

Package Leaflet: Information for the user

Acarbose 100 mg Tablets

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 any 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. See section 4.

In this leaflet:

1. What Acarbose is and what it is used for
2. What you need to know before you take Acarbose
3. How to take Acarbose
4. Possible side effects
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6. Contents of and other information

1. What is Acarbose 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 hypoglycemic 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

Do not take Acarbose

- if you are allergic to acarbose or any of the other ingredients of this medicine (listed in section 6).
- 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 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 Acarbose

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

- If you are taking insulin or sulphonylureas 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 Pregnancy, and breast-feeding and fertility).

Other medicines and Acarbose

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.

Acarbose 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.

3. How to take Acarbose

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 50 mg tablet or two 50 mg tablets or one 100 mg tablet 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 Acarbose 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 Acarbose

If you forget to take one or more doses of Acarbose 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

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following side effects have been observed during treatment with acarbose.

Very Common side effects

(may affect more than 1 in 10 people)

- wind (*flatulence*)

Common side effects

(may affect up to 1 in 10 people)

- diarrhoea
- stomach or abdominal pain

Uncommon side effects

(may affect up to 1 in 100 people)

- feeling sick (*nausea*)
- being sick (*vomiting*)
- indigestion
- increase in liver enzymes (*transaminases*) in the blood

Rare side effects

(may affect up to 1 in 1,000 people)

- swelling
- yellowing of the whites of the eyes or skin (*jaundice*)

Other side effects

(Frequency not known: frequency cannot be estimated from the available data)

- a decrease in the number of blood cells necessary for clotting
- allergic reaction, such as rash, redness of the skin, skin eruptions, itching
- a decrease in bowel activity
- inflammation of the liver (*hepatitis*)
- gas pockets in the bowel (*pneumatosis cystoides intestinalis*)
- rash with pus filled pimples/blisters (*acute generalised exanthematous pustulosis*)

In addition, side effects like liver disorder, abnormal liver function and liver injury have been reported. Individual cases of a rapidly progressive and fatal form of liver injury have also been reported, particularly from Japan.

By not following with the prescribed diet, intestinal side effects (e.g. diarrhoea, flatulence) may intensify. In case you are complying with the prescribed diabetic diet and these side effects appear or get worse, you should contact your doctor.

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 Yellow Card Scheme at: 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 Acarbose

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 to protect the environment.

6. Contents of the pack and other information

What Acarbose 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 Acarbose looks like and contents of the pack

White or yellowish, circular, plain 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:

Morningside Healthcare Ltd
Unit C, Harcourt Way
Leicester, LE19 1WP, UK

Manufacturer:

Atlantic Pharma – Produções Farmacêuticas, S.A
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