Olistat 120mg hard capsules

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

- Keep this leaflet. You must need to read it again.
- If you have any further questions, please 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 of the side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

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

1. What Olistat is and what it is used for

Olistat 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. Olistat 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.

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

2. What you need to know before you take Olistat

Do not take Olistat:
- If you are allergic to orlistat or any of the other ingredients of this medicine listed in section 6.
- If you have chronic malabsorption syndrome (insufficient absorption of nutrients fromenteral tract).
- If you have cholestasis (liver disorder).
- If you are breast-feeding (see "Pregnancy and breast-feeding").

Warnings and precautions
Talk to your doctor or pharmacist before taking Olistat.

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

Losing weight may mean you need adjustments to the doses of these medicines.

To gain the maximum benefit from Olistat 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 harmful changes in your bowel habit, such as tarry or oily stools, due to the diminution of undigested fat in your faeces. The possibility of this happening may increase if Olistat is taken with a diet high in fat. In addition your daily intake of fat should be distributed evenly over three main meals because it Olistat 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 oral anticoagulants 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
Olistat is not intended to be used in children.

Other medicines and Olistat
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

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

Olistat may modify the activity of:
- Anti-coagulant (medicine used to thin blood, e.g. warfarin). Your doctor may need to monitor your blood coagulation.
- Cidofovir (medicine dampening down the body’s immune system). Co-administration with cidofovir is not recommended. Your doctor may need to monitor your cidofovir’s blood levels more frequently than usual.
- Steroids (medicine used for inflammatory conditions). Your doctor may need to increase your steroid’s blood levels more frequently than usual.
- Lithium (medicine used for bipolar disorder). Your doctor may need to increase your lithium’s blood levels more frequently than usual.

Olistat reduces the absorption of supplements of some ‘fat soluble’ vitamins, 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.

Olistat may unbalance an anticonvulsant (antiepileptic) treatment, by decreasing the absorption of antiepileptic medicines, thus leading to convulsions. Contact your doctor if you think that the frequency and/or severity of the convulsions (fits) have changed when taking Olistat together with antiepileptic medicines.

Olistat is not recommended for people taking warfarin (an anti-platelet medicine used to treat type 2 diabetes mellitus).

Olistat with food and drink
Olistat 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
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Taking Olistat during pregnancy is not recommended. You must not breast-feed your infant during treatment with Olistat as it is not known whether Olistat passes into human milk (see "Do not take Olistat").

Driving and using machines
Olistat has no known effect on your ability to drive a car or operate machinery.

3. How to take Olistat
Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose of Olistat 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.

Olistat 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.

Olistat only works in the presence of dietary fat. Therefore, if you miss a main meal or if you have a meal containing no fat, Olistat 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 is not effective or well tolerated and may change your treatment unnecessarily.

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

Olistat 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.

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 (may affect more than 1 in 10 people):
- headache
- abdominal pain/discomfort
- urgent or increased need to open the bowels
- intolerance (wind) with or without discharge
- oily discharge, oily or fatty stools
- liquid stools
- low blood sugar levels (experienced by some people with type 2 diabetes)
- upper respiratory infections
- flu (influenza)

Common (may affect up to 1 in 10 people):
- rectal pain/discomfort
- soft stools
- incontinence (stools)
- bloating (experienced by some people with type 2 diabetes)
- tooth/jaw disorder
- irregularity of menstrual cycle
- tiredness
- anxiety
- lower respiratory infections
- urinary tract infections

Not known (frequency cannot be estimated from the available data):
- allergic reactions: the main symptoms are itching, rash, wheals (slightly elevated, itchy skin patches that are pale or redder than surrounding skin), severe difficulty in breathing, nausea, vomiting and feeling unwilling. Contact your doctor immediately if you experience any of these.
- skin blistering (including blisters that burst)
- diverticulitis (inflammation of small outpouchings along the wall of the colon)
- 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.
- gallbladders
- pancreatitis (inflammation of the pancreas)
- exocrine nephropathy (build up of calcium oxalate which may lead to kidney stones), (see Section 3, ‘Warnings and precautions’),
- effects on dieting with anti-coinsonablers.

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 MAH’s View Card Scheme — Website: www.mhra.gov.uk/yellicard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Orlistat
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 carton. 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.

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 contains
- The active substance is orlistat. Each hard capsule contains 120 mg of orlistat.
- The other ingredients are cellulose, microcrystalline PH 112, sodium starch glycolate (type AI), silica, colloidal anhydrous and sodium laurilsulphate. The capsule shell consists of gelatine, titanium dioxide (E171) and indigo carmine (E132).

What Orlistat looks like and contents of the pack
Orlistat capsules are hard gelatin, blue capsules: content in white powder or slightly compacted pellets: size of capsules No 1 and are supplied in blister pack, containing 21, 42 and 84 capsules. Not all pack sizes may be marketed.

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