For the use of only a Registered Medical Practitioner or a Hospital or a Laboratory

Not to be sold by retail without the prescription of a Registered Medical Practitioner

Prescribing Information

1. Generic Name

Voglibose Mouth Dissolving Tablets 0.2 mg / 0.3 mg
(Brand Name: K-VOG® 0.2 mg / K-VOG® 0.3 mg Tablets)

2. Qualitative and Quantitative Composition

Each uncoated mouth dissolving tablet contains:
Voglibose IP ……. 0.2 mg
Excipients ……..… q.s.

Each uncoated mouth dissolving tablet contains:
Voglibose IP ……. 0.3 mg.
Excipients ……..… q.s.
Colour: Tartrazine.

3. Dosage Form and Strength

Dosage Form: Tablets.
Dosage Strength: Voglibose 0.2 mg and 0.3 mg per tablet.

4. Clinical Particulars

4.1 Therapeutic Indication

K-VOG Tablets are indicated for improvement of post-prandial hyperglycemia in diabetic patients, when diet, exercise and/or other antidiabetic drugs do not result in adequate glycemic control. K-VOG Tablets can also be used in combination with other oral antidiabetic agents and/or insulin.

4.2Posology and Method of Administration

For oral administration.
Usual Adult Dose: Voglibose 0.2 mg to be administered 3 times a day, just before each meal. If adequate glycemic control is not achieved with 0.2 mg dose, the quantity of single dose of voglibose may be increased to 0.3 mg. Total dose should not exceed the maximum recommended dose of 0.6 mg, three times a day. Dosage should be individualized on the basis of both, efficacy and gastrointestinal tolerance.
K-VOG Tablets to be disintegrated in the mouth/oral cavity and then swallowed.
Or, as prescribed by the physician.

4.3Contraindications

K-VOG Tablets are contraindicated in the following:

- Hypersensitivity to voglibose or to any component of the formulation.
- Diabetic ketoacidosis, diabetic pre-coma.
- Severe infection, before and after surgery, serious trauma.
- Gastrointestinal obstruction or predisposed to it.

4.4Special Warnings and Precautions for Use

Glycemic Control: In patients who are being managed with lifestyle modifications (diet and/or exercise), voglibose must be given only when the 2-hour post-prandial blood glucose levels are > 200 mg/dl. During administration of voglibose, disease progression should be closely observed with monitoring of blood glucose levels at regular intervals. If the effect on post-prandial glucose levels is not satisfactory even after the administration of voglibose for 2 to 3 months (post-prandial glucose >200 mg/dl), consider a change to more appropriate treatment.

Voglibose should be administered with caution in the following category of patients:

- Patients with history of laparotomy or ileus.
- Patients with chronic intestinal disease accompanied by disturbance in digestion and absorption.
- Patients with aggravating symptoms due to increased generation of intestinal gas (e.g., Roemheld syndrome, severe hernia, stenosis, and ulcer of the large intestine).
- Patients with serious hepatic or renal disorders.

Other precautions:

- All patients should continue their dietary restriction with a regular distribution of carbohydrate intake during the day. Overweight patients should continue their energy restricted diet.
- The usual laboratory tests for diabetes monitoring should be performed regularly.
- Patients should be educated to recognize hypoglycemic symptoms and its management.
- When patients with diabetes are exposed to unusual stress(es) such as fever, trauma, infection, or surgery, a temporary loss of control of blood glucose may occur. In this case, it may be necessary to administer insulin therapy temporarily.

4.5Drug Interactions

Anti-Diabetic Drugs: When voglibose is used in combination with derivative(s) of sulfonylamide, sulfonylurea or biguanide, or with insulin, hypoglycemic symptoms may occur. Therefore, when used in combination with any of these drugs, care should be taken, such as to initiate therapy with lower dosage.

Drugs Affecting Glycemic Control: When voglibose is administered concomitantly with drugs that enhance or diminish the hypoglycemic action of antidiabetic drugs, caution should be taken

as this might additionally delay the action of voglibose on the absorption of carbohydrates. Examples of drugs enhancing the hypoglycemic action of antidiabetic drugs include alpha-blockers, salicylic acid preparations, monoamine oxidase inhibitors, and fibrate derivatives. Examples of drugs diminishing the hypoglycemic action of antidiabetic drugs include epinephrine, adrenocortical hormone, and thyroid hormone.

Warfarin: Voglibose does not affect the pharmacokinetics of warfarin; hence, it can be safely administered along with warfarin.

4.6Use in Special Populations

Pregnant Women

Pregnancy Category B. The safety of voglibose in pregnancy has not been established. Animal studies do not indicate harmful effects with respect to pregnancy, embryonal or fetal development, parturition or post-natal development. However, no adequate and well controlled studies have been done in pregnant women. Therefore, voglibose should be given to pregnant women only when the potential benefits to the mother outweigh the possible hazards to the fetus.

Lactating Women

Animal studies (e.g., rats) have revealed a suppressive action of voglibose on body weight increase in newborns probably due to suppression of milk production due to reduced carbohydrate absorption. Although the levels of voglibose reached in human milk are exceedingly low, it is recommended that voglibose may not be administered to lactating women. When the administration of voglibose is unavoidable, nursing should be discontinued.

Paediatric Patients

The safety and effectiveness of voglibose in children has not been established. Thus, K-VOG Tablets are not recommended for use in paediatric patients.

Geriatric Patients

Since elderly patients generally have a physiological hypofunction, it is desirable to initiate therapy with lower dosage. Moreover, this drug should be carefully administered under close observation, throughout the course of the disease, with careful attention to the blood sugar level and the onset of gastrointestinal symptoms.

Renal Impairment Patients

Voglibose is poorly absorbed after oral doses and renal excretion is negligible. Thus, in general, no dosage adjustment is required in patients with renal dysfunction.

4.7Effect on Ability to Drive and Use Machines

With voglibose, effect on ability to drive a vehicle or operating machinery has not been reported.

4.8Undesirable Effects

Gastrointestinal: Gastrointestinal adverse events such as diarrhoea, loose stools, abdominal pain, constipation, anorexia, nausea, vomiting, or heartburn may occur with the use of voglibose. Also, abdominal distention, increased flatus, and intestinal obstruction like symptoms due to an increase in intestinal gas may occur with use of voglibose.

Hypersensitivity: Rash and pruritus may rarely occur. In such cases, voglibose should be discontinued immediately.

Hepatic: When voglibose is administered to patients with liver cirrhosis, hyperammonia may worsen with the development of constipation followed by disturbance of consciousness.

Laboratory Tests: Elevation of SGOT (serum glutamate oxaloacetate), SGPT (serum glutamate pyruvate transaminase), LDH (lactate dehydrogenase), alpha-GPT (alpha-glutamate pyruvate transaminase) or alkaline phosphatase may infrequently occur.

Hypoglycemia: When voglibose is used in combination with other antidiabetic drugs, hypoglycemia may occur (0.1% to <5%).

Psychoneurologic: Headache may rarely occur.

Hematologic: Anemia, thrombocytopenia, and leucopenia may rarely occur.

Others: Numbness, edema of face, blurred vision, hot flushes, malaise, weakness, hyperkalemia, increased serum amylase, decreased HDL-cholesterol, diaphoresis, or alopecia may occur rarely with the use of voglibose.

4.9Overdose

Voglibose is unlikely to produce hypoglycemia in overdose, but abdominal discomfort and diarrhoea may occur. If overdose occurs, supportive and symptomatic treatment should be provided.

5. Pharmacological Properties

5.1 Mechanism of Action

Voglibose competitively and reversibly inhibits the alpha glucosidase enzymes (e.g., glucoamylase, sucrase, maltase, and isomaltase) in the brush border of the small intestine.

Alpha-glucosidase enzymes are essential for hydrolysis/decomposition of complex carbohydrates (starch, dextrin, polysaccharides, and disaccharides) into simpler carbohydrates (such as glucose/dextrose or fructose). Inhibition of these enzymes leads to delay in the absorption of glucose into the bloodstream resulting in improvement of post-prandial hyperglycemia.

5.2Pharmacodynamic Properties

Voglibose exerts its activity in the intestinal tract. Alpha glucosidase enzyme normally converts complex carbohydrates into simple monosaccharides (glucose) which can be absorbed through the intestine.

The action of voglibose depends on an inhibition of intestinal enzymes (alpha-glucosidase) involved in the degradation of ingested disaccharides, oligosaccharides, and polysaccharides into

monosaccharides. Inhibition of these enzyme systems reduces/delays the rate of digestion of complex carbohydrates. As there is delay in digestion of complex carbohydrates, monosaccharides releases slowly and hence absorbed more slowly into the blood i.e., less glucose absorption from intestine into the blood circulation. Voglibose, thus dose dependently reduces the postprandial rise in blood glucose level.
Although voglibose reduces the impact of complex carbohydrates on blood sugar level, it does not affect/inhibit absorption of glucose from the intestine.
Alpha-glucosidase inhibitors such as voglibose do not stimulate insulin release and therefore do not result in hypoglycemia. Voglibose improves post-prandial hyperglycemia and thereby lowers abnormally high levels of glycosylated hemoglobin. Voglibose is highly useful in elderly patients or in patients with predominantly post-prandial hyperglycemia.

5.3Pharmacokinetic Properties

Absorption: Voglibose is poorly absorbed after oral doses. Plasma concentrations after oral doses have usually been undetectable. Following repeated administration to healthy subjects (n=6) in a single dose of 0.2 mg, 3 times a day, for 7 consecutive days, voglibose was not detected in plasma or urine. Similarly, when voglibose was administered to healthy male adults (n=10) as a single dose of 2 mg, voglibose was not detected in plasma or urine.
Distribution: After ingestion of voglibose, the majority of active unchanged drug remains in the lumen of the gastrointestinal tract to exert its pharmacological activity.
Metabolism: Voglibose is metabolized by intestinal enzymes and by the microbial flora.
Excretion: Voglibose is mainly excreted in the feces.

6. Nonclinical Properties

6.1 Animal Toxicology

No animal studies of safety pharmacology, repeated-dose toxicity, genotoxicity, carcinogenic potential, toxicity to reproduction and development have been conducted with voglibose.

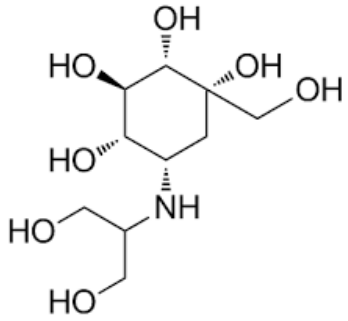
7. Description

K-VOG 0.2 mg Tablets are white to off-white circular biconvex, uncoated tablet plain on both the sides.
K-VOG 0.3 mg Tablets are light yellow coloured, circular biconvex, uncoated tablet plain on both the sides.

Each tablet of K-VOG 0.2 mg contains 0.2 mg of voglibose for oral administration in adults.
Each tablet of K-VOG 0.3 mg contains 0.3 mg of voglibose for oral administration in adults.

Voglibose is an alpha-glucosidase inhibitor used for lowering post-prandial blood glucose levels in people with diabetes mellitus.
Voglibose is available in the form of white powder.

Molecular Weight: 267.28 g/mol.
Molecular Formula: C10H21NO7.
Chemical Name: (1S,2S,3R,4S,5S)-5-(1,3-dihydroxypropan-2-ylamino)-1-(hydroxymethyl)cyclohexane-1,2,3,4-tetrol.
Structural Formula:



Inactive ingredients (excipients) of K-VOG 0.2 mg Tablet contain Microcrystalline Cellulose, Xylitol 300, Sucralose, Flavour Tutti-Frutti, Talcum, Magnesium Stearate, Pearlitol Flash, and Polyplasdone XL-10.

Inactive ingredients (excipients) of K-VOG 0.3 mg Tablet contain Microcrystalline Cellulose, Xylitol 300, Sucralose, Flavour Tutti-Frutti, Talcum, Colour Tartrazine Lake, Magnesium Stearate, Pearlitol Flash, and Polyplasdone XL-10.

8. Pharmaceutical Particulars

8.1 Incompatibilities

None known.

8.2Shelf-life

24 months.

8.3Packaging Information

15 tablets per strip.

8.4Storage and Handling Instructions

Store protected from light and moisture at a temperature not exceeding 25°C.
Keep out of reach of children.

9. Patient Counseling Information

Instructions to Patients

- Instruct patients to take this medicine exactly as prescribed by your doctor. Do not change the dose or stop therapy without consulting your doctor.
- Advise pregnant women and breastfeeding mothers not to use this medicine without doctor consultation.
- Patients are advised not to take this medicine for the treatment of diabetic ketoacidosis or diabetic pre-coma.
- This medicine is not advisable for use in children.
- Patients should be instructed to avoid use of this medicine during severe infection or before and after surgery or in serious trauma cases.
- Inform patients to disintegrate K-VOG Tablets in the mouth/oral cavity and then swallow.

10. Details of Manufacturer

Pure & Cure Healthcare Pvt. Ltd.
(A Subsidiary of Akums Drugs & Pharmaceuticals Ltd.)
Plot No. 26A, 27-30, Sector-8A, I.I.E., SIDCUL,
Ranipur, Haridwar – 249 403, Uttarakhand.

11. Details of Permission or License Number with Date

Mfg. Lic. No. : 31/UA/2013; Date of FDA Product Permission: 05/11/2014.

12.Date of Revision

April 2021.

Marketed by:
BLUE CROSS LABORATORIES PVT LTD.
A-12, M.I.D.C., NASHIK-422 010.
Regd. Off.: Peninsula Chambers, G. K. Marg, Mumbai-400 013.