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

Abridged Prescribing Information

Cetapin® V
Metformin Hydrochloride Sustained Release and Voglibose Tablet

COMPOSITION
Cetapin® V 0.2mg: Metformin hydrochloride IP (as sustained release) 500mg & Voglibose 0.2 mg.
Cetapin® V 0.3mg: Metformin hydrochloride IP (as sustained release) 500mg & Voglibose 0.3 mg.

THERAPEUTIC INDICATIONS: 2nd line treatment for type II diabetes mellitus when diet, exercise, single agent do not result in adequate glycemic control.
DOSAGE AND ADMINISTRATION: Adults - 1 tablet to be given 2-3 times daily with heavy meals. Safety and efficacy not established in children. Initiation at lower dose and close observation in case of elderly. Monitoring of renal function is necessary in elderly. Avoid in patients of hepatic insufficiency. Contraindicated in case of renal dysfunction.

SAFETY-RELATED INFORMATION
CONTRAINDICATIONS: Known hypersensitivity to metformin hydrochloride, voglibose or any of the excipients, severe renal failure, hepatic insufficiency, alcoholism, Diabetic ketoacidosis, diabetic pre-coma, severe infections before or after operation or with severe trauma, Gastrointestinal obstruction or predisposed to it
WARNINGS/PRECAUTIONS: Metformin: Lactic acidosis: Metformin accumulation increases the risk of lactic acidosis. In case of dehydration, discontinue metformin and contact heath care professional Renal function: GFR should be assessed before treatment initiation and regularly thereafter. Cardiac function: 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. Administration of iodinated contrast agents: 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. Surgery: Metformin must be discontinued at the time of surgery under general, spinal or epidural anaesthesia. 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, overweight patients should continue their energy-restricted diet. The usual laboratory tests for diabetes monitoring should be performed regularly. Caution is advised when used in combination with insulin or other oral antidiabetics. Regular monitoring of thyroid-stimulating hormone (TSH) levels is recommended in patients with hypothyroidism. Monitoring of the vitamin B12 level is recommended. The tablet shells may be present in the faeces, this is normal. Voglibose: It should be administered with caution to the 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, and stenosis and ulcer of the large intestine) and patients with serious hepatic or renal disorders.

PREGNANCY & LACTATION: When a patient plans to become pregnant and during pregnancy, it is recommended that insulin be used to maintain blood glucose levels. Breast feeding is not recommended during metformin treatment.

ADVERSE REACTIONS: Metformin: Very common / common adverse events include nausea, vomiting, diarrhoea, abdominal pain, loss of appetite and taste disturbance. Voglibose: Gastrointestinal adverse effects like diarrhea, loose stools, abdominal pain, constipation, anorexia, nausea, vomiting and heartburn, abdominal swelling, increased flatus may occur. Serious hepatic dysfunction accompanied with jaundice, increased AST, ALT may occur. When administered to patients with serious liver cirrhosis, hyperammonemia may worsen with the development of constipation, etc, followed by disturbance of consciousness. Hypoglycemia may occur.

For full prescribing information please write to Sanofi India Ltd., Sanofi House, CT Survey No 117-B, L&T Business Park, Saki Vihar Road, Powai, Mumbai 400072

Updated: Sept 2024
Source: 1) Metformin Hydrochloride CCDS V1 dated 25th Mar 2021 2) VOLICOSE 0.2/0.3 mg Prescribing Information, Mfg by Biocon Ltd accessed on 6th Sept 2024