

## PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

Orlistat Sandoz® 120 mg, hard capsules  
orlistat

Read the entire leaflet carefully before you start using this medicine because it contains important information for you.

Keep this leaflet. You may need to read it again.

Do you have any questions? Contact your doctor or pharmacist.

Do not pass this medicine on to others, as it has been prescribed for you only. It may harm them, even if their symptoms are the same as yours.

Do you experience any side effects listed in section 4? Or do you experience a side effect not listed in this leaflet? Then contact your doctor or pharmacist.

### Contents of this leaflet

1. What is Orlistat Sandoz 120 mg and what is it used for?
2. When should you not use this medicine or be extra careful?
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### 1. WHAT IS ORLISTAT SANDOZ 120 MG AND WHAT IS IT USED FOR?

Orlistat Sandoz 120 mg is an anti-obesity medication. It works in your digestive system by preventing about one-third of the fat in the food you eat from being digested.

This medication binds to the enzymes (proteins) in your digestive system (lipases) and prevents them from breaking down some of the fats you have eaten during your meal. The undigested fat cannot be absorbed and is removed from your body.

This medication is used in the treatment of obesity, in conjunction with a calorie-restricted diet.

### 2. WHEN SHOULD YOU NOT USE THIS MEDICATION OR BE EXTRA CAUTIOUS?

When should you not use this medication?

You are allergic to any of the ingredients in this medicine. You can find these ingredients in section 6.

You suffer from chronic malabsorption syndrome (insufficient absorption of food from the digestive tract).

You suffer from cholestasis (a liver disorder).

You are breastfeeding.

When should you be extra cautious with this medication?

Weight loss can affect the dosage of medications for other conditions (e.g., high cholesterol or diabetes). Therefore, you should discuss these and any other medications you are using with your doctor. Weight loss may mean that adjustment of the dosage of those medications is necessary.

To achieve maximum effect from this medication, you should adhere to the dietary plan recommended by your doctor. As with other weight loss programs, consuming too much fat and calories can reduce any effect on weight loss.

This medication can cause an innocent change in your bowel habits, such as fatty or oily stools, due to the excretion of undigested fat in the stool. The likelihood of this happening may increase if this medication is taken with a high-fat diet. Furthermore, the daily intake of fat should be evenly distributed over the three main meals, as the likelihood of stomach and/or intestinal disturbances increases if this medication is used with a very high-fat meal.

The use of an additional contraceptive method is recommended to prevent possible failure of oral (by mouth) contraception (methods to prevent pregnancy, contraceptives) that could occur with severe diarrhea.

The use of this medication may be associated with kidney stones in patients suffering from chronic kidney disease. Contact your doctor if you have kidney problems.

Children and adolescents up to 18 years

This medication is not intended for use in children and adolescents under 18 years.

Are you using any other medications?

Are you using any other medications besides Orlistat Sandoz 120 mg, have you done so recently, or is there a possibility that you will use other medications in the near future? Then tell your doctor or pharmacist. This also applies to medications for which you do not need a prescription. This is important because it use of more than one medicine at the same time can enhance or weaken the effects of the medicines.

This medicine can alter the effects of the following medicines:

acarbose (a medicine for diabetes mellitus type 2). This medicine is not recommended for people using acarbose.

anticoagulants (e.g., warfarin). Your doctor may need to monitor your blood clotting.

ciclosporin (a medicine that suppresses the immune system). Concurrent use with this medicine is not recommended. However, if combined use is truly necessary, your doctor will need to check your ciclosporin blood levels more frequently than usual.

iodine salts and/or levothyroxine. Cases of hypothyroidism (reduced thyroid function) and/or reduced control of hypothyroidism may occur.

amiodarone (a medicine for irregular heartbeat). Consult your doctor for advice.

medicines for the treatment of HIV

antidepressants (medicines for, among other things, a depressive mood)

antipsychotics (medicines for psychosis)

benzodiazepines (a certain group of medicines with calming, sleep-inducing, and/or muscle-relaxing effects)

This medicine reduces the absorption of some fat-soluble nutrients, particularly beta-carotene (a vitamin converted by the body into vitamin A) and vitamin E. Therefore, you should follow your doctor's advice to use a balanced diet rich in fruits and vegetables. The doctor may advise you to use a multivitamin supplement.

Orlistat can interfere with anticonvulsant treatment (treatment to prevent seizures with muscle twitching) by reducing the absorption of anti-epileptic drugs, which can lead to seizures (fits: uncontrollable body shaking). Therefore, contact your doctor if you think the frequency and/or severity of the seizures has changed when using this medicine together with anti-epileptic drugs.

What should you pay attention to with food and drink?

This medicine can be taken immediately before, during, or up to 1 hour after a meal. The capsule should be taken with some water.

Pregnancy and breastfeeding

Are you pregnant, do you think you might be pregnant, do you want to become pregnant, or are you breastfeeding? Then contact your doctor or pharmacist before using this medicine.

Use of this medicine during pregnancy is not recommended.

It is not known whether this medicine passes into breast milk. Therefore, you should not breastfeed while using this medicine.

Driving and using machines

This medicine has no known effect on the ability to drive and use machines.

Orlistat Sandoz contains sodium

This medicine contains less than 1 mmol (23 mg) of sodium per hard capsule, which means it is essentially 'sodium-free'.

### 3. HOW TO USE THIS MEDICINE?

Always use this medicine exactly as your doctor or pharmacist has told you. If you are unsure about the correct use, contact your doctor or pharmacist.

Dosage

The usual dosage of this medicine is one 120 mg capsule with each of the three daily meals. The capsule can be taken immediately before, during, or up to 1 hour after a meal. The capsule should be taken with some water.

General information

This medicine should be combined with a balanced, calorie-restricted diet that is rich in fruits and vegetables and where approximately 30% of the calories come from fat. Your daily intake of fat, carbohydrates, and proteins should be distributed over three meals. This means you generally take one capsule at breakfast, one capsule at lunch, and one capsule at dinner. To achieve optimal results, you should avoid consuming foods that contain fat, such as biscuits, chocolate, and savory snacks, between meals.

This medicine is only effective with a meal that contains fat. Therefore, it is not necessary to take this medicine if you skip a meal or have a meal that contains no fat.

If, for any reason, you have not taken your medicine exactly as prescribed, inform your doctor. Otherwise, your doctor might think that the medicine is not working properly or is not well tolerated and unjustly change the treatment.

If you have not lost at least 5% of your body weight after 12 weeks of starting treatment with this medicine, the doctor will discontinue the treatment.

This medicine has been studied in long-term clinical studies lasting up to 4 years.

Have you used too much of this medicine?

If you have taken more capsules than prescribed or if someone else accidentally took your capsules, contact a doctor, pharmacist, or hospital immediately, as medical assistance may be required.

Have you forgotten to use this medicine?

If you have forgotten to take the medicine once, take it as soon as you remember, provided it is within one hour after the last meal, and then continue the treatment at the usual times. Do not take a double dose to make up for a forgotten dose. If you have forgotten to take the medicine multiple times, contact your doctor and follow his/her advice. Do not change the prescribed dosage without consulting your doctor.

If you stop using this medicine

Do not stop using this medicine unless your doctor tells you to stop.

Do you have any other questions about the use of this medicine? Then contact your doctor or pharmacist.

#### 4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Tell your doctor or pharmacist as soon as possible if you do not feel well during treatment with this medicine.

The majority of side effects associated with the use of this medicine arise from the local action on the digestive system. These symptoms are generally mild, occur at the start of treatment, and are mainly observed after meals with a high fat content. In general, these symptoms disappear with continued treatment and if you adhere to the prescribed diet.

Very common (affects more than 1 in 10 users)

- headache
- abdominal pain/discomfort
- urgent or increased need to defecate
- flatulence with discharge
- oily discharge
- fatty or oily stools
- liquid stools
- low blood sugar (occurs in some people with type 2 diabetes)

Common (affects less than 1 in 10 users)

- pain/discomfort in the rectum
- soft stools
- incontinence (the inability to hold stool)
- bloating (occurs in some people with type 2 diabetes)
- condition of teeth/gums
- irregular menstruation
- fatigue

Not known (the frequency cannot be determined from the available data):

- allergic reactions. The main symptoms are itching, rash, hives (slightly raised, itchy areas of skin that are paler or redder than the surrounding skin), severe breathing difficulties, nausea, vomiting, and a feeling of malaise. Contact your doctor immediately if you experience these symptoms
- blood in the stool (from your rectum)
- increase in the amount of certain liver enzymes; can be detected by blood tests
- diverticulitis (the most common symptom is abdominal pain. Cramps, nausea, vomiting, fever, chills, or a changed bowel pattern may also occur)
- gallstones
- hepatitis (liver inflammation). Symptoms include yellowing of the skin and eyes, itching, dark-colored urine, abdominal pain, and liver tenderness (noticed as pain on the right side under the rib cage), sometimes with loss of appetite
- blistering (including bursting blisters)
- effect on blood clotting with anticoagulants (medicines that prevent blood clotting)
- pancreatitis (inflammation of the pancreas)
- oxalate nephropathy (accumulation of calcium oxalate that can lead to kidney stones). See section 2, "When should you be extra careful with this medicine?"

Reporting side effects

If you experience side effects, contact your doctor or pharmacist. This also applies to possible side effects not listed in this leaflet. You can also report side effects directly via the Netherlands Pharmacovigilance Centre Lareb, website: [www.lareb.nl](http://www.lareb.nl). By reporting side effects, you can help us obtain more information about the safety of this medicine.

## 5. HOW TO STORE THIS MEDICINE?

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date. It can be found on the blister pack and the box after "EXP.:". It includes a month and a year. The last day of that month is the expiry date.

Store below 25°C. Store in the original package to protect from light and moisture.

Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. They will then be destroyed responsibly and will not enter the environment.

## 6. CONTENTS OF THE PACKAGE AND OTHER INFORMATION

What substances are in this medicine?

The active substance in this medicine is orlistat. Each hard capsule contains 120 mg of orlistat.

The other substances in this medicine are:

Contents of the capsule: microcrystalline cellulose, sodium starch glycolate (type A), silica, hydrophobic colloidal, sodium lauryl sulfate.

Capsule shell: gelatin, titanium dioxide (E171), indigotine (E132).

What does Orlistat Sandoz look like and what is in a package?

Blue hard capsules, size 1. The size of a hard capsule is approximately 20 mm x 7 mm. The content is a loose white powder or slightly compacted white agglomerates.

The hard capsules are packed in Alu/PVDC/PVDC blisters and packed in a cardboard box.

Package sizes:

21, 42, 84, 3x84 capsules.

Not all package sizes may be marketed.

Marketing authorization holder and manufacturer

Marketing authorization holder

Sandoz B.V., Hospitaaldreef 29, 1315 RC Almere, Netherlands

Manufacturers

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

Salutas Pharma GmbH  
Otto-von-Guericke Allee 1  
39179 Barleben  
Germany

LEK S.A.  
ul. Domaniewska 50 C  
02-672 Warsaw  
Poland

Lek Pharmaceuticals d.d.  
Verovškova 57  
1526 Ljubljana  
Slovenia

LEK S.A.  
ul. Podlipie 16  
95-010 Strykow  
Poland

Registered under  
Orlistat Sandoz 120 mg, hard capsules – RVG 105761

This medicine is registered in EEA member states under the following names

Belgium:	Orlistat Sandoz 120 mg capsules, hard
Czech Republic:	Orlistat Sandoz 120 mg
Germany:	Orlistat – 1 A Pharma 120 mg Hartkapseln
Estonia:	Orlistat Sandoz 120 mg
Finland:	Orlistat Sandoz

This leaflet was last approved in June 2024.