAL 60 mg 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 HEXAL 60 mg if you are receiving treatment for HIV.
- medicines for depression, psychiatric disorders or anxiousness

Ask your doctor or pharmacist when taking Orlistat HEXAL 60 mg and

- 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 HEXAL 60 mg with food and drink

Orlistat HEXAL 60 mg 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 "Additional helpful information" in section 6. Take Orlistat HEXAL 60 mg with your main meals. This usually means one capsule at breakfast, lunch and dinner (see section 3, Taking Orlistat HEXAL 60 mg).

If you miss a meal, or your meal contains no fat, do not take a capsule. Orlistat HEXAL 60 mg does not work unless there's some fat in the meal.

Do not take more than the recommended dose even if you eat a high fat meal. Taking the capsule with a meal containing too much fat may increase your chance of getting diet-related side effects (see section 4). Make every effort to avoid any high-fat meals while taking Orlistat HEXAL 60 mg.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be

pregnant or breast-feeding or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Do not take Orlistat HEXAL 60 mg if you are pregnant or breast-feeding.

Driving and using machines

No effect on ability to drive or use machines has been observed.

Orlistat HEXAL 60 mg contains sodium

This medicinal product contains less than 1 mmol (23 mg) sodium per hard capsule, i.e. it is almost "sodium free".

3 How to take Orlistat HEXAL 60 mg

Always take this medicine exactly as described in this leaflet or exactly as instructed by your doctor or pharmacist. 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 enable you to track what you are eating, how much you are eating, and make it easier for you to change your eating habits.

2. Set a goal for your weight loss

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 per week.

3. Set goals for your calorie and fat intake

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 "Additional helpful information" in section 6.

Taking Orlistat HEXAL 60 mg

Adults 18 and over

- Take one capsule, three times a day.
- Take Orlistat HEXAL 60 mg at mealtimes. 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 HEXAL 60 mg does not work unless there's some fat in the meal.
- Take Orlistat HEXAL 60 mg just before, during or up to one hour after meals.
- 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 side 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 are not used to physical exercise.
- Continue to be active while taking Orlistat HEXAL 60 mg and after you stop taking it.

How long should Orlistat HEXAL 60 mg be taken for

- Orlistat HEXAL 60 mg should not be taken for more than six months.
- If you do not lose weight after taking Orlistat HEXAL 60 mg for 12 weeks, see your doctor or pharmacist for advice. You may need to stop taking Orlistat HEXAL 60 mg.
- 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 HEXAL 60 mg than you should

Do not take more than 3 capsules a day.

If you take too many capsules, contact a doctor as soon as possible.

If you forget to take Orlistat HEXAL 60 mg

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. Do not take a double dose to make up for a forgotten one.

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 HEXAL 60 mg (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 side 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 heartbeat, 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 of 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 Chapter 2, "Take special care with Orlistat HEXAL 60 mg"

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

Very common (may affect more than 1 in 10 treated persons)

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

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

Common (may affect up to 1 in 10 treated persons)

- stomach (abdominal) pain

Continued overleaf >>

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

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

Effects seen in blood tests

It is not known how frequently these effects occur.

- 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 HEXAL 60 mg when you have a blood test.

How to control diet-related side effects

The most common side effects are caused by the way the capsules work and result from increased amounts of 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 side 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 side effects by following these guidelines:

- Start your lower-fat diet a few days, or even better, 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.

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

Bundesinstitut für Arzneimittel und Medizinprodukte [Federal Institute for Drugs and Medical Devices],
Abt. Pharmakovigilanz [Pharmacovigilance Dept.],
Kurt-Georg-Kiesinger-Allee 3,
D-53175 Bonn,
website: www.bfarm.de.

By reporting side effects, you can help provide more information on the safety of this medicine.

5 How to store Orlistat HEXAL 60 mg

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

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

Do not use this medicine after the “verwendbar bis” [“use by”] expiry date on the packaging and the outer carton. The expiry date refers to the last day of that month.

Never throw away any medicines via wastewater (for example in the toilet or sink). Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment. You can find additional information at www.bfarm.de/arnzmittelentsorgung.

6 Contents of the pack and other information

What Orlistat HEXAL 60 mg contains

The active substance is orlistat.
Each hard capsule contains 60 mg of orlistat.

The other ingredients are:
Capsule content: microcrystalline cellulose, sodium carboxymethyl starch (type A), (Ph.Eur.) highly dispersed silicon dioxide, sodium dodecyl sulfate;
Capsule shell: gelatine, titanium dioxide (E171), indigo carmine (E132).

What Orlistat HEXAL 60 mg looks like and contents of the pack

Light blue, hard capsules size No. 3. Capsule dimensions are approx. 17 mm x 5 mm.

The content is a white powder or slightly compacted agglomerates.

Hard capsules are packaged in aluminium/PVC/PCTFE or aluminium/PVC/PVDC blister packs and are inserted into a cardboard box.

Package sizes:

21, 42, 60, 84, 90, 126, 3x84 hard capsules

Not all pack sizes may be available on the market.

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This medicinal product is authorised in the Member States of the EEA under the following names:

Belgium:	Orlistat Sandoz 60 mg harde capsules
Czech Republic:	Orlistat Sandoz 60 mg
Germany:	Orlistat Hexal 60 mg Hartkapseln
Denmark:	Orlistat Sandoz
Estonia:	Orlistat Sandoz 60 mg
Finland:	Orlistat Sandoz 60 mg kovat kapselit
Netherlands:	Orlistat Sandoz 60 mg, harde capsules

This leaflet was last approved in December 2019.

Your doctor, your pharmacy and Hexal wish you a speedy recovery!

ADDITIONAL HELPFUL INFORMATION

What are the health risks if you are 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.

Why is it important to lose 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 intake while taking Orlistat HEXAL 60 mg

Orlistat HEXAL 60 mg 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.

Why is it important to reduce the calorie and fat intake?

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 recommended calorie intake is the maximum number of calories you should eat each day. See the chart further on in this section.
- The recommended fat intake is the maximum number of grams of fat you should eat in each meal. To see the amount that is applicable for you, see the information below which states the recommended number of calories.
- Controlling your fat target is essential because of the way the capsules work. Taking Orlistat HEXAL 60 mg means your body will pass more fat through. If you consume the same amount of fat as before, this may mean that your body cannot process this amount of fat. By keeping to the recommended fat intake, you can maximise your weight loss and at the same time you can reduce the likelihood of diet-related side effects.
- You should aim to lose weight gradually and steadily. Losing around 0.5 kg per week is ideal.

How do you determine your recommended calorie intake per day?

The following table advises you the maximum amount of calories you should consume each day. It is around 500 kcal less than the amount that would ensure that you would maintain your current weight. If you follow your guideline in the table, you can save 3,500 calories per week which is approximately the amount of calories equivalent to 0.5 kg of fat.

This reduced calorie intake should enable you to gradually and continuously lose around 0.5 kg per week in weight without feeling frustrated or deprived.

Consuming 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 in 15 minutes. Choose the level that most closely fits your daily routine. If you're unsure which level you are, choose “low activity”.

Women

Low physical activity	below 68.1 kg	1,200 kcal
	68.1 kg - 74.7 kg	1,400 kcal
	74.8 kg - 83.9 kg	1,600 kcal
	84.0 kg and over	1,800 kcal
Medium physical activity	below 61.2 kg	1,400 kcal
	61.3 kg - 65.7 kg	1,600 kcal
	65.8 kg and over	1,800 kcal

Men

Low physical activity	below 65.7 kg	1,400 kcal
	65.8 kg - 70.2 kg	1,600 kcal
	70.3 kg and over	1,800 kcal
Medium physical activity	59.0 kg and over	1,800 kcal

How to determine your recommended fat intake per meal?

The following chart shows how to determine your fat intake based on the amount of calories you are allowed per day. You should 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.

Recommended daily calorie intake	Maximum amount of fat allowed per meal	Maximum amount of fat allowed from snacks per day
1,200 kcal	12 g	3 g
1,400 kcal	15 g	3 g
1,600 kcal	17 g	3 g
1,800 kcal	19 g	3 g

Keep in mind:

- 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 HEXAL 60 mg and after you stop taking it.

The Orlistat HEXAL 60 mg 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.