Package leaflet: Information for the user

Beacita120 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, please ask your doctor or your 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 /.../ is and what it is used for

/.../ 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.

/.../ 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.

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

2. What you need to know before you take /.../

Do not take /.../
- 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 across the gastrointestinal (GI) 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 /.../ 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 /.../ 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 /.../ 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 and adolescents
/.../ is not intended to be used in children and adolescents below 18 years.

Other medicines and /…/
Tell your doctor or pharmacist if you are taking, have recently taken or might take 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.

/.../ may modify the activity of:
- acarbose. /.../ is not recommended for people taking acarbose (an anti-diabetic drug used to treat type 2 diabetes mellitus).
- 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 /.../ 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.
- medicines to treat HIV.
- medicines for depression, psychiatric disorders or anxiousness

/.../ 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 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 /.../ together with antiepileptic drugs.

Orlistat should be used with caution in patients treated with antidepressants and antipsychotics (including lithium).

/.../ with food and drink
/.../ 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 /.../ during pregnancy is not recommended.
You must not breast-feed your infant during treatment with /.../ as it is not known whether /.../ passes into human milk.

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

/.../ contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per hard capsule, that is to say essentially ‘sodium-free’.

3. How to take /.../

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

Dose:
The recommended dose of /.../ 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:
/.../ 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.

/.../ only works in the presence of dietary fat. Therefore, if you miss a main meal or if you have a meal containing no fat, /.../ 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 /.../ after 12 weeks if you have not lost at least 5 % of your body weight as measured at the start of treatment with /.../.

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

If you take more /.../ 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 /.../
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 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 /.../.

The majority of unwanted effects related to the use of /.../ 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 (may affect more than 1 in 10 people)

- headache
- upper respiratory tract infection
- abdominal pain/discomfort
- urgent or increased need to open the bowels
- flatulence (wind)
- flatulence (wind) with discharge
- oily discharge
- oily or fatty stools
- liquid stools
- increased elimination of stools
- influenza ('flu')
- low blood sugar levels (experienced by some people with type 2 diabetes).

Common side effects (may affect up to 1 in 10 people)
- lower respiratory tract infection
- rectal pain/discomfort
- soft stools
- faecal incontinence (inability to control your bowel movements)
- bloating (experienced by some people with type 2 diabetes)
- tooth/gum disorder
- urinary tract infection
- irregularity of menstrual cycle
- tiredness
- anxiety.

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
- 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). 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.
- skin blistering (including blisters that burst)
- effects on clotting with anti-coagulants
- pancreatitis (inflammation of the pancreas)
- oxalate nephropathy (build up of calcium oxalate which may lead to kidney stones). See section 2.

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

5. How to store /.../

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 packaging after “EXP”. The expiry date refers to the last day of that month.

Do not store above 25ºC.
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 /.../ contains
- The active substance is orlistat. Each hard capsule contains 120 mg of orlistat.
- The other ingredients are:
  capsule filling: microcrystalline cellulose PH112, sodium starch glycolate (type A), silica, hydrophobic colloidal, sodium laurilsulfate.
  capsule shell: gelatin, titanium dioxide (E171), indigo carmine (E132).

What /.../ looks like and contents of the pack
/.../ capsules are blue and are supplied in blister packs, containing 21, 42, 84 and 90 capsules.
Not all pack sizes may be marketed.

Marketing authorisation holder
Actavis Group PTC ehf.
Reykjavíkurvegi 76-78
220 Hafnarfjörður
Iceland

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

RONTIS HELLAS MEDICAL AND PHARMACEUTICAL PRODUCTS S.A.
p.o. BOX 3012 Larisa Industrial Area,
Larisa, 41004
GREECE

This medicinal product is authorised in the Member States of the EEA under the following names:
<{Name of the Member State}> <{Name of the medicinal product}>
<{Name of the Member State}> <{Name of the medicinal product}>

This leaflet was last revised in 1 November 2017.

<[To be completed nationally]>