

## Package leaflet: Information for the user

### OLBETAM® 250 mg Capsules Acipimox

**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, pharmacist or nurse.
- 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 Olbetam Capsules are and what they are used for
2. What you need to know before you take Olbetam Capsules
3. How to take Olbetam Capsules
4. Possible side effects
5. How to store Olbetam Capsules
6. Contents of the pack and other information

#### **1. What Olbetam Capsules are and what they are used for**

This medicine contains acipimox, which is used to treat lipid disorders by reducing high blood levels of certain types of fats called triglycerides. Olbetam Capsules should only be used in patients where diet alone or other non-drug measures (weight loss or exercise) failed to correct the levels of these fats.

Olbetam Capsules should be used in addition to other medicines, such as medicines called ‘statins’ or ‘fibrates’ or instead of these medicines where they may not be appropriate or of expected benefit.

Olbetam Capsules prevent the release of fatty acids from fatty tissue and decrease the blood level of triglyceride and cholesterol.

Your doctor will advise you whether Olbetam Capsules will be of benefit to you in reducing the level of fat in your blood.

Your doctor will prescribe this medicine to you only once it is clear that low fat diets and stopping drinking alcohol are not having the desired effect.

You must talk to your doctor if you do not feel better or if you feel worse.

#### **2. What you need to know before you take Olbetam Capsules**

##### **Do not take Olbetam Capsules:**

- If you are allergic to acipimox or any of the other ingredients of this medicine (listed in section 6).
- If you have an ulcer affecting the stomach or gut.
- If you have a severe kidney problem. Your doctor will tell you if this is the case.

## **Warnings and precautions**

Talk to your doctor or pharmacist before taking Olbetam Capsules.

- This medicine is not effective for all lipid disorders.
- You should have made changes to your diet, alcohol intake and physical exercise before being given this medicine.
- This medicine is for long term use, blood tests should be performed before taking this medicine, and at regular intervals during treatment.
- Your kidney and liver functions should be monitored while you are taking this medicine.
- Tell your doctor if you are taking other medicines to reduce blood fat levels (see Other medicines and Olbetam).
- This medicine is not given to prevent heart disease.
- Your doctor will assess how well this medicine is working for you based on your response to it over time.
- Tell your doctor immediately if you have unexplained muscle pain, muscle tenderness or muscle weakness while you are taking this medicine.

## **Other medicines and Olbetam**

Tell your doctor if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

Please tell your doctor if you are taking any other lipid lowering agents. Although no interaction has been shown with other lipid lowering agents, caution should be taken if Olbetam Capsules are used in combination with statins (e.g. simvastatin) or fibrates (e.g. clofibrate).

The absorption of Olbetam Capsules is not affected by taking colestyramine (another lipid lowering agent) at the same time.

## **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.

## **Driving and using machines**

Olbetam does not affect the ability to drive and operate machines, however please consult your doctor if you wish to drive whilst taking Olbetam Capsules.

## **Olbetam contains sodium**

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

## **3. How to take Olbetam Capsules**

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

The usual dosage is one 250 mg capsule 2 or 3 times a day. This should be taken with or after main meals. The capsules should be swallowed with a glass of water.

If you have mild kidney problems you may need to take a lower dose and to take your tablets less often. The doctor will advise you how much to take and how often (usually one capsule 1 or 2 times a day).

## **If you take more Olbetam Capsules than you should**

If you accidentally take more than the recommended dose, your doctor should be contacted immediately.

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

If you forget to take your medicine, take it as soon as you remember. If it is nearly time for the next dose, take it at the usual time. **Do not take a double dose to make up for a forgotten dose.**

### **If you stop taking Olbetam Capsules**

Do not stop taking your medicine or alter the dose you are currently taking without seeing your doctor first.

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.

### **Please contact your doctor immediately if any of the following side effects occur:**

- Serious allergic reaction which causes difficulty in breathing (due to narrowing of the airways), swelling of the tongue, throat, face and / or neck. **These effects are uncommon.**
- Dilation of blood vessels in the skin causing a feeling of heat, flushing or itching, rash or redness. These reactions usually disappear quickly during the first day of treatment.

### **Other side effects may include:**

Very common: may affect more than 1 in 10 people

- Headache
- Flushing
- Indigestion

Common: may affect up to 1 in 10 people

- Stomach ache
- Weakness
- Hives

Uncommon: may affect up to 1 in 100 people

- Serious allergic reaction which causes difficulty in breathing or dizziness
- Difficulty in breathing or wheezing
- Nausea (feeling sick)
- Rash, itching, redness
- Inflammation of muscle tissue causing pain in the muscles and joints
- Feeling hot, malaise (generally not feeling well)

Not known: frequency cannot be estimated from the available data

- Eye problems including dry or gritty eye
- Vasodilatation (widening of the blood vessels)
- Diarrhoea

### **Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects via the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Olbetam Capsules**

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date printed on the carton or blister after EXP. The expiry date refers to the last day of that month.

Store below 30°C in the original carton to protect from moisture.

Do not throw away any medicines via wastewater or household waste. Ask your doctor or 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 Olbetam Capsules contains**

The active substance is acipimox. Each capsule contains 250 mg of acipimox.

The other ingredients are corn starch, silicon dioxide, magnesium stearate, sodium lauryl sulfate, gelatin, titanium dioxide (E171) and red and yellow iron oxides (E172).

### **What Olbetam Capsules look like and contents of the pack**

This medicine is a hard gelatin self-locking capsule, with a red-brown cap and dark pink body, containing a white to cream powder.

The capsules are available in blister packs (strips of 10) packed in cartons of 90 capsules.

### **Marketing Authorisation Holder**

Pfizer Limited, Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom

### **Manufacturer**

Pharmacia Italia SpA, Via Del Commercio, Zona Industriale, Ascoli Piceno, 63046, Italy.

### **Company Contact address**

For further information on your medicine contact Medical Information at Pfizer Limited, Walton Oaks, Tadworth, Surrey, UK, Tel: +44 1304 616161

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