

GARBOSE® TABLET

Ingredient(s):

Garbose Tablet 50mg

Each tablet contains:

Acarbose 50mg

Garbose Tablet 100mg

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Acarbose 100mg

Pharmacodynamics:

Acarbose, as α -glucosidase inhibitor, can inhibit intestinal α -glucosidase (especially sucrase) involved in the degradation of disaccharides, oligosaccharides and polysaccharides. This will lead to a dose- dependent delay in digestion and absorption of these carbohydrates in the small intestines and thus lowering postprandial glucose concentrations. Fluctuations in the daily blood glucose profile are also reduced. Acarbose has no stimulatory action on the pancreas.

Pharmacokinetics:

Following oral administration of acarbose, the majority of active unchanged drug remains in the lumen of the gastro-intestinal tract to exert its pharmacological activity and is metabolized by the microbial flora. Ultimately about 35% of a dose is absorbed in the form of metabolites. Acarbose is excreted in the urine and faeces.

Indication(s):

Additional therapy in association with diet in patients with diabetes mellitus.

Dosage and Administration:

The dosage must be adjusted by the doctor to suit each patient, because efficacy and tolerability vary from one individual to another. Unless otherwise prescribed the recommended dosage is as follow:

Initially: 3 times, 1 tablet of 50mg acarbose/day or 3 times, ½ tablet of 100mg acarbose/day. Up to 3 times, 2 tablets of 50mg acarbose/day or 3 times, 1 tablet of 100mg acarbose/day.

A further increase in dosage to 3 times, 200mg acarbose/day may occasionally be necessary. The dose may be increased after 4-8 weeks, and if patients show an inadequate clinical response in the later course of the treatment.

If distressing complaints develop in spite of strict adherence to the diet, the dose should not be increased further, and if necessary should be somewhat reduced. The average dose is 300mg acarbose/day (corresponding to 3 times, 2 tablets of Garbose tablet 50mg/day or 3 times, 1 tablet of Garbose tablet 100mg/day).

Elderly (above 65 years): No alteration of dosage or dosing frequency is recommended with regard to the age of the patients.

Hepatic impairment: No dose adjustment is required in patients with pre-existing impaired hepatic function.

Duration of use: It is not envisaged that there will be any time restriction in the use of Garbose tablets.

Method and frequency of administration: To be swallowed whole with a little liquid directly before meal or be chewed with the first few mouthfuls of the meal.

For oral use only.

Instruction for use / handling:

At higher temperatures and/or higher relative humidity, discoloration can occur in tablets that are not in the pack. The tablets should therefore only be removed from the foil immediately prior to use.

Precaution(s) / Warning(s):

Hypoglycaemia: Acarbose does not cause hypoglycaemia when used alone. However, it may potentiate the hypoglycaemic effects of insulin and sulphonylurea drugs, and the dosage of these agents may need to be modified. If hypoglycaemia occurs, it is essential that glucose, not sucrose, should be taken as acarbose will delay the digestion and absorption of disaccharides, but not monosaccharides.

Transaminases: At higher dose, acarbose may cause asymptomatic elevations of serum hepatic transaminases. Liver enzymes should be monitored during the first six to 12 months of treatment. Reduction of dose or even withdrawal of therapy may be warranted, if the elevation persists.

Bloating: Antacids containing magnesium and aluminium salts do not help in reduce the acute gastrointestinal symptoms of acarbose in higher dosage.

Lifestyle: Patients should be advised that strict adherence to diabetic diet and exercise regularly are still necessary when taking acarbose.

Compliance: Regular ingestion of acarbose tablet should not be interrupted without consulting a doctor, as blood glucose level may rise.

Interaction with Other Medicaments:

Sucrose and sucrose containing foods: Abdominal discomfort and even diarrhea as a result of increased carbohydrates fermentation in the colon.

Hypoglycaemic agents: Hypoglycaemia may occur as acarbose may potentiates hypoglycaemic effects of other hypoglycaemic agents.

Intestinal absorbents and digestive enzymes products: May reduce the effects of acarbose and should not be administered concomitantly.

Neomycin: May enhance reduction of postprandial blood glucose and increase severity of gastro-intestinal side effects. Temporary dose reduction of acarbose is recommended.

Cholestyramine: May enhance effect of acarbose, concomitant administration should be avoided.

Digoxin: Digoxin bioavailability may be affected. Serum digoxin level monitoring should be considered.

Pregnancy and Lactation

Acarbose tablet is contra-indicated in pregnant women and nursing mothers.

Side Effect(s) / Adverse Reaction(s):

Very common: flatulence

Common: diarrhea, gastrointestinal pain

Uncommon: nausea, vomiting, dyspepsia, transient increase in liver enzymes

Rare: oedema

Frequency unknown: thrombocytopenia, allergic reaction, subileus / ileus, hepatitis
Intestinal side effects may be intensified if prescribed diabetic diet is not observed.

Contraindications:

Hypersensitivity to acarbose or other ingredients in the formula.

Pregnant women, breastfeeding mother, children under 18 years old.

Chronic intestinal disorders associated with distinct disturbances of digestion and absorption, inflammatory bowel disease, colonic ulceration, partial intestinal obstruction or patients predisposed to it, conditions which may deteriorate as a result of increased gas formation (e.g. major hernia, Roemheld's Syndrome).

Hepatic impairment, severe renal impairment (creatinine clearance < 25ml/min).

Symptoms and Treatment for Overdosage, and Anti-Dote:

When Garbose tablets are taken with drinks and/or meals containing carbohydrates (polysaccharides, oligosaccharides, or disaccharides), overdosage can lead to meteorism, flatulence, and diarrhea. In the event of acarbose tablets being taken in an overdose independently of food, excessive intestinal symptoms need not be anticipated. In cases of overdosage the patient should not be given drinks or meals containing carbohydrates (polysaccharides, oligosaccharides, and disaccharides) for next 4-6 hours.

Shelf-Life:

3 years from the manufacture date.

Storage Condition(s):

Store at temperature below 30°C. Protect from light and moisture.

Product Description and Packing(s):

Garbose Tablet 50mg

A white to yellowish white color round tablet, one side is impressed with a score in the middle, 'G' on the top and '50' on the bottom. "



Blister packing of 10's x 10, 10's x 20, 10's x 50 and 10's x 100.

Garbose Tablet 100mg

A white to yellowish white color round tablet, one side is impressed with a score in the middle, 'G' on the top and '100' on the bottom. "



Blister packing of 10's x 10, 10's x 20, 10's x 50 and 10's x 100.



Manufacturer and Product Registration Holder:
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