

Package leaflet: Information for the user

Orlistat 120 mg Capsules, hard orlistat

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- 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.

What is in this leaflet

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

1. What Orlistat is and what it is used for

Orlistat is a medicine used to treat obesity. It works in your digestive system to block about one-third of the fat in the food you eat from being digested.

Orlistat attaches to the enzymes in your digestive system (lipases) and blocks them from breaking down some of the fat you have eaten during your meal. The undigested fat cannot be absorbed and is eliminated by your body.

Orlistat is indicated in the treatment of obesity in conjunction with a low calorie intake diet.

2. What you need to know before you take Orlistat

Do not take Orlistat:

- if you are allergic (hypersensitive) to orlistat or to any of the other ingredients of Orlistat,
- if you have chronic malabsorption syndrome (insufficient absorption of nutrients from alimentary tract)
- if you have cholestasis (liver disorder)
- if you are breast-feeding.

Warnings and precautions

Weight loss may also affect the dose of medicines taken for other conditions (e.g. high cholesterol or diabetes). Be sure to discuss these and other medicines you may be taking with your doctor. Losing weight may mean you need adjustments to the dose of these medicines.

To gain the maximum benefit from Orlistat you should follow the nutrition program recommended to you by your doctor. As with any weight-control program, over-consumption of fat and calories may reduce any weight loss effect.

This medicine can cause harmless changes in your bowel habits, such as fatty or oily stools, due to the elimination of undigested fat in your faeces. The possibility of this happening may increase if Orlistat is taken with a diet high in fat. In addition your daily intake of fat should be distributed evenly over three main meals because if Orlistat is taken with a meal very high in fat, the possibility of gastrointestinal effects may increase.

The use of an additional contraceptive method is recommended to prevent possible failure of oral contraception that could occur in case of severe diarrhoea.

The use of orlistat may be associated with renal stones in patients suffering from chronic kidney disease. Inform your doctor whether you suffer from problems with your kidney.

Children

Orlistat is not intended to be used in children.

Other medicines and Orlistat

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, even those not prescribed.

This is important as using more than one medicine at the same time can strengthen or weaken the effects of the medicines.

Orlistat may modify the activity of:

- Anticoagulant drugs (e.g. warfarin). Your doctor may need to monitor your blood coagulation.
- Ciclosporin. Co-administration with ciclosporin is not recommended. Your doctor may need to monitor your ciclosporin blood levels more frequently than usual.
- Iodine salts and/or levothyroxine. Cases of hypothyroidism and/or reduced control of hypothyroidism may occur.
- Amiodarone. You may ask your doctor for advice.
- Medicines to treat HIV
- Medicines for depression, psychiatric disorders or anxiousness.

Orlistat reduces the absorption of supplements of some fat soluble nutrients, particularly beta-carotene and vitamin E. You should therefore follow your doctor's advice in taking a well-balanced diet rich in fruit and vegetables. Your doctor may suggest you take a multivitamin supplement.

Orlistat may unbalance an anticonvulsant treatment, by decreasing the absorption of antiepileptic drugs, thus leading to convulsions. Please contact your doctor if you think that the frequency and/or severity of the convulsions have changed when taking Orlistat together with antiepileptic drugs.

Orlistat is not recommended for people taking acarbose (an anti-diabetic drug used to treat type 2 diabetes mellitus).

Orlistat with food and drink

Orlistat can be taken immediately before, during a meal or up to one hour after a meal. The capsule should be swallowed with water.

Pregnancy and breast-feeding

Taking Orlistat during pregnancy is not recommended.

You must not breast-feed your infant during treatment with Orlistat as it is not known whether Orlistat passes into human milk.

Driving and using machines

Orlistat has no known effect on your ability to drive a car or operate machinery.

Orlistat contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per dosage unit, that is to say essentially 'sodium-free'.

3. How to take Orlistat

Always take Orlistat exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. The usual dose of Orlistat is one 120 mg capsule taken with each of the three main meals per day. It can be taken immediately before, during a meal or up to one hour after a meal. The capsule should be swallowed with water.

Orlistat should be taken with a well-balanced, calorie controlled diet that is rich in fruit and vegetables and contains an average of 30 % of the calories from fat. Your daily intake of fat, carbohydrate and protein should be distributed over three meals. This means you will usually take one capsule at breakfast time, one capsule at lunch time and one capsule at dinner time. To gain optimal benefit, avoid the intake of food containing fat between meals, such as biscuits, chocolate and savoury snacks.

Orlistat only works in the presence of dietary fat. Therefore, if you miss a main meal or if you have a meal containing no fat, Orlistat need not be taken.

Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed. Otherwise, your doctor may think that it was not effective or well tolerated and may change your treatment unnecessarily.

Your doctor will discontinue the treatment with Orlistat after 12 weeks if you have not lost at least 5 % of your body weight as measured at the start of treatment with Orlistat.

Orlistat has been studied in long-term clinical studies of up to 4 years duration.

If you take more Orlistat than you should

If you take more capsules than you have been told to take, or if someone else accidentally takes your medicine, contact a doctor, pharmacist or hospital as you may need medical attention.

If you forget to take Orlistat

If you forget to take your medicine at any time, take it as soon as you remember provided this is within one hour of your last meal, then continue to take it at the usual times. Do not take a double dose. If you have missed several doses, please inform your doctor and follow the advice given to you. Do not change the prescribed dose yourself unless your doctor tells you to.

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

If you stop taking Orlistat

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.

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Orlistat. The majority of unwanted effects related to the use of Orlistat result from its local action in your digestive system. These symptoms are generally mild, occur at the beginning of treatment and are particularly experienced after meals containing high levels of fat. Normally, these symptoms disappear if you continue treatment and keep to your recommended diet.

Very common side effects (affects more than 1 user in 10)

- Headache
- Abdominal pain/discomfort, urgent or increased need to open the bowels, flatulence (wind) with discharge, oily discharge, oily or fatty stools, liquid stools, low blood sugar levels (experienced by some people with type 2 diabetes).

Common side effects (affects 1 to 10 users in 100)

- Rectal pain/discomfort, soft stools, incontinence (stools), bloating (experienced by some people with type 2 diabetes)
- Tooth/gum disorder
- Irregularity of menstrual cycle
- Tiredness.

The following side effects have also been reported but their frequency cannot be estimated from the available data:

- Allergic reactions. The main symptoms are itching, rash, wheals (slightly elevated, itchy skin patches that are paler or redder than surrounding skin), severe difficulty in breathing, nausea, vomiting and feeling unwell
- Skin blistering (including blisters that burst)
- Diverticulitis
- Bleeding from the back passage (rectum)
- Increases in the levels of some liver enzymes may be found in blood tests
- 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. **Stop Orlistat if such symptoms occur and tell your doctor.**
- Gallstones
- Pancreatitis (inflammation of the pancreas)
- Oxalate nephropathy (build up of calcium oxalate which may lead to kidney stones). See Section 2, Warnings and Precautions.
- Effects on clotting with anti-coagulants.

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 national reporting system:

United Kingdom: Yellow Card Scheme. Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

Ireland: HPRa Pharmacovigilance: www.hpra.ie.

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

5. How to store Orlistat

Keep out of the sight and reach of children.

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

Do not store above 25°C.

Store in original package and keep the blister in the outer carton 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 to protect the environment.

6. Contents of the pack and other information

What Orlistat contains

- The active substance is orlistat. Each capsule contains 120 mg of orlistat.
- The other ingredients are microcrystalline cellulose (E460), sodium starch glycolate (type A), silica hydrophobic colloidal and sodium laurilsulfate. The capsule shell consists of gelatin, indigo carmine (E132) and titanium dioxide (E171).

What Orlistat looks like and contents of the pack

Orlistat capsules are blue capsules and are supplied in blister packs, containing 21, 42 and 84 capsules. Not all pack sizes may be marketed.

Marketing Authorisation Holder

Alissa Healthcare Research Limited

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Manufacturer

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

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

United Kingdom: Orlistat 120 mg Capsules, hard

Ireland: Orlistat 120 mg Capsules, hard

This leaflet was last revised in 09/2020.