

# Acarbose Tablets IP

## Hibose

### Composition:

Each uncoated tablet contains:  
Acarbose IP.....25mg  
Excipients.....q.s.

### Composition:

Each uncoated tablet contains:  
Acarbose IP.....50mg  
Excipients.....q.s.

### Indications:

Acarbose Tablets are recommended for the treatment of non-insulin dependent (NIDDM) diabetes mellitus in patients inadequately controlled on diet alone, or on diet and oral hypoglycaemic agents.

### Posology and method of administration:

Acarbose Tablets are administered orally and should be chewed with the first mouthful of food, or swallowed whole with a little liquid directly before the meal. Owing to the great individual variation of glucosidase activity in the intestinal mucosa, there is no fixed dosage regimen, and patients should be treated according to clinical response and tolerance of intestinal side-effects.

#### Adults

The recommended initial dose is 50mg three times a day. However, some patients may benefit from a more gradual initial dose titration to minimise gastrointestinal side-effects. This may be achieved by initiating treatment at 50mg once or twice a day, with subsequent titration to a three times a day regimen.

If after six to eight weeks of treatment patients show an inadequate clinical response, the dosage may be increased to 100mg three times a day. A further increase in dosage to a maximum of 200mg three times a day may occasionally be necessary.

If distressing complaints develop in spite of strict adherence to the diet, the dose should not be increased further and if necessary should be reduced according to the severity of the side-effects and the clinical judgment of the prescriber.

Acarbose is intended for continuous long-term treatment.

#### Elderly patients

No modification of the normal adult dosage regimen is necessary.

#### Children and adolescents under 18 years

The efficacy and safety of Acarbose in children and adolescents have not been established. Acarbose is not recommended for patients under the age of 18 years.

### Contraindications:

- Hypersensitivity to Acarbose or any of the excipients
- Use during pregnancy and in nursing mothers.

Acarbose Tablets are also contra-indicated in patients with colonic ulceration, inflammatory bowel disease, partial intestinal obstruction or in patients predisposed to intestinal obstruction.

In addition, Acarbose Tablets should not be used in patients who have chronic intestinal diseases associated with marked disorders of digestion or absorption and in patients who suffer from states which may deteriorate as a result of increased gas formation in the intestine, e.g. larger hernias.

Acarbose Tablets are contra-indicated in patients with hepatic impairment.

As Acarbose has not been studied in patients with severe renal impairment, it should not be used in patients with a creatinine clearance of less than 25 ml/min/1.73m<sup>2</sup>.

### Special warnings and precautions for use:

Hypoglycaemia: When administered alone, Acarbose does not cause hypoglycaemia. Episodes of hypoglycaemia occurring during therapy must, where appropriate, be treated by the administration of glucose, not sucrose. This is because Acarbose will delay the digestion and absorption of disaccharides but not of monosaccharides.

**Transaminases:** Patients treated with Acarbose may, on rare occasions, experience an idiosyncratic response with either symptomatic or asymptomatic hepatic dysfunction.

The administration of antacid preparations containing magnesium and aluminium salts has been shown not to ameliorate the acute gastrointestinal symptoms of Acarbose in higher dosage and should, therefore, not be recommended to patients for this purpose.

**Interaction with other medicinal products and other forms of interaction:**

Sucrose (cane sugar) and foods containing sucrose, Intestinal adsorbents (e.g. charcoal) and digestive enzyme preparations containing carbohydrate splitting enzymes (e.g. amylase, pancreatin), Neomycin, Cholestyramine, Digoxin, Nifedipine.

**Fertility, pregnancy and lactation:**

The use of Acarbose is contra-indicated in pregnancy and in nursing mothers.

**Effects on ability to drive and use machines**

None known.

**Side effects:**

**Blood and lymphatic system disorders-** Thrombocytopenia

**Immune system disorders-** Allergic reaction (rash, erythema, exanthema, urticaria)

**Vascular disorders-** Oedema

**Gastrointestinal disorders-** Flatulence, Diarrhoea, Gastrointestinal and abdominal pains, Nausea, Vomiting, Dyspepsia,

**Hepatobiliary disorders-** Increase in liver enzymes, Jaundice, Hepatitis.

In patients receiving the recommended daily dose of 150 to 300 mg Acarbose, clinically relevant abnormal liver function tests (three times above upper limit of normal range) were rarely observed. Abnormal values may be transient under ongoing therapy with Acarbose.

**Storage:**

Store protected from light & moisture.

Keep out of reach of children.

Manufactured By:



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(An ISO 9001-2015 Certified Company)

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