

PACKAGE LEAFLET: INFORMATION FOR THE USER

Glucobay

50 & 100 mg Tablets

ACARBOSE

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • 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 •

What is in this leaflet?

1. What acarbose is and what it is used for
2. Before you take Glucobay Tablets
3. How to take Glucobay Tablets
4. Possible side effects
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1. WHAT ACARBOSE IS AND WHAT IT IS USED FOR

Acarbose belongs to a group of medicines called 'alpha glucosidase inhibitors' which are used to treat non-insulin dependent diabetes.

Acarbose works by controlling your blood sugar levels. This is achieved by slowing down the digestion of carbohydrates (complex sugars) in your food into simpler sugars and therefore reduces the high blood sugar levels which can occur after each meal.

Acarbose can be used to treat diabetes when a restricted diet alone or in combination with other sugar-lowering medicines does not work well enough.

2. BEFORE YOU TAKE GLUCOBAY TABLETS

Do not take Glucobay Tablets:

- if you are allergic (hypersensitive) to acarbose
- if you are allergic to any of the other ingredients in the tablets
- you are pregnant, likely to become pregnant or are breast-feeding
- you are suffering from inflammation or ulceration of the bowel e.g. ulcerative colitis or Crohn's disease

- you have or are susceptible to an obstruction in your intestines (gut)
- you have trouble digesting or absorbing food properly due to a problem with your gut
- you have a large hernia or any other condition where increased gas in your gut may make your condition worse
- you have liver disease
- you have severe kidney disease.

Take special care with Glucobay Tablets

As a diabetic you may also be receiving other treatments for your diabetes. If you are taking insulin or certain medicines (e.g. glibenclamide or chlorpropamide) to control your blood sugar, you will probably be used to avoiding hypoglycaemic episodes ('hypos') 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). You must instead take some glucose (also known as dextrose) in the form of tablets, syrup, or sweets which should be available from your local pharmacist.

Glucobay Tablets may also affect the levels of certain proteins called enzymes in your blood. Your doctor may wish to see you more often to monitor the levels of these enzymes particularly in the first year of your treatment.

Taking other medicines

Tell your doctor if you are already taking any of the following as they may interact with your medicine. Your doctor may therefore need to adjust the dose of acarbose or the other medicine:

- medicines known as 'intestinal adsorbents' such as charcoal, as these can reduce the effect of acarbose
- medicines to aid digestion containing digestive enzymes (e.g. amylase), as these can reduce the effect of acarbose
- neomycin (an antibiotic), as this can increase the side-effects acarbose can cause
- cholestyramine (used for the treatment of high cholesterol), as this can increase the effect of acarbose
- digoxin (used for the treatment of heart failure), as acarbose can alter its effect.

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

Taking Glucobay Tablets with food and drink

As you will be on a restricted diet, do not take food or drinks containing carbohydrates (including ordinary sugar (sucrose)) at the same time as your tablets as this can lead to diarrhoea, wind and stomach pain.

You should always follow your doctor's advice on your diet.

Pregnancy and breast-feeding

Do not take Glucobay Tablets if you are pregnant, think you may be pregnant or are breast-feeding. If you think you may have become pregnant whilst taking these tablets, you should contact your doctor as soon as possible.

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

3. HOW TO TAKE GLUCOBAY TABLETS

Always take Glucobay Tablets exactly as your doctor has told you.

You should check with your doctor or pharmacist if you are not sure.

It is important that you take your tablets at the start of a meal and not at any other time. They should preferably be chewed with the first mouthful of food. If you prefer not to chew your tablets they should be swallowed whole with a little liquid immediately before your meal.

Dosage:

The usual starting dose is one 50 mg tablet taken three times a day with meals. However at the start of the treatment your doctor may recommend that you take your tablets once or twice a day before increasing the dose to three times a day.

Six to eight weeks after the start of the treatment your doctor may decide to increase your dose depending on how the tablets are working. You should be aware that acarbose is intended for long-term treatment.

To gain the maximum benefit from your Glucobay Tablets you should adhere to the diet prescribed by your doctor. This should also help in reducing any side effects you may experience. If any distressing side effects develop in spite of strict adherence to your diet, contact your doctor as your dose of acarbose may need to be reduced.

Use in children:

Glucobay Tablets are not recommended for children and adolescents under the age of 18 years.

If you take more Glucobay Tablets than you should, you may suffer from flatulence (wind), stomach pain and diarrhoea especially if you take the tablets with food and drink containing carbohydrates. If you take too many tablets, you should contact your doctor immediately or go to the nearest casualty department. Remember to take the pack and any remaining tablets with you.

If you forget to take your Glucobay Tablets, simply take your next dose on time. Do not take the missed dose or a double dose to make up for the one you missed. Do not take the tablets between meals.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Glucobay Tablets can cause side effects, although not everybody gets them.

If you get any of the following side effects you should stop taking your tablets and tell your doctor immediately:

- swelling of the lips, face and tongue, difficulty in breathing, feeling faint, rash or itching (affecting the whole body)
- unusual bruising, nosebleeds or bleeding gums
- your skin or eyes start turning yellow or you have severe stomach ache.

The following side effects have been reported:

Very common side effects (probably affecting more than 1 in 10 people):

- flatulence (wind)*

Common side effects (probably affecting fewer than 1 in 10 people):

- diarrhoea*
- stomach pain*

Uncommon side effects (probably affecting fewer than 1 in 100 people):

- nausea and vomiting (feeling and being sick)*
- indigestion*
- increase in liver enzymes

Rare side effects (probably affecting fewer than 1 in 1,000 people):

- swelling
- jaundice (yellowing of the skin and eyes)

Other side effects (frequency unknown):

- a decrease in the number of blood cells needed for clotting (thrombocytopenia)
- inflammation of the liver (hepatitis)
- allergic reactions
- gas pockets in the bowel
- a decrease in bowel activity

* Do not take indigestion (antacid) preparations for the treatment of these symptoms as they have been shown to have no effect. If your symptoms persist for more than 2-3 days or if they are severe, please consult your doctor, especially in the case of diarrhoea.

In addition, side effects including liver disorder, abnormal liver function and liver injury have been reported. Individual cases of severe liver infection have also been reported, but it is not clear whether these are as a result of taking acarbose.

Blood tests have sometimes shown an increase in liver enzymes in patients taking acarbose. If you are having a test on your liver you should inform the doctor that you are taking acarbose.

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.

5. HOW TO STORE GLUCOBAY TABLETS

Keep out of the reach and sight of children.

Do not use Glucobay Tablets after the expiry date which is stated on the blister and carton after EXP:. The expiry date refers to the last day of that month.

Store in the original package in order to protect from light.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

This leaflet was last approved in 04/2011