

For application with adults

Please read the entire package leaflet carefully before taking the medicine.

-Keep this package leaflet. You may wish to read it again at a later date.

-If you have any further questions, please consult your doctor or pharmacist.

-This medicine has been prescribed to you personally. It should not be given to third parties. It could cause injury to other people, even if they have the same complaints that you do.

-Please inform your doctor or pharmacist if one of the side effects listed is considerably inhibiting for you or if you notice other side effects that are not specified in this package leaflet.



Glucobay® 50 mg

tablets

Active substance: Acarbose

1. What Glucobay 50 mg is and what it is used for

2. Before you take Glucobay 50 mg

3. How to take Glucobay 50 mg

4. Possible side effects

5. How to store Glucobay 50 mg

6. Further information

1. WHAT GLUCOBAY 50 mg IS AND WHAT IT IS USED FOR

Glucobay 50 mg belongs to a group of drug products used to treat diabetes (α -glucosidase inhibitor). The active substance of Glucobay 50 mg is produced biologically. Its main site of action is the small intestine. Almost none of the active substance is absorbed by the body: Glucobay 50 mg delays the digestion of carbohydrates. This slows down the release of glucose from carbohydrates and its absorption into the bloodstream. In this way, Glucobay 50 mg reduces the increase in blood glucose after meals. Due to the controlling effect on glucose uptake from the intestine, fluctuations in blood glucose over the day are reduced and blood glucose concentrations are lowered. Glucobay 50 mg is used as a supplement to dietary therapy in patients with diabetes mellitus.

2. BEFORE YOU TAKE Glucobay 50 mg

Do NOT take Glucobay 50 mg:

- If you are allergic (hypersensitive) to acarbose and/or any of the other ingredients of Glucobay 50 mg,

- If you suffer from chronic intestinal disorders associated with distinct disturbances of digestion and of the uptake of nutrients into the blood (impaired resorption),

- If you suffer from conditions which can worsen as a result of gas build-up in the intestine (e.g. elevation of the diaphragm due to intestinal distension (Roerheid's syndrome), serious inguinal and diaphragmatic hernias, intestinal obstructions and intestinal ulcers),

- If you have a severe kidney disorder (creatinine clearance below 25 ml/min).

Take special care with Glucobay 50 mg:

- During the first 6 - 12 months of treatment.

- Very rarely, an increase in the liver enzymes in the blood may occur during treatment with Glucobay 50 mg, without however you experiencing any complaints. Therefore, your doctor will check your liver enzymes at regular intervals during the first 6 - 12 months of treatment. In the cases reported, the increase in liver enzymes subsided after treatment with Glucobay 50 mg was discontinued (see also "Side effects").

- If acute symptoms of hypoglycaemia develop (such as rapid pulse, perspiration, trembling). You must take glucose and not sucrose (cane sugar) to relieve the problem (see also "Interactions with other drugs").

Even if you are taking Glucobay 50 mg, it is still vital for you to keep strictly to your prescribed diet.

Treatment with Glucobay 50 mg must be recorded on your diabetes card.

Children and adolescents

The efficacy and safety of acarbose have not been investigated in patients aged below 18.

Taking other medicines:

Please inform your doctor or pharmacist if you are taking other medicines or have taken other medicines recently, even if they are non-prescription medicines.

Acute episodes of hypoglycaemia are not likely to occur if you are being treated solely with Glucobay 50 mg and diet. If Glucobay 50 mg is prescribed in addition to other blood-glucose reducing treatment with sulphonylureas or metformin tablets or with insulin, the doses of these tablets or of insulin must be suitably reduced to prevent hypoglycaemia. In isolated cases, shock can occur as a result of hypoglycaemia. If acute hypoglycaemia develops, remember that sucrose (cane sugar) is digested and absorbed more slowly during treatment with Glucobay 50 mg. This means that hypoglycaemia can be corrected rapidly only with glucose and not with sucrose (cane sugar).

In isolated cases, acarbose may affect the bioavailability of digoxin (an active substance used mainly to treat heart failure); the dosage of digoxin may have to be adjusted.

Do not take the following medicines at the same time as Glucobay 50 mg because they may weaken its effect:

- cholestyramine (a drug which lowers elevated blood cholesterol),

- charcoal products and other intestinal adsorbents,

- substances that promote digestion (digestive enzyme products).

The simultaneous administration of neomycin (an antibiotic) and Glucobay 50 mg can lead to an increased lowering of blood glucose after meals and to an enhanced frequency and severity of gastrointestinal side effects. If the symptoms are severe, talk to your doctor; he may consider a temporary dose reduction of Glucobay 50 mg.

Taking Glucobay 50 mg with food and drink

Sucrose (cane sugar) and foods containing it can easily lead to severe abdominal discomfort and diarrhoea during treatment with Glucobay 50 mg (see "Side effects").

Pregnancy and breast-feeding

Do not take Glucobay 50 mg at any stage during pregnancy because no experience has been gained regarding its safety in pregnant women.

Do not use Glucobay 50 mg while breast-feeding.

Driving and operating machinery

Monotherapy with Glucobay 50 mg does not cause hypoglycaemia and therefore will not affect your ability to drive or operate machinery. Combination treatment with other blood-glucose-reducing drug products (metformin, sulphonylureas, insulin) could negatively affect your ability to drive or operate machinery by potentially leading to hypoglycaemia.

3. HOW TO TAKE Glucobay 50 mg

Always take Glucobay 50 mg precisely in accordance with your doctor's instructions. Please consult your doctor or pharmacist if you are not completely sure how to use this medicine.

Your doctor will decide how much Glucobay 50 mg you need to take depending on your personal requirements because Glucobay 50 mg works differently in different people, and not everyone tolerates it the same way.

Unless otherwise prescribed by your doctor, the usual dose is:

3x 1 Glucobay 50 mg tablet daily

(equivalent to 150 mg acarbose per day).

In some patients, a gradual increase in the dosage has helped to reduce gastrointestinal side effects, starting with:

1x to 2x 1 Glucobay 50 mg tablet daily

(equivalent to 50 to 100 mg acarbose per day).

The doctor will increase the dose gradually depending on your blood glucose level, and also as treatment progresses if it is not effective enough, up to:

3x 2 Glucobay 50 mg tablet daily

(equivalent to 300 mg acarbose per day).

Tablets containing 100 mg of the active ingredient are also available.

If distressing complaints develop in spite of strict adherence to your diet (see "Side effects"), the dose should not be increased further, and if necessary should be slightly reduced.

How and when should you take Glucobay 50 mg?

Glucobay 50 mg tablets should be taken with the first mouthful of food in order to achieve the maximum effect.

Therefore, swallow the tablets without chewing them, but with a little liquid, immediately before

meals or with the first mouthful of food.

Note:

If your doctor has prescribed other antidiabetic drugs in addition to Glucobay 50 mg, take these drugs as well. You should never discontinue any medication or change the dosage on your own without first consulting your doctor.

For how long should you take Glucobay 50 mg?

Your doctor will decide how long you should take Glucobay 50 mg. The length of treatment depends on the severity and course of your illness.

Please consult your doctor or pharmacist if you have the impression that the effects of Glucobay 50 mg are too strong or too weak.

If you have taken more Glucobay 50 mg than you should:

If you do exceed the prescribed dose, you may experience severe flatulence (wind) and diarrhoea when Glucobay 50 mg is taken with beverages and/or meals containing carbohydrates. Overdose without taking any food is unlikely to cause extreme gastrointestinal complaints.

If you have taken too much Glucobay 50 mg, it is important to avoid food and drink containing carbohydrates for the next 4 - 6 hours.

If you have forgotten to take Glucobay 50 mg:

If you forget to take one or more doses of Glucobay 50 mg, do not take the tablets between meals but, instead, wait until your next scheduled dose and meal and continue as before.

Effects of discontinuing treatment

If you want to interrupt treatment with Glucobay 50 mg or stop it early (because you are experiencing side effects, for example) please do not fail to talk to your doctor before doing so.

If you stop taking Glucobay 50 mg without consulting your doctor, this may lead to a distinct increase in your blood glucose concentration.

Consult your physician or pharmacist if you have any further questions regarding the application of this drug.

4. POSSIBLE SIDE EFFECTS

As is the case with all drugs, Glucobay 50 mg could cause side effects, although these need not be experienced by every patient. The following categories are used as the basis for establishing the frequency data for side effects:

Very common:	Affects more than 1 in 10 users
Common:	Affects less than 1 in 10 but more than 1 in 100 users
Uncommon:	Affects less than 1 in 100 but more than 1 in 1,000 users
Rare:	Affects less than 1 in 1,000 but more than 1 in 10,000 users
Very rare:	Affects less than 1 in 10,000 users
Unknown:	Side effects where frequency is not known

Possible side effects

Blood and lymphatic system

Unknown: Reduced levels of blood platelets (thrombocytopenia)

Immune system

Unknown: Allergic reactions (reddening, skin rash and nettle rash)

Blood vessels

Rare: Oedema (accumulation of fluid, particularly in the legs)

Gastrointestinal tract

Very common: Flatulence, abdominal noise

Common: Diarrhoea, abdominal pain

Uncommon: Nausea, vomiting, digestive disorders

Unknown: Incomplete obstruction of the intestines (subileus), complete obstruction of the intestines (ileus), gas in the bowel wall (Pneumatosis cystoides intestinalis), inflammation of the liver (hepatitis)

Liver and gallbladder

Uncommon: Elevated liver enzymes

Rare: Jaundice

Unknown: Inflammation of the liver (hepatitis)

Countermeasures

These gastrointestinal side effects may be especially intensified if you do not follow the prescribed diabetic diet. If you experience severe pain despite following the prescribed diet precisely, please consult your doctor. In such cases, your doctor may consider temporarily or permanently reducing the dose.

The gastrointestinal complaints may be severe and pronounced. In such cases please consult your doctor who will decide whether treatment with Glucobay 50 mg should be continued. Please inform your doctor or pharmacist if one of the side effects listed is considerably inhibiting for you or if you notice other side effects that are not specified in this package leaflet.

5. HOW TO STORE Glucobay 50 mg

Keep medicines out of the reach of children.

Do not use the drug after the expiration date specified on the outer packaging with "Use before".

The expiration date refers to the last day of the respective month.

No special precautions for storage are required for this drug.

- Not to be stored above 30°C - 86°F

Do not remove the tablets from the foil until immediately before use.

6. FURTHER INFORMATION

What Glucobay 50 mg contains:

- The pharmaceutically active substance is acarbose.

- One 50 mg tablet contains 50 mg acarbose.

- The other ingredients are microcrystalline cellulose, magnesium stearate (Pharm. Eur.), maize starch, colloidal silicone dioxide.

What Glucobay 50 mg looks like and contents of the pack:

Glucobay 50 mg are white to yellow-tinged round, convex tablets of 7 mm diameter and 10 mm radius of curvature. On one side the tablet code is "G" and "50" and on the other side "Bayer cross".

Glucobay 50 mg is available in original pack sizes with 30 tablets

Manufacturer

Bayer Schering Pharma AG

Operations: 51368 Leverkusen

This package leaflet was last revised in 12/2009.

This is a medicament

- A medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.

- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.

- The doctor and the pharmacist are experts in medicine, its benefits and risks.

- Do not by yourself interrupt the period of treatment prescribed.

- Do not repeat the same prescription without consulting your doctor.

- Keep medicament out of reach of children

Council of Arab Health Ministers

Bayer Schering Pharma AG, Germany

Union of Arab Pharmacists

Bayer