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 another component of this product ; renal disease or renal dysfunction (e.g., as suggested by serum creatinine levels ≥ 1.5mg/dL (males), ≥ 1.4 mg/dL (females) or abnormal creatinine clearance) which may also result from conditions such as cardiovascular collapse, acute myocardial infarction and septicaemia; acute or chronic metabolic acidosis including diabetic ketoacidosis with or without coma. Cetapin V should be temporarily discontinued in patients undergoing radiologic studies. Not to be used in patients with severe ketosis or in a state of diabetic coma or precoma, severe infections before or after operation or with severe trauma, Gastrointestinal obstruction or predisposed to it, Excessive alcohol intake, acute or chronic, Pregnancy and lactation
WARNINGS: If lactic acidosis is suspected, discontinue Cetapin V and institute general supportive measures in a hospital setting. Prompt hemodialysis is recommended.. . For patients undergoing basic treatment for diabetes mellitus, voglibose should be given when 2-hr post prandial blood sugar is 200mg/dl or more. For patients on oral hypoglycemic drugs or insulin preparations, in addition to dietary treatment and/or exercise therapy, voglibose is to be given when the fasting blood sugar is about 140mg / dl or more. Closely monitor blood sugar at regular intervals.
PRECAUTIONS : No clinical studies establishing conclusive evidence of macrovascular risk reduction with metformin or any other anti-diabetic drug. Before initiation of Cetapin V therapy and annually while on Cetapin V therapy renal function should be assessed and verified as being within normal range. Concomitant medication that may affect renal function or result in significant hemodynamic change or may interfere with disposition of metformin should be used with caution. Intravascular contrast studies with iodinated material can lead to acute alteration of renal function, hence metformin should be temporarily discontinued in whom such studies are planned. Drug should be promptly discontinued in case of cardiovascular collapse, acute congestive heart failure, acute myocardial infarction and other conditions characterized by hypoxemia (may be associated with lactic acidosis). Cetapin V must be temporarily suspended before surgical intervention. Regular monitoring of thyroid-stimulating hormone (TSH) levels is recommended in patients with hypothyroidism . 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.Alcohol potentiates effect of metformin on lactate metabolism therefore patients should be warned against excessive alcohol intake. Cetapin V is to be avoided in patients with clinical or laboratory evidence of hepatic disease. Measurement of serum vitamin B12 levels every two to three years is recommended. Patient with Type II diabetes, previously well controlled on metformin, who develops laboratory abnormality or clinical illness should be promptly evaluated for lactic acidosis or ketoacidosis. Hypoglycemia could occur when caloric intake is deficient or strenuous exercise is not compensated. Withhold Cetapin V and temporarily administer insulin in case of temporary loss of glycemic control due to fever, trauma, infection or surgery. Periodic measurements of fasting blood glucose and glycosylated haemoglobin levels are required. Initial and periodic monitoring of hematologic parameters and renal function should be performed on annual basis. Administer carefully in patients receiving other antidiabetic drugs or with a history of laparotomy or ileus or with chronic intestinal disease accompanied by a disturbance in digestion and absorption or with Roemheld's syndrome, severe hernia or stenosis or ulceration of the large intestine or with serious hepatic dysfunction or with serious renal dysfunction.

PREGNANCY & LACTATION: Should not be used in pregnancy unless clearly needed. Avoid administration of voglibose in lactation, however, if the administration is indispensable, nursing should be discontinued. Safety and efficacy in paediatric patients has not been established.
ADVERSE REACTIONS: 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. Metformin : Commonly reported adverse events include diarrhoea, nausea, vomiting.

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

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Source: **CCDS ver version 8 dated June 2016 for Glimepride + Metformin +Metformin GLU ver 1 dt March 2015 and ver 2 dt July 2015 + Glucophage XR leaflet dated May 2018 +** VOLICOSE - 0.2/0.3 mg Prescribing Information, Mfg by Biocon Ltd accessed on 09th April 2021