

## Package leaflet: Information for the user

**<Invented name>**

Acarbose

**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 further questions, 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 side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

### **What is in this leaflet**

1. What **<Invented name>** is and what it is used for
2. What you need to know before you take **<Invented name>**
3. How to take **<Invented name>**
4. Possible side effects
5. How to store **<Invented name>**
6. Contents of the pack and other information

#### **1. What **<Invented name>** is and what it is used for**

Acarbose is used in the treatment of non-insulin dependent diabetes mellitus in patients inadequately controlled on diet alone, or on diet and oral hypoglycaemic agents.

This medicine has been prescribed for you by your doctor to treat your diabetes. Acarbose will help to control your blood sugar levels. This is because Acarbose works by slowing down the digestion of carbohydrates (complex sugars) from your diet, and this reduces the abnormally high blood sugar levels that occur after each meal.

#### **2. What you need to know before you take **<Invented name>****

##### **Do not take **<Invented name>****

- if you are allergic to acarbose or any of the other ingredients of this medicine (listed in section 6). If you are unsure about this ask your doctor.
- if you suffer from inflammation or ulceration of the bowel, e.g. ulcerative colitis or Crohn's disease.
- if you have, or are susceptible to, an obstruction in your intestines.
- if you have a liver disorder.
- if you have an intestinal disease whereby you do not digest or absorb food properly.
- if you have a large hernia or any other condition where increased gas in your intestine may make it worse.

If you have a kidney disorder do not take acarbose without consulting your doctor first.

If you are unsure whether you might have any of these conditions, please ask your doctor.

No modification of the normal adult dosage regimen is necessary for elderly patients.

Acarbose is not recommended for patients under 18 years of age.

### **Warnings and precautions**

Talk to your doctor or pharmacist before taking <Invented name>.

*Treating hypoglycaemic episodes ("hypos").* As a diabetic you may also be receiving other treatments for your diabetes.

- If you are taking insulin or sulphonylurea drugs to control your blood sugar, you will probably be used to avoiding hypoglycaemic episodes by taking sugar when you feel that your blood sugar level is too low.
- When taking acarbose do not treat a hypoglycaemic episode with ordinary sugar (sucrose). Instead take some glucose (also known as dextrose) tablets, syrup, or sweets which should be available from your local pharmacist. If you are pregnant or breastfeeding (see section on Pregnancy, breast-feeding and fertility below)

This medicine may affect the levels of certain proteins called enzymes in your blood. Your doctor may wish to see you more frequently in order to monitor the levels of these enzymes.

### **Other medicines and <Invented name>**

Acarbose may alter the effect of other drugs or, alternatively, some drugs may alter the effect of acarbose. If you are using any of the following drugs, speak to your doctor or pharmacist before taking this medicine:

- Drugs known as intestinal adsorbents, e.g. charcoal.
- Drugs to help your digestion (digestive enzyme preparations e.g. amylase, pancreatin).
- The antibiotic, neomycin.
- Colestyramine, a drug used to treat high cholesterol.
- Digoxin.

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

### **<Invented name> with food, drink and alcohol**

Acarbose tablets can be swallowed with a little liquid immediately before the meal.

### **Pregnancy, breast-feeding and fertility**

Acarbose is not recommended if you are pregnant or breastfeeding. 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**

Acarbose should not affect your ability to drive or operate machinery.

<Invented name> contains: microcrystalline cellulose, pregelatinised starch, colloidal anhydrous silica, and magnesium stearate.

### **3. How to take <Invented name>**

To gain the maximum benefit from Acarbose you should adhere to the diet prescribed for you by your doctor. This will also help in reducing any side-effects you may experience

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 recommended dose is one or two tablets taken with meals three times a day. However, when you first start your treatment, your doctor may recommend that you take your tablets once or twice a day before increasing your dose to three times a day. This medicine is intended for long-term use.

Acarbose tablets should be chewed with the first mouthful of food. If you prefer not to chew the tablets then swallow them whole with a little liquid **immediately before the meal**.

The scoreline is only there to help you break the tablet if you have difficulty swallowing it whole and not to divide into equal doses.

#### **If you take more <Invented name> than you should**

If you do exceed the prescribed dose, or in the event of an overdose, you may experience diarrhoea and other intestinal symptoms such as flatulence (wind) and abdominal pain.

If you take more than the prescribed dose, or in the event of an overdose, avoid the intake of carbohydrate-containing food or drinks and seek medical advice immediately. If possible, take your tablets or the pack with you to show the doctor.

#### **If you forget to take <Invented name>**

If you forget to take one or more doses of <Invented name> do not take the tablets between meals but, instead, wait until your next scheduled dose and meal and continue as before.

Do not take a double dose to make up for a forgotten tablet.

### **4. Possible side effects**

The frequency of the following effects is unknown and based on isolated reports: However, if you get any of these reactions, seek urgent medical attention.

- A decrease in the number of platelets in the blood (associated with rash, easy bruising or bleeding)
- Allergic reactions such as rash, redness of the skin, skin eruptions, itching
- Decrease in bowel activity (ileus associated with severe abdominal pain, vomiting and absence of gas or bowel motions)
- Inflammation of the liver (hepatitis associated with jaundice-yellowing of the skin and eyes)

Like all medicines, this medicine can cause side effects, although not everybody gets them. During the first few days or weeks of treatment with <Invented name> you may experience increased flatulence (wind), rumbling in your stomach, a feeling of fullness and possibly abdominal cramps. It is also possible that you may pass softer stools or even experience diarrhoea, particularly after a meal containing sugar or sucrose-containing foods. Normally, these symptoms will disappear if you continue treatment and keep to your prescribed diet

The following side effect occurred very commonly (in more than 1 in 10 patients) in clinical trials:

- Flatulence (wind)

The following side effects occurred commonly (in less than 1 in 10 patients but more than 1 per 100 patients) in clinical trials:

- Diarrhoea
- Stomach and abdominal pain

Normally, these symptoms will disappear if you continue treatment and keep to your prescribed diet.

The following side effects occurred uncommonly (in less than 1 in 100 patients but in more than 1 per 1000 patients) in clinical trials:

- Nausea
- Vomiting
- Indigestion
- Transient increase in liver enzymes
- Jaundice (yellowing of the skin)

Do not take indigestion (antacid) preparations for treating symptoms of abdominal pain, diarrhea, and flatulence as they are unlikely to have any beneficial effect. If your symptoms persist for more than 2 or 3 days, or if they are severe, consult your doctor, particularly in the case of diarrhoea.

These effects go away when treatment is stopped.

If you get any side effects, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet.

## **5. How to store <Invented name>**

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 blister and carton, after the EXP. The expiry date refers to the last day of that month.

Do not store above 30° C. Store in the original packaging 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 <Invented name> contains**

- The active substance is acarbose. Each tablet contains 100 mg of acarbose.
- The other ingredients are microcrystalline cellulose, pregelatinised starch, colloidal anhydrous silica, and magnesium stearate.

**What <Invented name> looks like and contents of the pack**

White, plane, round tablets, scored on one side.

The scoreline/breakline is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

Acarbose is available as 100 mg tablets in packages of 10, 20, 30, 40, 50, 60, 90, 120 and 270 tablets.

Not all pack sizes may be marketed.

### **Marketing Authorization Holder and Manufacturer:**

Marketing Authorization Holder:

**<To be completed nationally>**

Manufacturer:

West Pharma – Produções Especialidades Farmacêuticas, S.A.  
Rua João de Deus, nº 11, Venda Nova  
2700 - 486 Amadora  
Portugal

Atlantic Pharma – Produções Farmacêuticas, S.A.  
Rua da Tapada Grande, nº 2, Abrunheira  
2710-089 Sintra  
Portugal

**This medicinal product is authorised in the Member States of the EEA under the following names:**

United Kingdom: Acarbose 100 mg Tablets  
Ireland: Acarbose Tecnimede 100 mg Tablets  
Italy: Acarbose Tecnigen 100 mg compresse  
Poland: Symrose

**This leaflet was last revised in**