Glucobay® 50mg tablets

Acarbose

85300873

Package leaflet - information for the user

Glucobay® 50mg tablets

Acarbose

Read all of this leaflet carefully before you start taking this medicine.

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

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1. What Glucobay is and what it is used for

Glucobay contains acarbose which belongs to a group of medicines called *glucosidase inhibitors*.

Glucobay is used to treat diabetes.

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

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

2. Before you take Glucobay

Do not take Glucobay:

- **If you are allergic** to the active ingredient (acarbose), or to any of the other ingredients. The ingredients are listed in section 6.
- **If you are pregnant or breastfeeding.**
- **If you have 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 an intestine disease** 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.
- **If you have severe liver impairment** (e.g. liver cirrhosis)
- **If you have severe renal impairment.**

→ **Tell your doctor** if any of these apply to you and **do not take Glucobay**.

- **The doctor will take special care:**

  If you are under 18

  If you have a kidney disorder

  If you have recently started to take Glucobay for diabetes.

→ **Tell your doctor before you take Glucobay** if any of these applies to you.

Glucobay may affect enzyme levels in your blood. Your doctor may want to test this regularly.

Other medicines and Glucobay

Tell your doctor about any other medicines that you are taking, or took recently. This includes any products you bought without a prescription. Some medicines affect the way Glucobay works in the body. Other medicines are affected by Glucobay.

Tell your doctor if you are taking:

- Medicines called intestinal adsorbants, such as **charcoal**.
- Medicines intended to reduce symptoms of indigestion caused by excess acid in the stomach.
- Medicines containing digestive enzymes that help digestion such as **amylase, pancreatin** and **lipase**.
- **Neomycin**, an antibiotic.
- **Colestyramine**, to treat high cholesterol.
- **Digoxin**, to treat heart problems.
- **Other drugs for diabetes**

Food and drink with Glucobay

Keep to the diet prescribed by your doctor. This will help the tablets to work better and reduce any side effects you might get.

Sucrose (cane sugar) and foods containing it often cause abdominal discomfort or even diarrhoea during treatment with Glucobay (see 'Side effects')

Hypoglycaemic Episodes and Glucobay

If you use other medicines for diabetes, such as insulin or sulphonylurea drugs, you may be used to taking ordinary sugar to treat a hypoglycaemic episode.

→ **Do not take ordinary sugar** *(sucrose)* to treat a hypoglycaemic episode if you take Glucobay.

Take glucose or dextrose to treat a hypoglycaemic episode. Glucose tablets, syrup or sweets are available from your pharmacist *(chemist).*

Pregnancy and breastfeeding

Do not take Glucobay if you are pregnant or breastfeeding. If you think you might be pregnant or are planning a family, tell your doctor before taking Glucobay.

Driving and using machines

It is unknown if taking Glucobay affects your ability to drive or operate machinery.

3. How you take Glucobay

Take Glucobay as prescribed by your doctor

- **The usual dose is** 1 or 2 tablets, three times a day
- **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.

Take Glucobay 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.

If you take too many tablets

→ **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.

Taking too much Glucobay may cause diarrhoea, wind *(flatulence)* and abdominal pain.

If you forget to take the tablets

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.

Children and adolescents under 18 years of age: Not recommended.

4. Possible side effects

Like all medicines, Glucobay can cause side effects, although not everybody gets them. The following side effects have been observed during treatment with Glucobay.

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 side effects

(*These may affect more than 1 in 10 people)*

- wind *(flatulence)*

Common side effects

(These may affect up to 1 in 10 people)

- diarrhoea
- stomach or abdominal pain

Uncommon side effects

(These may affect up to 1 in 100 people)

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

Rare side effects

(These 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)

- 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)*
- the condition known as pneumatosis cystoidis intestinalis, in which there is gas in the bowel wall

Individual cases of severe liver infection with fatal outcome have been reported in 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 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 Glucobay

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

Do not store above 25ºC and keep in a dry place.

Store in the original carton.

Do not use after the expiry date which is marked on both the outer container and on each blister strip of tablets.

Do not dispose of medicines in waste water or household rubbish. Any unused Glucobay tablets should be returned to a pharmacist *(chemist)* who will dispose of them properly. This helps the environment.

6. Further information

What Glucobay 50 contains

Glucobay Tablets contain the active ingredient, acarbose.

Glucobay tablets also contain maize starch, cellulose, magnesium stearate and colloidal anhydrous silica.

What's in the pack

Each tablet contains 50 mg acarbose.

Each pack contains 90 tablets.

What Glucobay 50mg tablets look like?

White to yellow-tinged round, convex tablets. On one side the tablet code is 'G' and '50'and on the other side 'Bayer Cross'.

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This leaflet was last revised: February 2017

Product Authorisation Number: PA1410/29/1

Bayer