

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 or pharmacist. 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

Acarbose contains the active substance acarbose, which belongs to a group of medicines called glucosidase inhibitors.

Acarbose is used in the treatment of non-insulin dependent (type II) diabetes mellitus in patients inadequately controlled on diet alone, or on diet and oral hypoglycaemic agents. Acarbose is for adults aged over 18 years. 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 Acarbose

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 are pregnant or breast-feeding
- if you suffer from inflammation or ulceration of 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 large hernia, or any other condition where increased gas in your intestine may make it worse
- if you have an intestinal disease where you do not digest or absorb food properly
- if you have severe kidney problems
- if you have a severe liver disorder.

If you have a kidney or liver 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.

Warnings and precautions

Treating hypoglycaemic episodes ('hypos')

As a diabetic you may also be receiving other treatments for your diabetes.

- If you are taking insulin, metformin or sulfonylureas (e.g. glimepiride, glipizide) 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 pharmacist.

Talk to your doctor or pharmacist before taking acarbose if you have any questions on the above.

This medicine may affect the level of certain proteins called enzymes in your blood which show how your liver is working. Your doctor may wish to see you more frequently in order to monitor the levels of these enzymes. Your doctor may decide to reduce the dose or stop treatment with Acarbose.

Other medicines and Acarbose

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Acarbose may alter the effect of other drugs, or alternatively, some drugs may alter the effect of acarbose:

In particular tell your doctor or pharmacist if you are taking:

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

Acarbose with food and drink

Keep to the diet prescribed by your doctor. If distressing stomach or digestive 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 cause abdominal discomfort or even diarrhoea due to carbohydrate-fermentation in the colon during treatment with acarbose.

You may notice side effects such as severe wind (flatulence) and diarrhoea if you have taken acarbose together with carbohydrate containing drinks or food. In this case, do not eat or drink carbohydrate containing drinks or food for 4 to 6 hours.

Pregnancy and breast-feeding

Do not take acarbose if you are pregnant or breastfeeding. If you think you might be pregnant or are planning to have a baby, tell your doctor 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 this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Adults (including over 65s):

The recommended initial dose is 50 mg, three times a day. To start treatment your doctor may recommend taking 50 mg only once or twice a day to help minimise side effects. Your doctor will then increase your dose to 50 mg, three times a day.

If after six to eight weeks treatment your medicine is not working as well as it should your doctor may increase your dose up to 100 mg, three times a day. The maximum dose is 200 mg, three times a day.

Use in children and adolescents:

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

Method of administration

Tablets are swallowed whole with a glass of water immediately before the meal or chewed with the first mouthful of food.

The score line on the 100 mg tablet is not intended for breaking the tablet.

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

If you take more Acarbose than you should

Go to your doctor or nearest hospital immediately. Take the container and any remaining tablets with you. If you have taken more tablets than you should do not take food or drinks containing carbohydrates for the next 4 to 6 hours. Symptoms of overdose may include: severe flatulence and diarrhoea.

If you forget to take Acarbose

Do not take a double dose to make up for a forgotten dose. Take the next dose with your next meal. Do not take the tablets between meals.

If you stop taking Acarbose

If you suddenly stop taking Acarbose your blood glucose level may rise. Speak to your doctor before stopping this medicine.

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.

Side effects which may occur in the first two or three days of treatment:

- increased wind (flatulence)
- rumbling in your stomach
- 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.

If you think you may have any of the following side effects, stop taking this medicine and contact your doctor or go to your nearest hospital emergency department immediately:

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

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

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

- inflammation of the liver (hepatitis). You may feel sick, notice yellowing of the skin and eyes, and have abdominal pain and swelling. Some cases of hepatitis with a fatal outcome have been reported, but it is not clear if this occurs as a result of taking acarbose.
- allergic reaction, such as rash, redness of the skin, skin eruptions, itching
- gas pockets in the bowel (Pneumatosis cystoides intestinalis). This will show up in a radiograph (e.g. CT scan, MRI).
- a decrease in bowel activity (e.g. severe constipation)

Other possible side effects

Very common (may affect more than 1 in 10 people):

- wind (flatulence).

Common (may affect up to 1 in 10 people):

- diarrhoea
- stomach or abdominal pain.

These side effects are likely to occur after a meal containing sugar (sucrose). Symptoms may be reduced by avoiding foods and drinks that contain sugar (sucrose, cane sugar). If your diarrhoea does not go away your doctor will need to reduce your dose or in some cases stop treatment. Do not take indigestion remedies to treat the above side effects as this can make the symptoms worse.

Uncommon (may affect up to 1 in 100 people):

- feeling sick (nausea)
- being sick (vomiting)
- indigestion (dyspepsia)
- increase in liver enzymes (transaminases) in the blood. This would show in blood tests.

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

- swelling (oedema).

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

- a decrease in the number of blood cells necessary for clotting (thrombocytopenia)
- rash with pus filled pimples/blisters (acute generalised exanthematous pustulosis)

In addition, events reported as liver disorder, abnormal liver function and liver injury have been received.

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. 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 carton and blister after ‘EXP’. The expiry date refers to the last day of that month.
- This medicine does not require any special temperature storage conditions. Store in the original package in order to protect from moisture.
- Do not use this medicine if you notice any discolouration.
- 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 Acarbose contains

- The active substance is acarbose. Each tablet contains either 50 mg or 100 mg of acarbose.
- The other ingredients are silica, colloidal anhydrous; maize starch; magnesium stearate; cellulose, microcrystalline.

What Acarbose looks like and contents of the pack

Your medicine comes as a white to off-white round tablet.

Acarbose 50 mg tablets are marked “A” over “50” on one side of the tablet and “M” on the other side.

Acarbose 100 mg tablets are marked “AB” (breakline) “100” on one side of the tablet and “M” on the other side.

Acarbose is available in blister packs of 90 and 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

McDermott Laboratories Ltd, T/A:
Gerard Laboratories
35/36 Baldoyle Industrial Estate,
Grange Road, Dublin 13, Ireland

Manufacturer

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

Ireland	Acarbose 50 mg Tablets Acarbose 100 mg Tablets
United Kingdom	Acarbose 50 mg Tablets Acarbose 100 mg Tablets

This leaflet was last revised in 07/2015.