1. WHAT BEACITA IS AND WHAT IT IS USED FOR

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

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

2. BEFORE YOU TAKE BEACITA

Do not take Beacita:

- if you are allergic (hypersensitive) to orlistat or any of the other ingredients of Beacita
- if you have clinical malabsorption syndrome (inadequate absorption of nutrients across the gastrointestinal tract)
- if you have ileostomy (overflow)
- if you are breast-feeding.

Take special care with Beacita

Weight loss may also reduce the dose of medicines taken for other conditions (e.g. high cholesterol or diabetes). Beacita may change doses of medicines you are taking. Consult your doctor about any necessary adjustments to the dose of these medicines.

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

The 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 frequency and/or severity of this happening may increase if Beacita is taken with a diet high in fat. In addition your daily intake of fat should be divided equally over three main meals because if Beacita 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 contraceptives that could occur in case of severe diarrhoea.

It is recommended that patients suffering from chronic kidney disease inform your doctor whether you suffer from problems with your kidney.

Pregnant and breast-feeding women are recommended not to breast-feed during treatment with Beacita.

3. HOW TO TAKE BEACITA

Beacita are 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 effect of the medicine. Your doctor or pharmacist can help you to avoid any possible interaction.

Beacita may modify the activity of:

- antibiotics. Beacita are not recommended for people taking antibiotics (an anti-bacterial drug used to treat type 2 diabetes mellitus).
- antiglucocorticoids. Your doctor may need to adjust your daily blood sugar levels.
- ciclosporin (medicine dampening down the body's immune system). Co-administration with Beacita is not recommended. If ciclosporin 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.
- acarbose. Beacita are not recommended for people taking acarbose (an anti-diabetic drug used to treat type 2 diabetes).

Beacita may unbalance an anticonvulsant treatment, by decreasing the absorption of antiepileptic drugs such as carbamazepine, valproate or lamotrigine.

Drinking and using machines

Beacita have no known effect on your ability to drive a car or operate machinery.

3. HOW TO TAKE BEACITA

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

Do not:

- exceed the maximum dose of Beacita. Beacita is one 120mg capsule taken with each of the three main meals per day. It can be taken immediately before, during or up to one hour after a meal. The capsules should be swallowed with water.

General information:

Beacita should be taken with a well-balanced, calorie-controlled diet that is rich in fruit and vegetables and contains an average of 35% of the calories from fat. Your daily intake of fat, carbohydrate and protein should be distributed over three meals. The means you will usually take one capsule at breakfast time, one capsule at lunch time and one capsule at dinner time. Go on optimal benefits, avoid the intake of food containing fat between meals, such as biscuits, chocolate and savoury snacks.

By following your doctor's advice in taking a well-balanced diet rich in fat and vegetables and in taking the medicine regularly according to your doctor's instructions, Beacita may unbalance an anticonvulsant treatment, by decreasing the absorption of antiepileptic drugs such as carbamazepine, valproate or lamotrigine.

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 as effective or well tolerated and may recommend that you discontinue the treatment.

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

Beacita have been studied in long-term clinical studies of up to 4 years duration.
If you take more Beacita than you should
If you take more capsules than you have been told to take, or if someone else accidentally takes your medicine, immediately contact your doctor or pharmacist. Call a doctor or pharmacist immediately if you think you may have taken too much Beacita.

IF YOU FORGET TO TAKE BEACITA
If you forget to take your medicine at any time, take it as soon as you can. If it is more than 12 hours since your last dose, then continue to take your usual dose at the usual time. Do not take a double dose to make up for the missed dose.

4. POSSIBLE SIDE EFFECTS
Like most medicines, Beacita can cause side effects, although not everybody gets them.
Tell your doctor or pharmacist as soon as possible if you notice any side effects. Beacita is not used in the majority of unusual reactions related to the use of Beacita rather than from the normal action of the digestive system.
These symptoms are usually 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
• diarrhea
• rectal bleeding
• dry cough
• skin rash
• flatulence
• upper respiratory infection
• anxiety

Common side effects (may affect up to 1 in 10 people)
• lower respiratory tract infection
• pain/discomfort
• soft stools
• facial oedema
• insomnia (difficulty to keep your bowels movements)
• bleeding (impotence by some people with type 2 diabetes)
• tooth gum disorder
• urinary tract infection
• irregularity of menstrual cycle
• tiredness

These symptoms are usually 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.

The following side effects have also been reported but their frequency cannot be estimated from the available data:
• allergic reactions: The main symptoms are: rash, redness, hives, skin rash, swelling, breathing difficulty, severe difficulty in breathing, wheezing, swelling and feeling unusual.
• change in bowel habits (may affect more than 1 in 10 people)
• nausea: limit the amount of liquid you drink and eat meals containing high levels of fat. Normally, these symptoms disappear if you continue treatment and keep to your recommended diet.

5. HOW TO STORE BEACITA
Keep out of the reach and sight of children. Beacita should be stored in the original package in order to protect from light and moisture. Do not store above 25ºC.

These symptoms are usually 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.

IF YOU DO NOT FEEL WELL WHILE YOU ARE TAKING BEACITA
Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Beacita. These symptoms are usually 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.

6. FURTHER INFORMATION
What Beacita contains
• The active substance is orlistat. Each hard capsule contains 120 mg orlistat.
• The other ingredients are:
capsule filling: microcrystalline cellulose PH112, sodium starch glycolate (type A), colloidal silicon dioxide, magnesium stearate
capsule shell: gelatin, titanium dioxide (E171), indigo carmine (E132).

What Beacita looks like and contents of the package
Beacita capsules are blue and are supplied in blister packs, containing 84 capsules.

Marketing authorisation holder
Actavis Group PTC Ltd.
Red Rock Lane, Benfleet EP 7R
Benfleet, Essex, UK

Manufacturer
Pharmaceutical Works, POLPHARMA SA
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This leaflet was last approved in November 2012.

If you would like a leaflet with larger text, please contact 01271 311257.