APPROVED
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INSTRUCTION
for medical use

VOXID®

***Composition*:**
active substance: voglibose;
1 tablet contains voglibose 0.2 mg or 0.3 mg;
excipients: lactose monohydrate, maize starch, povidone K30, sodium starch glycolate (type A), colloidal anhydrous silica, magnesium stearate.

Pharmaceutical form: Tablets.
Main physicochemical properties:
Voxid®, tablets 0.2 mg: white round flat tablets with bevelled edges, embossed with "K" on one side and a score line on the other side;
Voxid®, tablets 0.3 mg: white round flat tablets with bevelled edges, embossed with "K" on one side.

Pharmacotherapeutic group.
Hypoglycemic agents, excluding insulins. Code ATC A10B F03.

Pharmacological properties.
Pharmacodynamics.
Voglibose is an oral hypoglycemic agent, a competitive inhibitor of intestinal alpha-glucosidases (hydrolase enzymes), which are involved in the cleavage of di-, oligo- and polysaccharides. The inhibition of α-glucosidase activity reduces the cleavage of complex carbohydrates and glucose absorption, resulting in a reduction in postprandial blood glucose level (postprandial hyperglycemia).
Voglibose does not affect the activity of β-glucosidase.
Pharmacokinetics.
Voglibose is slowly and poorly absorbed and rapidly excreted in feces. Currently, no metabolites of the substance have been identified in the human blood and urine. The animal studies have shown that voglibose penetrates through the placenta and into breast milk.

Clinical characteristics.
Indications.
- Treatment of type II diabetes mellitus, if a diet and/or physical exercises can not adequately maintain the blood glucose level; as monotherapy or in combination with other oral hypoglycemic agents or with insulin.
- Treatment of the I type of diabetes mellitus, as part of combined therapy in conjunction with insulin.
- Prevention of the II type of diabetes mellitus in patients with impaired glucose tolerance.

Contraindications.

- Hypersensitivity to the active substance or to any other component of the drug.
- Diabetic ketoacidosis, diabetic pre-coma, diabetic coma.
- Severe infections.
- Major surgeries and traumas.
- Pathological conditions andenteropathy, which may deteriorate under the conditions of enhanced gas production (inflammatory bowel diseases, erosive and ulcerative changes in the intestine, partial or complete intestinal obstruction, etc.).
- Severe pathological conditions and bowel diseases, accompanied by impaired digestion and absorption.

Interaction with other medical products and other forms of interaction.

Combinations requiring precautions for use.

- Antidiabetic drugs: sulfonamide and sulfonylurea derivatives, biguanide derivatives, insulin drugs, and agents that improve insulin resistance (the risk of hypoglycemia appearance).
- Drugs that increase the hypoglycemic effect of antidiabetic drugs (including β-blockers, salicylic acid drugs, monoamine oxidase inhibitors, fibrate derivatives for the treatment of hyperlipidemia and warfarin).
- Drugs that reduce the hypoglycemic effect of antidiabetic drugs (including adrenalin, adrenal hormones and thyroid hormones).

Administration details.

Voxid® should be used with caution in such cases:

- concomitant use of other hypoglycemic agents (the possibility of hypoglycemia) (see. section "Adverse reactions")
- laparotomy or intestinal obstruction in past medical history (the possibility of the patient's condition deterioration due to excessive gas formation in the intestine);
- chronic bowel diseases, accompanied by indigestion and malabsorption (the possibility of the patient's condition deterioration due to voglibose mechanism of action);
- Roemheld's syndrome (the possibility of the patient's condition deterioration due to excessive gas formation in the intestine);
- hernia, stenosis or ulceration of the large intestine (the possibility of the patient's condition deterioration due to excessive gas formation in the intestine);
- severe hepatic dysfunction (the possibility of significant fluctuations in patient’s blood glucose levels because of metabolic disorders);
- hepatic cirrhosis (the possibility of further impairment of consciousness due to hyperammonemia);
- severe renal impairment (the possibility of significant fluctuations in patient’s blood glucose levels because of metabolic disorders).

Voxid® administration should be limited to patients with diabetes mellitus or impaired glucose tolerance.

In patients with diabetes mellitus, who keeps a diet and/or physical exercises, voglibose should be prescribed only when the post-prandial blood glucose levels are 11.1 mmol/L or more in 2 hours after meal.

In patients with diabetes mellitus who are recommended to keep a diet, physical exercises, oral hypoglycemic agents or insulin, voglibose should be prescribed only when the fasting blood glucose level is 7.77 mmol/L or more.

Patient’s condition and blood glucose level should be closely monitored while administering Voxid®. In addition, an important role in achieving the therapeutic effect plays a continuous administration of this drug.

If after 2-3 months of voglibose continuous administration (as mono-or combined therapy of diabetes mellitus) the hypoglycemic effect is unsatisfactory (post-prandial blood glucose levels are 11.1 mmol/L or more in 2 hours after meal), then a treatment should be appropriately adjusted.
If in case of voglibose administration (as mono- or combined therapy of diabetes mellitus) the hypoglycemic effect is satisfactory (postprandial blood glucose levels are 8.88 mmol/L or less in 2 hours after meal), then discontinue the drug administration and monitor the further disease progression.
If the patient has intolerance to some sugars, consult your doctor before taking this drug because the product contains lactose.

Administration during pregnancy and breast-feeding.
Voxid®, tablets, can be administered to pregnant women or to women with presumable pregnancy only if the expected therapeutic benefit exceeds any potential risk. Safety usage of this drug for pregnant women is not identified.
It is preferable to avoid using voglibose by breast feeding women. In case of necessity of drug administration it should be decided to terminate breastfeeding.

Effects on the ability to drive and operate machinery.
The drug therapy may cause adverse effects which can affect the ability to drive and operate other mechanisms.

Administration and dosage.
The drug Voxid® is administered orally, directly before each meal time, followed with a sufficient amount of water.
Usually, the initial dose of the drug Voxid® for adults compiles 0.2 mg 3 times a day. If the therapeutic effect is insufficient, the drug dosage can be increased to 0.3 mg 3 times a day, provided that the disease course is closely observed.
For elderly patients the initial dose of the drug Voxid® is 0.1 mg 3 times a day. If the therapeutic effect is insufficient, the drug dosage can be increased to 0.2–0.3 mg 3 times a day provided that the disease course is closely observed.

Children.
There is no data on using voglibose in children, therefore, it is not recommended in this age category of patients.

Overdose.
In case of overdose, a patient should consult a doctor.

Adverse reactions.
Metabolic disorder: hypoglycemia.
Gastro-intestinal tract: relaxation of excrement, diarrhea, feeling bloated in the abdomen, meteorism, pain, abdominal discomfort, nausea, vomiting, intestinal pneumatosis, intestinal obstruction.
Hepatobiliary system: fulminant hepatitis, severely impaired liver function, level increase of liver transaminase (AST, ALAT), jaundice, severe cholestasis.
Nervous system: dizziness.

Shelf-life.
3 years.

Storage conditions.
Store at a temperature NMT 25°C in the original package.
Keep it out of reach of children.

Package.
10 tablets are in a blister. 3 or 10 blisters are in a carton pack.

Conditions of supply.
By prescription.

Manufacturer.
Kusum Pharm LLC.

Address.
54, Skryabina Str., Sumy, Sumy region, 40020, Ukraine.

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