

Package leaflet: Information for the patient
Acarbose 50 mg tablets
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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is 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
5. How to store Acarbose
6. Contents of the pack and other information

1. What Acarbose is and what it is used for

The active ingredient in this medicine is Acarbose. This medicine belongs to group medicines called glucosidase inhibitors.

Acarbose is used to treat non-insulin dependant diabetes.

It helps to control your blood sugar levels . It works by slowing down digestion carbohydrates complex sugars) which reduces the abnormally high blood sugar levels in your body after each meal.

Acarbose can be used to treat diabetes when a restricted diet alone or a restricted diet plus other sugar-lowering drugs do not work well enough.

2. What you need to know before you take Acarbose

Do not take Acarbose Tablets

- if you are allergic to acarbose or any of the other ingredients of this medicine (listed in section 6)
- if you are pregnant or breast-feeding
- if you have inflammation or ulceration in the bowel,for example ulcerative colitis or Crohn's disease
- if you have an obstruction in your intestines, or are likely to get this
- if you have a severe liver disorder
- if you have anintestinedisease where 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.

Do not take Acarbose if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Acarbose tablets

- If you have a kidney disorder tell your doctor before you take Acarbose
- Acarbose may affect the enzyme levels in your blood. Your doctor may want to do regular test to check this.

Other medicines and Acarbose

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

Some medicines affect the way acarbose works in the body. Other medicines are affected by acarbose.

- medicines called intestinal absorbants, such as charcoal
- medicines containing digestive enzyme that help digestion, such as amylase (amylase) and lipase
- neomycin, an antibiotic
- colestyramine, to treat high cholesterol • digoxin, to treat heart problems).
- other blood glucose lowering drugs (e.g. sulphonylureas, metformin, or insulin)

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy and breast-feeding

Do not take Acarbose if you are pregnant or 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

Acarbose is unlikely to affect your ability to drive or use machines.

3. How to take Acarbose

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

- Adults including old people: the usual dose is 1 or 2 tablets, three times a day
- Children and adolescents: Acarbose is not recommended.

- The treatment is for long-term use. Take the tablets for as long as your doctor has told you to.

To start treatment your doctor may recommend taking the tablets only once or twice a day. He or she will then increase your dose to three times a day. The maximum dose is 200 mg three times a day.

Food and drink with Acarbose

Take Acarbose with your meal. Chew the tablets with your first mouthful of food. If you prefer not to chew, swallow the tablets whole with a little liquid immediately before your meal.

Keep to the diet prescribed by your doctor. If distressing complaints develop in spite of strict adherence to your diet (see section 4), contact your doctor as your dose of Acarbose may need to be reduced.

Household sugar (cane sugar) and foods containing it can lead to severe abdominal discomfort and diarrhoea during treatment with Acarbose (see section 4).

Hypos and Acarbose

You may be used to taking ordinary sugar to treat a hypo. Do not take ordinary sugar (sucrose) if you take Acarbose. Take glucose (or dextrose) to treat a hypo. Glucose tablets, syrup or sweets are available from your pharmacist (chemist).

If you take more Acarbose than you should

Get medical help immediately. Do not take food or drinks containing carbohydrates. If possible take your tablets or the box with you to show the doctor.

If you forget to take Acarbose

If you forgot to take a dose of your medicine then do not take the missed dose between meals. Wait until your next scheduled dose and meal and continue taking your tablets as per normal. Do not take a double dose to make up for a forgotten tablet.

If you stop taking Acarbose

If you forget a dose, wait until the next mealtime and take your next dose. Do not take the missed dose. Do not take the tablets between meals.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

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.

Effects occurring in first 2 or 3 days

- increased wind (flatulence)
- rumbling in your stomach
- a feeling of fullness or abdominal cramps.

➔ Contact your doctor if these effects continue for more than 2 or 3 days, if they are severe, or particularly if you have diarrhoea.

Do not take indigestion preparations (antacids) as they are unlikely to help.

Very common (affects more than 1 user in 10):

- Wind (flatulence)

Common (affects 1 to 10 users in 100):

- Diarrhoea
- Stomach or abdominal pain

Uncommon (affects 1 to 10 users in 1,000):

- Feeling sick (nausea)
- Being sick (vomiting)
- Indigestion
- Increase in liver enzymes (transaminases), in the blood

Rare (affects 1 to 10 users in 10,000):

- Swelling
- Yellowing of the skin and whites of the eyes (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.

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 directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

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.

Store below 25°C.

Do not use this medicine after the expiry date which is stated on the outer carton after EXP. The expiry date refers to the last day of that month.

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 of Acarbose 100 mg tablets contains 100 mg of the active substance acarbose.

Each tablet of Acarbose 50 mg tablets contains 50 mg of the active substance acarbose.

- The other ingredients are: colloidal silicon dioxide, magnesium stearate, maize starch and microcrystalline cellulose.

What Acarbose looks like and contents of the pack

The tablets of 50 mg are white to white to yellowish, round, biconvex.

The tablets of 100 mg are white to yellowish, round, biconvex, with a score on one side. The score line is only there to help you break the tablet if you have difficulty swallowing it whole.

Acarbose Tablets 100 mg is available in packages of 90 tablets.

Acarbose Tablets 50 mg is available in packages of 90 tablets.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

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Manufacturer:

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For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder

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