

**ORLISTAT 120 mg CAPSULES,  
HARD**

**PACKAGE LEAFLET: INFORMATION  
FOR THE USER**

**Read all of this leaflet carefully before you start taking this medicine.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

**IN THIS LEAFLET:**

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**1 WHAT ORLISTAT 120 mg CAPSULES ARE AND WHAT THEY ARE USED FOR**

Orlistat Capsules 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.

**Use in paediatric population (children and adolescents below 18 years)**

Orlistat Capsules is not intended to be used in children and adolescents below 18 years.

**Taking other medicines**

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 Capsules may modify the activity of:

- acarbose (an anti-diabetic drug used to treat type 2 diabetes mellitus). Co-administration with Orlistat Capsules is not recommended
- anticoagulant drugs (e.g. warfarin). Your doctor may need to monitor your blood coagulation
- ciclosporin (medicine dampening down the body's immune system). Co-administration with Orlistat Capsules is not recommended. However, if such use is unavoidable, 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 (medicine used for irregular heart beat). You may ask your doctor for advice.

Orlistat Capsules 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 and in taking a multivitamin supplement.

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

## 2 BEFORE YOU TAKE ORLISTAT 120 mg CAPSULES

### Do not take Orlistat Capsules

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

### Take special care with Orlistat Capsules

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 Capsules 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 Capsules 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 Capsules 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 cases 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.

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 Capsules together with antiepileptic drugs.

### Taking Orlistat 120 mg Capsules with food and drink

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.

### Pregnancy and breast-feeding

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

### Driving and using machines

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

## 3 HOW TO TAKE ORLISTAT 120 mg CAPSULES

Always take Orlistat Capsules exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

### Dose:

The usual dose of Orlistat Capsules 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.

### General information:

Orlistat Capsules 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 Capsules 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 Capsules does not need to 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 Capsules after 12 weeks if you have not lost at least 5% of your body weight as measured at the start of treatment with Orlistat Capsules

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

#### **If you take more Orlistat Capsules 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 immediately as you may need medical attention.

#### **If you forget to take Orlistat Capsules**

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 to make up for a forgotten one. 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 product, ask your doctor or pharmacist.

### **4 POSSIBLE SIDE EFFECTS**

Like all medicines, Orlistat 120 mg Capsules can cause side effects, although not everybody gets them.

- diverticulitis (the most common symptom is abdominal pain. Cramping, nausea, vomiting, fever, chills, or a change in bowel habits may also appear)
- gallstones
- hepatitis (inflammation of the liver)
- skin blistering (including blisters that burst)
- effects on clotting with anti-coagulants
- pancreatitis (inflammation of the pancreas)
- oxalate nephropathy (renal disease).

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

### **5 HOW TO STORE ORLISTAT 120 mg CAPSULES**

**Keep out of the reach and sight of children.**

Do not use Orlistat 120 mg Capsules after the expiry date which is stated on the packaging after "EXP". The expiry date refers to the last day of that month.

Do not store above 25°C.

Store in the original package in order to protect from light and moisture.

Medicines should not be disposed via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

### **6 FURTHER INFORMATION**

#### **What Orlistat 120 mg Capsules contains**

- The active substance is orlistat. Each hard capsule contains 120 mg of orlistat.
- The other ingredients are:  
**capsule filling:** microcrystalline cellulose, sodium starch glycolate (type A), silica colloidal anhydrous, sodium laurilsulfate;  
**capsule shell:** gelatin, titanium dioxide (E171), indigo carmine (E132).

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Orlistat Capsules.

The majority of unwanted effects related to the use of Orlistat Capsules 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 (these may affect more than 1 in 10 patients)**

- 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 (these may affect up to 1 in 10 patients)**

- 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. **Contact your doctor immediately if you experience any of these.**
- bleeding from the back passage (rectum).
- increases in the levels of some liver enzymes may be found in blood tests

**What Orlistat 120 mg Capsules looks like and contents of the pack**

Orlistat 120 mg Capsules are blue and are supplied in blister packs, containing 21, 42 and 84 capsules. Not all pack sizes may be marketed.

**Marketing Authorisation holder and Manufacturer**

**Marketing Authorisation holder:**  
TEVA UK Limited, Eastbourne, BN22 9AG, United Kingdom.

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

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