Dilitus™

Voglibose Tablet

Presentation
Dilitus™ 0.2 mg Tablet : Each tablet contains Voglibose INN 0.2 mg
Dilitus™ 0.3 mg Tablet : Each tablet contains Voglibose INN 0.3 mg

Indications
Dilitus™ is an alpha-glucosidase inhibitor & indicated -

- in non-insulin-dependent diabetes mellitus (NIDDM) patients as immunotherapy
- in combination with other oral hypoglycaemic agents
- in addition to insulin in diabetes mellitus patients
- in prevention of onset of type 2 diabetes mellitus in impaired glucose tolerance (only for Dilitus™ 0.2 mg tablets)
- in elderly patients and in those with hepatic dysfunction or mild to moderate renal impairments in whom other oral hypoglycaemic agents are contraindicated or they need to be used with caution, it will be helpful.
- in glycogen storage disease: It is helpful in prevention of hypoglycaemia in patients with type Ib glycogen storage disease.
- in non-diabetic hyperinsulinemia, it is helpful in preventing hypoglycaemic attacks.

Dosage & Administration
Adult Dose: Usually, Voglibose tablets are orally administered in a single dose of 0.2 mg, 3 times a day, before each meal. If the effect is not sufficient, the quantity of a single dose may be increased up to 0.3 mg.

Paediatrics: The safety and effectiveness of Voglibose in children has not been established.

Geriatrics: Since elderly patients generally have a physiological hypofunction, it is desirable that such caution should be taken as starting the administration at a lower dose (e.g. 0.1 mg at a time). Furthermore, this drug should be carefully administered under close observation, through the course of the disease condition, with careful attention to the blood sugar level and the onset of gastrointestinal symptoms.

Dosage in Renal Failure: Voglibose is poorly absorbed after oral doses and renal excretion is negligible, suggesting that no dose adjustment is required. However, pharmacokinetic studies in patients with renal insufficiency are not available.

Overdose: Unlike sulfonylureas or insulin, an overdose of Voglibose tablets will not result in hypoglycaemia. An overdose may result is transient increase in flatulence, diarrhoea and abdominal discomfort. Because of lack of extra-intestinal effects soon with Voglibose, no serious systemic reactions are expected in the event of an overdose.

Side Effects
Voglibose unlikely to produce hypoglycaemia in overdose, but abdominal discomfort and diarrhea may occur. Moreover loose stools, abdominal pain, constipation, loss of appetite, urge to vomit (nausea), vomiting, heartburn, increased gas, and intestinal obstruction like symptoms due to increased intestinal gas may cause. Oral hypoglycaemic agents plus Voglibose may cause hypoglycaemia (0.1% to <5%), delay in digestion and absorption of disaccharides, fulminant hepatitis, serious liver dysfunction with increased liver enzymes, jaundice, anemia, numbness, edema, blurred vision, hot flushes, malaise, weakness, hyperkalemia, increased pancreatic enzyme (serum amylase).

Precautions
The administration of Dilitus™ tablets should be limited to patients who have established diabetes as there are certain other disease conditions such as abnormal glucose tolerance and positive urinary sugar that represent diabetes-like symptoms (renal glycosuria, senile abnormal glucose tolerance, abnormal thyroid function, etc.) In patients who are being managed with lifestyle modifications (diet and/or exercise), this drug must be given only when the 2-hour postprandial blood glucose levels are ≥200 mg/dL. During administration of this drug, disease progression should be closely observed with monitoring of blood glucose levels at regular intervals. If the effect on postprandial glucose levels is not satisfactory even after the administration of this drug for 2 to 3 months (postprandial glucose ≥200mg/dL), consider a change to more appropriate treatment. After administration of this drug, if sufficient control of blood glucose is achieved (postprandial glucose ≤160 mg/dL) and can satisfactorily be maintained with lifestyle therapy or with additional use of oral hypoglycaemic drugs or insulin preparations, the administration of Dilitus™ tablet should be discontinued, and subsequent progresses of disease should be monitored.

Contraindications
Contraindicated in patients with Hypersensitivity to Voglibose or to any of the excipients; Diabetic ketoacidosis, diabetic pre-coma, severe infection, before and after operation or with serious trauma; gastrointestinal obstruction or predisposed to it.

Drug Interactions
Dilitus™ should be administered with care when co-administered with the following drugs:
Antidiabetic drugs- Derivative(s) of sulfonylamide and sulfonylurea, biguanide derivatives, insulin preparations and improving agents for insulin resistance.
For the concomitant use of anti-diabetic drugs and the drugs which enhance or diminish the hypoglycaemic action of antidiabetic drugs:

- Drugs enhancing the hypoglycaemic action of antidiabetic drugs: β-blockers, salicylic acid preparations, monoamine oxidase inhibitors, fibrate derivatives, warfarin, etc.
- Drugs diminishing the hypoglycaemic action of antidiabetic drugs: Adrenaline, adrenocortical hormone, thyroid hormone etc.

Use in Pregnancy & Lactation
Pregnancy: The safety of Voglibose in pregnancy has not been established. However, no adequate and well controlled studies have been found on pregnant women.

Lactating and Nursing Mothers: Although the levels of Voglibose reached in human milk are exceedingly low, it is recommended that Voglibose may not be administered to such women.

Storage
Store in a cool (below 30°C) and dry place, away from light. Keep out of the reach of children.

Packing
Dilitus™ 0.2 mg Tablet : Each box contains 3 blister packs with each blister of 10 Tablets.
Dilitus™ 0.3 mg Tablet : Each box contains 3 blister packs with each blister of 10 Tablets.

Manufactured by:
general GENERAL
Pharmaceuticals Ltd.
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