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PRANDIAL MD Tablets (Voglibose)

Composition

PRANDIAL 0.2 MD
Each mouth dissolving tablet contains:
Voglibose.....0.2 mg
Excipients.....q.s.
PRANDIAL 0.3 MD
Each mouth dissolving tablet contains:
Voglibose.....0.3 mg
Excipients.....q.s.

Dosage Form

Tablets

Pharmacology

Pharmacodynamics

Vogliboseis an alpha-glucosidase inhibitor which inhibits the activity of alpha glucosidasesthat catalyzethe decomposition of disaccharides into monosaccharides in the intestine, thereby delaying the digestion and absorption of carbohydrates, resulting in improvement of postprandial hyperglycaemia.

Pharmacokinetics

Voglibose is poorly absorbed after oral doses. Plasma concentrations after oral doses have usually been undetectable. After an 80 mg dose (substantially higher than recommended dose), peak plasma levels of about 20 ng/mL were observed in 1-1.5 hours.
Voglibose is metabolized negligibly and rapidly excreted. When voglibose tablets were repeatedly administered to healthy male adults in a single dose of 0.2 mg, three times a day, for 7 consecutive days, voglibose was not detected in plasma or urine. Also, on administration of vogliboseto 10 healthy male subjects in a single dose of 2 mg, voglibose was not detected in plasma or urine.
Special Populations
Renal Impairment
No pharmacokinetic studies for voglibose have been conducted in subjects with renal insufficiency.
Hepatic Impairment
Rises in liver enzymes have been observed in up to 20% of patients during voglibose therapy.
Geriatric
No pharmacokinetic data of voglibose in elderly population is available.

Paediatric

No pharmacokinetic data of voglibose in paediatric population is available.

Indications

PRANDIAL MD is indicated as an adjunct to diet and exercise to improve postprandial hyperglycaemiain patients with type 2 diabetes. PRANDIAL MD may also be used in combination with a sulphonylurea when diet plus either PRANDIAL MD or a sulphonylurea alone do not result in adequate glycaemic control. The effect of PRANDIAL MD to enhance glycaemic control is additive to that of sulphonylureas when used in combination, presumably because its mechanism of action is different.

Dosage And Administration

PRANDIALMD is orally administered in a single dose of 0.2 mg three times daily just before or with each meal. PRANDIALMD should be administered in conjunction with diet treatment or diet plus a sulphonylurea. In case of inadequate effect, the single dose may be increased upto 0.3 mg under close observation of the course of the disease.
PRANDIAL MD is a mouth dissolving formulation, thus there is no need to swallow.
The administration of PRANDIAL MD should be limited to the patients who have been definitely diagnosed as having diabetes as there are certain other diseases like abnormal glucose tolerance and positive urinary sugar that represent diabetes-like symptoms (renal glycosuria, senile abnormal glucose tolerance, abnormal thyroid function, etc).
For patients who are undergoing lifestyle modifications (diet and/ or exercise) as a treatment measure for diabetes, this drug must be given only when the 2 hour postprandial blood glucose levels are ≥ 200 mg/dL.
For patients who are using oral hypoglycaemic agents or insulin preparations, in addition to lifestyle modifications (diet and/ or exercise), a rough standard for administration of this drug is to give it when fasting blood glucose is ≥ 140 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 2-3 months (postprandial glucose ≥200 mg/dL), consider a change to more appropriate treatment. Post administration of this drug, if sufficient control of postprandial 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 voglibose should be discontinued and subsequent progress of disease should be observed.

Contraindications

Patients with a history of hypersensitivity to any of the components.
Patients with severe ketosis, or in a state of diabetic coma or pre-coma.
Patients with severe infection, before and after operation or with serious trauma.
Patients with gastrointestinal obstruction or predisposed to it.

Warnings And Precautions

▶ Hypoglycaemia

While on voglibose tablets, patients should be instructed and explained to recognize hypoglycaemic symptoms and its management.

▶ Loss of Control of Blood Glucose

When diabetes patients are exposed to stress such as fever, trauma, infection, or surgery, a temporary loss of control of blood glucose may occur. At such times, temporary insulin therapy may be necessary.

▶ Drug Interactions

Anti-diabetic Drugs
Hypoglycaemia may occur with co-administration of voglibose with insulin preparations or sulphonylurea derivatives.
Drugs Enhancing (Beta-blockers, salicylic acid preparations, monoamine oxidase inhibitors, fibrate derivatives) or diminishing (epinephrine, adrenocortical hormone, thyroid hormone, etc.)the hypoglycaemic action of anti-diabetic drugs
When voglibose is administered concomitantly with drugs that enhance or diminish the hypoglycaemic action of anti-diabetic drugs, caution should be taken as this might additionally delay the action of voglibose on the absorption of carbohydrates.
Warfarin
Voglibose does not affect the pharmacokinetics of warfarin, hence can be safely administered along with warfarin.

▶ Renal Impairment

Voglibose should be administered with precaution in patients with serious renal dysfunction.

▶ Hepatic Impairment

Voglibose should be administered with precaution in patients with serious hepatic dysfunction.

▶ Pregnancy

The safety and effectiveness of voglibose in pregnant women has not been established. Animal studies have shown that voglibose is transferred to the foetus. Voglibose should be used during pregnancy only if the potential benefit justifies the potential risk to the foetus.

▶ Lactation

Animal studies have shown a suppressive action of voglibose on body weight increase in newborns, mainly due to suppression of milk production resulting from inhibition of carbohydrate absorption in mother animals. Nursing should be discontinued if voglibose has to be administered.

▶ Paediatric Use

The safety and effectiveness of voglibose in children has not been established.

▶ Geriatric Use

The administration of voglibose should be initiated at a lower dose in elderly patients. The drug should be carefully administered under close observation of the course of disease conditions, with careful attention to the blood sugar level and the onset of gastrointestinal symptoms.

Undesirable Effects

The gastrointestinal adverse effects like diarrhoea, loose stools, abdominal pain, constipation, anorexia, nausea, vomiting or heartburn may occur with the use of voglibose. Abdominal swelling, increased flatus, and intestinal obstruction like symptoms due to an increase in intestinal gas, etc may occur. Serious hepatic dysfunction accompanied with jaundice, increased aspartate aminotransferase (AST) or alanine aminotransferase (ALT), etc. may also occur. One case of hepatitis with severe cholestasis attributed to voglibose hypersensitivity has been reported; a causal relationship

appears likely. When voglibose is administered to the patients with serious liver cirrhosis, hyperammonia may worsen with the development of constipation, etc., followed by disturbance of consciousness.
When voglibose is used in combination with other antidiabetic drugs, hypoglycaemia may occur (0.1% - < 5%). Furthermore, hypoglycaemia has been reported to occur (<0.1%) even when other antidiabetic drugswere not concomitantly used with this drug.

Overdosage

Voglibose competitively and reversibly inhibits the alpha-glucosidase enzymes in the brush border in the small intestine, which delays the hydrolysis of complex carbohydrates. It appears unlikely to produce hypoglycaemia in overdose, but abdominal discomfort and diarrhoea may occur.

Incompatibility

None.

Shelf-Life

2 years.

Storage And Handling Instructions

Protect from moisture.

Packaging Information

PRANDIAL 0.2 MD: Blister pack of 10 Tablets
PRANDIAL 0.3 MD: Blister pack of 10 Tablets
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