

# Vibose®

Voglibose

Tablet

## Description

Vibose® is a preparation of Voglibose, an alpha-glucosidase inhibitor used for lowering post-prandial blood glucose levels in people with diabetes mellitus and in patients with impaired glucose tolerance (IGT).

## Indications

Voglibose is used in diabetes mellitus (DM) for reduction in Post-Prandial Hyperglycaemia (PPHG), only when diet and/or exercise with lifestyle modification or Oral Hypoglycaemic Agents (OHAs) or insulin preparations, in addition to diet and/or exercise, do not result in an adequate glycaemic control.

Thus, Voglibose is indicated:

- In non-insulin-dependent diabetes mellitus (NIDDM) patients as immunotherapy
- In combination with other OHAs
- In addition to insulin in diabetes mellitus patients
- In prevention of onset of type 2 diabetes mellitus in impaired glucose tolerance (only for Voglibose INN 0.2 mg Tablets) (However, Vibose® Tablets should be used only when impaired glucose tolerance has not been improved in patients already undergoing appropriate dietary treatment and/or exercise therapy.)
- In elderly patients and in those with hepatic dysfunction or mild to moderate renal impairments in whom other OHAs are contraindicated or they need to be used with caution, Voglibose will be helpful.
- In glycogen storage disease: Voglibose is helpful in prevention of hypoglycaemia in patients with type Ib glycogen storage disease, it being an amylase (α glucosidase) inhibitor.
- In non-diabetic Hyperinsulinemia, Voglibose is helpful in preventing hypoglycaemic attacks.
- In steroid induced diabetes mellitus also, Voglibose is helpful. However, clinical data in this setting are limited.

## Dosage and Administration

**Normal Adult Dose:** Usually, Vibose® 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.

**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.

**Pediatrics:** 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 be taken as starting the administration at a lower dose (eg, 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.

## Precautions

**Careful Administration (should be administered with care in following patients)**

- 1) Patients who are receiving other antidiabetic drugs as hypoglycaemia may occur

- 2) Patients with a history of laparotomy or ileus (intestinal obstruction-like symptoms are liable to develop due to an increase in intestinal gas, etc.)
- 3) Patients with chronic intestinal disease accompanied by a disturbance in digestion and absorption (the action of this drug may aggravate the pathologic conditions)
- 4) Patients with Roemheld's Syndrome, severe hernia, Stenosis or ulceration of the large intestine, etc. (Symptoms may worsen due to an increase in the intestinal gas, etc.)
- 5) Patients with serious hepatic dysfunction (Because of possible changes in metabolic condition, the status of plasma glucose control may greatly vary. In patients with severe liver cirrhosis, hyperammonemia may worsen, followed by disturbance of consciousness.)
- 6) Patients with serious renal dysfunction (Because of possible changes in metabolic conditions, the status of plasma glucose control may greatly vary.)
- 7) Elderly patients

## Contraindications

- 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.

## Side Effects

Diarrhoea, 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. OHAs 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, anaemia, numbness, edema, blurred vision, hot flushes, malaise, weakness, hyperkalemia, increased pancreatic enzyme (serum amylase).

## Use in Pregnancy and Lactation

**Pregnancy:** The safety of Voglibose in pregnancy has not been established. However, no adequate and well controlled studies have been done 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.

## Drug Interaction

Vibose® should be administered with care when co-administered with the following drugs:

**Antidiabetic drugs:** Derivative(s) of sulfonamide and sulfonyleurea, biguanide derivatives, insulin preparations and improving agents for insulin resistance.

**For the concomitant use of antidiabetic 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, fibrates derivatives for the treatment of hyperlipemia,

warfarin, etc.

- Drugs diminishing the hypoglycemic action of antidiabetic drugs: Adrenaline, adrenocortical hormone, thyroid hormone, etc.

## Overdose

Unlike sulfonyleureas 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.

## Pharmaceutical Precautions

Keep in a cool and dry place. Keep out of the reach of children. Protect from light.

## Commercial Pack

Vibose® 0.2 Tablet: Box containing 30 tablets in 3x10's blister strips. Each tablet contains Voglibose INN 0.2 mg.

Vibose® 0.3 Tablet: Box containing 30 tablets in 3x10's blister strips. Each tablet contains Voglibose INN 0.3 mg.



Manufactured by

**BEXIMCO PHARMACEUTICALS LTD.**

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