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

This package insert is continually updated: Please read carefully before using a new pack

Metformin Hydrochloride Sustained Release and Voglibose Tablet
Cetapin® V

Cetapin® V 0.2 mg
Each uncoated bilayered tablet contains:
Voglibose IP.....0.2 mg
Metformin hydrochloride IP (as sustained release)....500mg
Colour: Lake of Indigo Carmine

Cetapin® V 0.3 mg
Each uncoated bilayered tablet contains:
Voglibose IP.....0.3 mg
Metformin hydrochloride IP (as sustained release)....500mg
Colour: Lake of Erythrosine & Lake of Indigo Carmine

THERAPEUTIC INDICATIONS
Cetapin® V is indicated as a second line treatment for type II diabetes mellitus when diet, exercise and single agent do not result in adequate glycemic control.

DOSAGE AND ADMINISTRATION
Dosage of Cetapin® V must be individualized on the basis of both effectiveness and tolerance, while not exceeding the recommended daily dose.

The maximum recommended daily dose of metformin in adults is 2000 mg while the usual daily dose of voglibose is 0.6mg – 0.9mg.

Adults - 1 tablet to be given 2-3 times daily with heavy meals.

Special Populations

Paediatrics
Safety and effectiveness have not been established in children.

Elderly patients
Due to the potential for decreased renal function in elderly subjects, the metformin dosage should be adjusted based on renal function. Regular assessment of renal function is necessary (see Renal impairment below and section Warnings/Precautions).
Since elderly patients generally have a physiological hypofunction, it is desirable that caution be taken as starting the administration at a low dose (eg, 0.1 mg at a time) for voglibose. Furthermore, voglibose 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.

Renal impairment

A GFR should be assessed before initiation of treatment with metformin containing products and at least annually thereafter. In patients at an increased risk of further progression of renal impairment and in the elderly, renal function should be assessed more frequently, e.g. every 3-6 months.

GFR (mL/min)	Total maximum daily dose (to be divided into 2-3 daily doses)	Additional considerations
60-89	3000 mg	Dose reduction may be considered in relation to declining renal function.
45-59	2000 mg	Factors that may increase the risk of lactic acidosis (see section Warnings/Precautions) should be reviewed before considering initiation of metformin. The starting dose is at most half of the maximum dose.
30-44	1000 mg	-
<30	-	Metformin is contraindicated.

CONTRAINDICATIONS

For Metformin

Hypersensitivity to the active substance or to any of the excipients.

- Any type of acute metabolic acidosis (such as lactic acidosis, diabetic ketoacidosis), diabetic pre-coma.
- Severe renal failure (GFR<30 mL/min).
- Acute conditions with the potential to alter renal function such: as dehydration, severe infection, shock.
- Disease which may cause tissue hypoxia (especially acute disease or worsening of chronic disease) such as: decompensated heart failure, respiratory failure, recent myocardial infarction, shock.
- Hepatic insufficiency, acute alcohol intoxication, alcoholism.

For Voglibose:

- Hypersensitivity to Voglibose or to any of the excipients.
- Diabetic ketoacidosis, diabetic pre-coma.
- Severe infections, before or after operation or with severe trauma.
- Gastrointestinal obstruction or predisposed to it.

WARNINGS/PRECAUTIONS

For Metformin

Lactic acidosis:

Lactic acidosis, a very rare but serious metabolic complication, most often occurs at acute worsening of renal function or cardiorespiratory illness or sepsis. Metformin accumulation occurs at acute worsening of renal function and increases the risk of lactic acidosis.

In case of dehydration (severe diarrhea or vomiting, fever or reduced fluid intake), metformin should be temporarily discontinued and contact with a health care professional is recommended.

Medicinal products that can acutely impair renal function (such as antihypertensives, diuretics and NSAIDs) should be initiated with caution in metformin-treated patients. Other risk factors for lactic acidosis are excessive alcohol intake, hepatic insufficiency, inadequately controlled diabetes, ketosis, prolonged fasting and any conditions associated with hypoxia, as well as concomitant use of medicinal products that may cause lactic acidosis (see sections Contraindications and Interactions).

Patients and/or caregivers should be informed of the risk of lactic acidosis. Lactic acidosis is characterized by acidotic dyspnea, abdominal pain, muscle cramps, asthenia and hypothermia followed by coma. In case of suspected symptoms, the patient should stop taking metformin and seek immediate medical attention. Diagnostic laboratory findings are decreased blood pH (< 7.35), increased plasma lactate levels (>5 mmol/L) and an increased anion gap and lactate/pyruvate ratio.

Renal function:
GFR should be assessed before treatment initiation and regularly thereafter, (see section Dosage and Administration). Metformin is contraindicated in patients with GFR<30 mL/min and should be temporarily discontinued in the presence of conditions that alter renal function, (see section Contraindications).

Cardiac function:
Patients with heart failure are more at risk of hypoxia and renal insufficiency. In patients with stable chronic heart failure, metformin may be used with a regular monitoring of cardiac and renal function. For patients with acute and unstable heart failure, metformin is contraindicated (see section Contraindications).

Administration of iodinated contrast agents:
Intravascular administration of iodinated contrast agents may lead to contrast induced nephropathy, resulting in metformin accumulation and an increased risk of lactic acidosis. Metformin should be discontinued prior to or at the time of the imaging procedure and not restarted until at least 48 hours after, provided that renal function has been re-evaluated and found to be stable (see sections Dosage and Administration and Interactions).

Patients with known or suspected mitochondrial diseases:
In patients with known mitochondrial diseases such as Mitochondrial Encephalopathy with Lactic Acidosis, and Stroke-like episodes (MELAS) syndrome and Maternal inherited diabetes and deafness (MIDD), Cetapin® V is not recommended due to the risk of lactic acidosis exacerbation and neurologic complications which may lead to worsening of the disease.
In case of signs and symptoms suggestive of MELAS syndrome or MIDD after the intake of Cetapin® V, treatment with Cetapin® V should be withdrawn immediately and prompt diagnostic evaluation should be performed.

Surgery:
Metformin must be discontinued at the time of surgery under general, spinal or epidural anesthesia. Therapy may be restarted no earlier than 48 hours following surgery or resumption of oral nutrition and provided that renal function has been re-evaluated and found to be stable.

Other precautions:
- All patients should continue their diet 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.
- Metformin alone does not cause hypoglycemia, but caution is advised when it is used in combination with insulin or other oral antidiabetics (e.g. sulfonylureas or meglitinides).
- Regular monitoring of thyroid-stimulating hormone (TSH) levels is recommended in patients with hypothyroidism (see section Adverse reactions).
- Long-term treatment with metformin has been associated with a decrease in vitamin B12 serum levels which may cause peripheral neuropathy. Monitoring of the vitamin B12 level is recommended (see section Adverse reactions).
- The tablet shells may be present in the feces. Patients should be advised that this is normal.

For Voglibose
Voglibose tablets should be administered with caution to the following 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 (eg, Roemheld syndrome, severe hernia, and stenosis and ulcer of the large intestine) and 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 instructed and explained to recognize hypoglycemic symptoms and its management.
- **When patients with diabetes are exposed to unusual stress such as fever, trauma, infection, or surgery, a temporary loss of control of blood glucose may occur. At such times insulin therapy may be necessary for some time.**

DRUG INTERACTIONS

For Metformin

Concomitant use not recommended

Alcohol

Alcohol intoxication is associated with an increased risk of lactic acidosis, particularly in case of fasting, malnutrition or hepatic impairment.

Iodinated contrast agents

Metformin must be discontinued prior to or at the time of the imaging procedure and not restarted until at least 48 hours after, provided that renal function has been re-evaluated and found to be stable (see sections Dosage and Administration and Warnings / Precautions).

Combinations requiring precautions for use:

Medicinal products with intrinsic hyperglycemic activity (e.g. glucocorticoids (systemic and local routes) and sympathomimetics)

More frequent blood glucose monitoring may be required, especially at the beginning of treatment. If necessary, adjust the metformin dosage during therapy with the respective medicinal product and upon its discontinuation.

Medicinal products affecting renal function

Some medicinal products can adversely affect renal function which may increase the risk of lactic acidosis, e.g. NSAIDs, including selective cyclo-oxygenase (COX) II inhibitors, ACE inhibitors, angiotensin II receptor antagonists and diuretics, especially loop diuretics. When starting or using such products in combination with metformin, close monitoring of renal function is necessary.

Organic cation transporters (OCT)

Metformin is a substrate of both transporters OCT1 and OCT2.

Co-administration of metformin with

- Inhibitors of OCT1 (such as verapamil) may reduce efficacy of metformin.
- Inducers of OCT1 (such as rifampicin) may increase gastrointestinal absorption and efficacy of metformin.
- Inhibitors of OCT2 (such as cimetidine, dolutegravir, ranolazine, trimethoprime, vandetanib, isavuconazole) may decrease the renal elimination of metformin and thus lead to an increase in metformin plasma concentration.
- Inhibitors of both OCT1 and OCT2 (such as crizotinib, olaparib) may alter efficacy and renal elimination of metformin.

Caution is therefore advised, especially in patients with renal impairment, when these drugs are coadministered with metformin, as metformin plasma concentration may increase. If needed, dose adjustment of metformin may be considered as OCT inhibitors/inducers may alter the efficacy of metformin.

Phenprocoumon

Metformin may decrease the anticoagulant effect of phenprocoumon. Therefore, a close monitoring of the INR is recommended.

Levothyroxine
Levothyroxine can reduce the hypoglycemic effect of metformin. Monitoring of blood glucose levels is recommended, especially when thyroid hormone therapy is initiated or stopped, and the dosage of metformin must be adjusted if necessary.

For Voglibose
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 starting the administration at a low dose.

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: alpha blockers, salicylic acid preparations, monoamine oxidase inhibitors and fibrate derivatives. Examples of drugs diminishing the hypoglycemic action of antidiabetic drugs: epinephrine, adrenocortical hormone, and thyroid hormone.

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

REPRODUCTION
Pregnancy
Uncontrolled diabetes during pregnancy (gestational or permanent) is associated with increased risk of congenital abnormalities and perinatal mortality.

A limited amount of data from the use of metformin in pregnant women does not indicate an increased risk of congenital abnormalities. Animal studies do not indicate harmful effects with respect to pregnancy, embryonic or fetal development, parturition or post-natal development (see section Contraindication).

When the patient plans to become pregnant and during pregnancy, it is recommended that diabetes is not treated with metformin but insulin be used to maintain blood glucose levels as close to normal as possible, to reduce the risk of malformations of the fetus.

Lactation
Metformin is excreted into human breast milk. No adverse effects were observed in breastfed newborns/infants. However, as only limited data are available, breast-feeding is not recommended during metformin treatment. A decision on whether to discontinue breast-feeding should be made, taking into account the benefit of breast-feeding and the potential risk to adverse effects on the child.

Fertility
Fertility of male or female rats was unaffected by metformin when administered at doses as high as 600 mg/kg/day, which is approximately three times the maximum recommended human daily dose based on body surface area comparisons.

DRIVING A VEHICLE OR PERFORMING OTHER HAZARDOUS TASKS
Metformin monotherapy does not cause hypoglycemia and therefore has no effect on the ability to drive or to use machines.
However, patients should be alerted to the risk of hypoglycemia when metformin is used in combination with other antidiabetic agents (e.g. sulfonylureas, insulin or meglitinides).

ADVERSE REACTIONS:

For Metformin

The following CIOMS frequency rating is used, when applicable

Very common ≥ 10%; Common ≥ 1 and < 10%; Uncommon ≥ 0.1 and < 1%;

Rare ≥ 0.01 and < 0.1%; Very rare < 0.01%; Not known (cannot be estimated from available data).

During treatment initiation, the most common adverse reactions are nausea, vomiting, diarrhea, abdominal pain and loss of appetite which resolve spontaneously in most cases. To prevent them, it is recommended to take metformin in 2 or 3 daily doses and to increase slowly the doses.

The following adverse reactions may occur under treatment with metformin.

Within each frequency grouping, adverse reactions are presented in order of decreasing seriousness

Blood and lymphatic system disorders

Not known:

- Hemolytic anemia.

Metabolism and nutrition disorders

Very rare:

- Lactic acidosis (see section Warnings / Precautions).
- Decrease of vitamin B12 absorption with decrease of serum levels during long-term use of metformin. Consideration of such etiology is recommended if a patient presents with megaloblastic anemia.

Not known:

- Cases of peripheral neuropathy in patients with vitamin B12 deficiency have been reported in postmarketing experience (see section Warnings/Precautions).

Nervous system disorders

Common:

- Taste disturbance.

Not known:

- Encephalopathy.

Gastrointestinal disorders

Very common:

- Gastrointestinal disorders such as nausea, vomiting, diarrhea, abdominal pain and loss of appetite. These undesirable effects occur most frequently during initiation of therapy and resolve spontaneously in most cases. To prevent them, it is recommended that metformin be taken in 2 or 3 daily doses during or after meals. A slow increase of the dose may also improve gastrointestinal tolerability.

Hepatobiliary disorders

Very rare:

- Isolated reports of liver function tests abnormalities or hepatitis resolving upon metformin discontinuation.

Skin and subcutaneous tissue disorders

Very rare:

- Skin reactions such as erythema, pruritus and urticaria.

Not known:

- Photosensitivity.

Investigations

Not known:

- Reduction of thyrotropin level in patients with hypothyroidism.
- Hypomagnesemia in the context of diarrhea.

Pediatric population

In published and post marketing data and in controlled clinical studies in a limited pediatric population aged 10 - 16 years treated during 1 year, adverse event reporting was similar in nature and severity to that reported in adults.

For Voglibose

Gastrointestinal adverse effects 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.

When Voglibose is administered to patients with serious liver cirrhosis, hyperammonia may worsen with the development of constipation followed by disturbance of consciousness. Elevation of GOT (glutamate oxaloacetate), GPT (glutamatepyruvate transaminase), LDH (lactate dehydrogenase), alpha GPT (alpha glutamate pyruvate) or alkaline phosphatase may infrequently occur.

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

Hypersensitivity: Rash and pruritus may rarely occur.

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,and perspiration.

OVERDOSAGE

For Metformin:

Hypoglycemia has not been seen with metformin hydrochloride doses of up to 85 g, although lactic acidosis has occurred in such circumstances. High overdose of metformin or concomitant risks may lead to lactic acidosis. Lactic acidosis is a medical emergency and must be treated in hospital. The most effective method to remove lactate and metformin is hemodialysis.

Pancreatitis may occur in the context of a metformin overdose

For Voglibose:

Voglibose competitively and reversibly inhibits the alpha glucosidase enzymes (glucoamylase, sucrase, maltase and isomaltase) in the brush border in the small intestine, which delays the hydrolysis of complex carbohydrates. It is unlikely to produce hypoglycemia in overdose, but abdominal discomfort and diarrhea may occur.

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