

PACKAGE LEAFLET: INFORMATION FOR THE USER

P3514T

ACARBOSE 50mg & 100mg TABLETS

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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get any of the side effects, talk 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 Tablets are and what they are used for
2. What you need to know before you take Acarbose Tablets
3. How to take Acarbose Tablets
4. Possible side effects
5. How to store Acarbose Tablets
6. Contents of the pack and other information

1. What Acarbose Tablets are and what they are used for

Your medicine belongs to a group of oral medicines called “Alpha-glucosidase inhibitors” and is used in the management of Type II diabetes (diabetes that does not require treatment with insulin injections). It can be used alone or in combination with a sulphonyl urea and / or metformin.

Acarbose works in the small intestine, the active ingredient is practically not absorbed by the body.

If you have Type II diabetes then levels of sugar (glucose) in your blood are too high. Your medicine works by slowing down digestion and absorption of sugars/carbohydrates from your diet. This stops levels of blood sugar from rising too high.

Acarbose is used as an additional treatment in patients with diabetes mellitus in conjunction with diet.

During treatment you should also ensure that you follow the diet recommended by your doctor.

2. What you need to know before you take Acarbose Tablets**Do NOT take Acarbose Tablets:**

- if you are allergic (hypersensitive) to acarbose (the active ingredient in your medicine) or any of the other ingredients of this medicine (listed in section 6.)
- if you have chronic inflammatory bowel disease
- if you suffer from ulcers in your colon – e.g. Crohn’s Disease or Ulcerative colitis. Ask your doctor if unsure
- if you have or have previously suffered from an obstruction in your intestines (gut)
- if you suffer from any digestive disorders caused by ongoing problems with your intestines (gut). Ask your doctor if unsure
- if you have any condition which may be made worse by the formation of gas in your intestine. For example, if you have a large hernia, high diaphragm due to bloated intestines (Roemheld symptom complex), larger inguinal and diaphragmatic hernias, narrowing and ulcers of the intestine. Ask your doctor if unsure.
- if you have severe liver dysfunction (e.g. liver cirrhosis).
- if you have severe kidney problems. (Creatinine clearance less than 25ml/min).

Warnings and precautions**Talk to your doctor or pharmacist before taking Acarbose Tablets.**

Particular caution is required during the first 6-12 months of the treatment. Cases of sudden life-threatening hepatitis have been reported during treatment with Acarbose. If increases in liver enzyme levels are observed, a dose reduction or discontinuation of treatment may be necessary, particularly if the increases persist. Therefore, your doctor will consider regular monitoring of your liver enzymes during the first 6-12 months of treatment (see also section “4. What are the possible side effects?”).

You may experience low blood sugar levels if you take other anti-diabetic agents at the same time as acarbose, such as sulphonylureas, metformin or insulin. Tell your doctor if you are already taking medicines for the treatment of your diabetes. Low blood sugar levels can cause some of the following symptoms:

- double vision
- confusion
- slurred speech
- tiredness, faintness, rapid pulse, nervousness
- severe hunger, trembling, cold sweat
- palpitations (abnormal awareness of your own heartbeat).

If hypoglycemia progresses, you can suffer from severe confusion (delirium), develop cerebral seizures, lose self-control, have shallow breathing and a slow heartbeat and become unconscious (development into shock).

Low blood sugar is a potentially serious condition. If you experience any of the above symptoms then take some glucose to increase your levels of blood sugar back to normal. You will be able to buy glucose tablets, syrup or sweets at your local pharmacy. It is a good idea to carry some glucose with you at all times in case you need to use it. **Other sugars such as sucrose (table sugar/household sugar/ cane sugar or sweeteners) will not work because Acarbose Tablets prevents them from being absorbed.** Acarbose delays the metabolism of cane sugar. This is therefore not suitable for quickly resolving hypoglycemia.

If you have experienced the above symptoms then you should make an appointment to see your doctor for your medication to be reviewed.

Your doctor may decide to conduct blood tests to monitor your liver during treatment with Acarbose Tablets, particularly during the first 6 to 12 months of treatment.

During treatment with acarbose, you should continue to strictly follow the diet prescribed by your doctor and make sure that you consume carbohydrates regularly throughout the day. Please have it recorded on your diabetic card that you are taking Acarbose.

Children

As there is insufficient information on efficacy, tolerability and safety in patients under 18 years of age, Acarbose Tablets should not be administered in this age group.

Other medicines and Acarbose Tablets

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

Talk to your doctor if you are taking any of the following:

- charcoal and other intestinal adsorbents (used for treatment of poisoning or drug overdose)
- digestive enzyme preparations (e.g. pancreatin and amylase)
- neomycin (antibiotic used before bowel surgery)
- colestyramine (used for treating itchiness resulting from liver problems, high cholesterol or diarrhoea)
- digoxin (used for treatment of heart failure or heart rhythm problems) Acarbose can reduce the bioavailability of digoxin hence dose adjustment is necessary.
- thiazides or calcium channel blockers (used in the treatment of high blood pressure)
- corticosteroids (used to treat inflammation)
- phenytoin (used to treat epileptic fits)
- phenothiazine (used to treat mental health)
- thyroid medicines
- female sex hormone (oestrogens), oral contraceptives
- nicotinic acid (used to lower blood cholesterol)
- medicines called “sympathomimetics” such as epinephrine and norepinephrine: these may be used in the treatment of cardiac arrest, severe drop in blood pressure or premature labour
- isoniazid (used to treat tuberculosis)
- blood sugar lowering medicines (e.g. sulphonylureas, metformin or insulin), if the blood sugar levels drop too much, the sulphonylurea or metformin treatment may need to be stopped due to the risk of hypoglycemia.

Acarbose Tablets with food and drink

Your tablets should be swallowed whole immediately before a meal or chewed with the first mouthful of food. Your tablets should not be taken between meals.

Sucrose (cane sugar) and foods containing sucrose can cause abdominal discomfort or even diarrhoea due to carbohydrate-fermentation in the colon during treatment with Acarbose Tablets.

Pregnancy, breast-feeding and fertility

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.

420 mm

26.25 mm

50 mm

5

Product:	Acarbose 50mg & 100mg Tablets
Item Code:	P3514T
Size:	160 x 420 mm
Min. Point size:	9pt
O. Artwork:	06/08/25
Proof No.	4
Amendment Date	12/09/25

Colours Used	
	Process Black
	Keyline - Does not print

Acarbose Tablets are not recommended for use during pregnancy or breast-feeding as the effects on your baby are not known.

There are no data on the use of acarbose during pregnancy. Small amount of acarbose pass into the milk of lactating rats. Its not known whether acarbose is also excreted in the breast milk of women.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Acarbose Tablets do not affect your ability to drive or operate machinery if taken on their own. However, you may experience low blood sugar levels if you take other anti-diabetic agents at the same time, such as sulphonylureas or metformin. This may affect your ability to drive or operate machinery safely.

3. How to take Acarbose Tablets

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

The required dose will be determined by your doctor according to your personal requirements, as acarbose works and is tolerated differently from case to case.

Adults and elderly patients

The usual dose is 50mg three times a day before meals. However, your doctor may start you on a lower dose (e.g. 50mg once or twice a day) and increase your dose slowly to reduce the risk of side effects occurring.

If you require a larger dose your doctor may decide to increase your dose further to 100mg three times a day. Occasionally it may be necessary to increase the dose to 200mg three times a day.

If bothersome symptoms occur despite careful adherence to the diet (see section "4. What side effects are possible?"), your doctor should not increase the dose any further but may reduce it slightly.

Acarbose Tablets should be swallowed whole immediately before meals or chewed with the first mouthful of food.

Children and adolescents under 18 years

Use of Acarbose Tablets is not recommended.

If you take more Acarbose Tablets than you should

If you (or someone else) swallow a lot of the tablets all together, or if you think a child has swallowed any of the tablets, contact your nearest hospital casualty department or your doctor immediately. You should also not consume any carbohydrate containing food or drink. An overdose is likely to cause a swollen abdomen (resulting from the presence of excessive amounts of gas), flatulence (wind) and diarrhoea. If you have overdosed do not take it for the next time. Wait for 4-6 hours without carbohydrate-containing drinks and meals. Please take this leaflet, any remaining tablets and the container with you to the hospital or doctor so that they know which tablets were consumed.

If you forget to take Acarbose Tablets

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 Tablets

It is important to keep taking Acarbose Tablets according to your doctor's instructions to ensure that levels of blood sugars do not rise too high. Do not stop taking Acarbose Tablets without discussing it with 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.

Some of the side effects are serious.

The frequencies of the following side effects are unknown. However, if you suffer from any of these reactions you should seek urgent medical attention:

- Bleeding or bruising more easily than normal (caused by a reduction in blood platelets)
- Allergic reaction (rash, redness of the skin, skin eruptions, nettle rash)
- Partial or complete obstruction of the intestine leading to pain and vomiting
- Inflammation of the liver (may cause abdominal discomfort, jaundice, loss of appetite)
- Rash with pus filled pimples/blisters (acute generalised exanthematous pustulosis)

The following side effects have also been reported:

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

- Flatulence (wind).

Common (affects 1 to 10 users in 100):

- Diarrhoea
- Pain in the stomach or abdomen.

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

- Nausea
- Vomiting
- Indigestion
- Increase in liver enzymes, which may cause a change in blood test results that report on how the liver is working

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

- Fluid retention causing swelling of arms and legs
- Jaundice (yellowing of the skin and whites of the eyes).

Other possible side effects (frequency cannot be estimated from the available data):

- Gas pockets in the bowel, general, acute pustular rash, inflammation of liver (hepatitis), intestinal obstruction (subileus), complete intestinal obstruction (ileus), gas accumulation in the intestinal wall (pneumatosis cystoides intestinalis), thrombocytopenia, hypersensitivity reactions.

During treatment it is important to follow the diet that your doctor has recommended carefully. If you do not follow this diet some of the side effects described above such as flatulence (wind), diarrhoea and abdominal pain may be made worse.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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 Tablets

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

Do not store above 25°C. Store in the original packaging in order to protect from moisture.

Do not use this medicine after the expiry date which is stated on the outer packaging. 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 no longer use. These measures will help to protect the environment.

6. Contents of the pack and other Information

What Acarbose Tablets contain:

- The active ingredient is acarbose.
- Each Acarbose 50mg Tablet contains 50mg acarbose.
- Each Acarbose 100mg Tablet contains 100mg acarbose.
- The other ingredients are microcrystalline cellulose, pregelatinized maize starch, anhydrous colloidal silica and magnesium stearate.

What Acarbose Tablets look like and contents of the pack:

- Acarbose 50mg Tablets are white to off-white, round, biconvex tablet, with the sign "5" on one side and plain on other side.
- Acarbose 100mg Tablets are white to off-white, round, biconvex tablet, with the sign "1" on one side and scoreline on other side. The scoreline is only to facilitate breaking for ease of swallowing and not to divide into equal doses.
- Acarbose Tablets are available in pack sizes of 20, 21, 30, 40, 50, 60, 90, 100, 105, 120 and 270 tablets.

Marketing Authorisation Holder and Manufacturer

Crescent Pharma Ltd., Key House, Sarum Hill, Basingstoke, RG21 8SR, UK.

This leaflet was last revised on 09/2025.



PL 20416/0693

PL 20416/0694

P3514T

26.25 mm

Product:	Acarbose 50mg & 100mg Tablets
Item Code:	P3514T
Size:	160 x 420 mm
Min. Point size:	9pt
O. Artwork:	06/08/25
Proof No.	4
Amendment Date	12/09/25

Colours Used	
	Process Black
	Keyline - Does not print