



Glucobay®

active ingredient: acarbose

Composition

Pharmacologically active constituents

1 tablet of Glucobay 50 contains 50 mg acarbose.

1 tablet of Glucobay 100 contains 100 mg acarbose.

Other constituents

Microcrystalline cellulose, colloidal silicon dioxide, magnesium stearate, maize starch

Presentation and properties

Packs of 30 tablets.

The active ingredient of Glucobay is produced biologically. Its main site of action is the intestine and its absorption is virtually zero. Glucobay delays the digestion of carbohydrates. This slows down the release of glucose from carbohydrates and its absorption into the bloodstream. In this way Glucobay reduces the postprandial increase in blood glucose. Due to the evening-out effect on glucose uptake from the intestine, fluctuations in blood glucose over the day are reduced and blood glucose concentrations are lower (antidiabetic for oral administration: α -glucosidase inhibitor).

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Indications

Supplement to dietary therapy in patients with diabetes mellitus.

Contraindications

When must Glucobay not be used?

Glucobay must not be used in:

- hypersensitivity to acarbose and/or the other constituents
- chronic intestinal disorders associated with distinct disturbances of digestion and of the uptake of nutrients into the blood (absorption disturbances)
- conditions which can worsen as a result of gas build-up in the intestine (e.g. elevation of the diaphragm due to intestinal distension [Roerhield's symptom complex], major inguinal and diaphragmatic hernias, intestinal obstructions, and intestinal ulcers)
- severe renal impairment (creatinine clearance < 25 ml/min).

Glucobay must not be taken during pregnancy and breastfeeding.

Since there is as yet inadequate information available on its effects and tolerability in children and adolescents, Glucobay must not be taken by patients under 18 years of age.

What must you do during pregnancy and breastfeeding?

Glucobay must not be taken during pregnancy, since no information is available on its use in pregnant women.

In principle it is also advisable not to take Glucobay during the breastfeeding period.

Safety measures and warnings

What safety measures should be observed?

If Glucobay is taken in a daily dose of 600 mg acarbose for longer than 6 months your doctor should carry out regular checks on the liver enzymes in your blood (see also "Side effects").

Strict adherence to the prescribed diet is also imperative when taking Glucobay. Treatment with Glucobay must be recorded on your diabetes card. Should acute episodes of hypoglycaemia (such as rapid pulse, perspiration, trembling) develop, glucose, **not** household sugar (cane sugar), **must** be taken (see also "Interactions with other drugs").

Interactions with other drugs

What drugs affect the action of Glucobay and what drugs are affected by Glucobay?

Please note that this information may also apply to drugs used recently.

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

Acute episodes of hypoglycaemia are not to be expected when you are treated solely with Glucobay and diet. If Glucobay is prescribed in addition to other blood-glucose reducing treatment with sulfonylureas or metformin tablets or with insulin, the doses of these tablets or of insulin must be suitably reduced in the event of an excessive fall in blood glucose into the hypoglycaemic region. If acute hypoglycaemia develops, it should be borne in mind that household sugar (cane sugar) is digested and absorbed more slowly during treatment with Glucobay. Glucose should therefore be used in place of household sugar (cane sugar) for a rapid alleviation of hypoglycaemia.

Because they may possibly impair the action of Glucobay, the simultaneous administration of the following drugs must be avoided:

- antacids (drugs to relieve hyperacidity and heartburn),
- cholestyramine (a drug which lowers elevated blood cholesterol),
- charcoal products and other intestinal adsorbents,
- substances that promote digestion (digestive enzyme products).

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Dosage, nature and duration of use

Unless Glucobay has been otherwise prescribed by your doctor, the following information applies. Please follow the instructions for use, otherwise Glucobay may not have the desired effect.

How much Glucobay and how often?

The dosage must be decided by your doctor in accordance with your own personal requirements, since the efficacy and tolerability of Glucobay vary from one patient to another.

Treatment should begin with:

3 x 1 tablet of Glucobay 50/day

or

3 x ½ tablet of Glucobay 100/day (corresponding to 150 mg acarbose/day).

The doctor will increase the dose gradually depending on the blood glucose level, and also in the later course of treatment if it is ineffective, up to

3 x 2 tablets of Glucobay 50/day

or

3 x 1 tablet of Glucobay/day (corresponding to 300 mg acarbose/day).

In rare cases the dose may be increased further up to

3 x 2 tablets of Glucobay 100/day (corresponding to 600 mg acarbose/day) if necessary.

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

How and when should Glucobay be used?

Glucobay is effective only if taken at mealtimes. Swallow the tablets whole with a little liquid immediately before meals or with the first mouthful.

Note

If your doctor has prescribed other antidiabetic drugs in addition to Glucobay, you must take these drugs as well. You should never discontinue any drug or change the dosage without consulting your doctor.

How long should Glucobay be used?

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

Incorrect use and overdose

What should be done if too much Glucobay has been taken (intentional or accidental overdose)?

Severe flatulence and diarrhoea may be the results of overdose when Glucobay is taken together with drinks and/or food containing carbohydrates. In the event of overdose without food extreme gastrointestinal complaints are not to be expected.

If you have taken too much Glucobay you must in all events avoid drinks and food containing carbohydrates for the next 4-6 hours.

What must you do if you do not take enough Glucobay or miss a dose?

Do not increase the next dose, but continue the treatment as prescribed.

What must be done if you wish to interrupt or prematurely discontinue the treatment?

If, for example, side effects occur and you wish to interrupt or discontinue treatment with Glucobay on your own accord, you must always inform your doctor before you do so. If you stop taking Glucobay without consulting your doctor, this may lead to a distinct increase in blood glucose. See also "Dosage, nature and duration of use".

Side effects

What side effects can occur when taking Glucobay, and what countermeasures are necessary?

If you experience any side effects not mentioned here, please inform your doctor or pharmacist.

Frequently flatulence and abdominal sounds and occasionally diarrhoea and abdominal pain may occur. These side effects may be intensified if the diabetic diet prescribed is not observed.

If highly distressing complaints develop in spite of adherence to the prescribed diet, you must inform your doctor who may consider temporarily or permanently reducing the dose.

There have been isolated cases of hypersensitivity reactions (e.g. redness, skin rash, and urticaria). You must inform your doctor at once if you experience any of these reactions. An increase in liver enzymes in the blood may occur after treatment with Glucobay. However, so far there have been only isolated reports of clinically significant side effects of this type, which have occurred at doses of 600 mg acarbose/day and above. These effects subside completely after termination of treatment with Glucobay. You should allow your doctor to check your liver enzymes regularly if you are taking doses of this magnitude for more than 6 months.

Information on storage stability of the medicine

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

The expiry date of this drug is printed on the box. Do not use this drug after the expiry date.

Keep Glucobay out of the reach of children.

Information status

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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 the doctor.

Keep medicament out of reach of children.