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

Abridged Prescribing Information
Metformin Hydrochloride (SR), Glimepiride, & Voglibose Tablets
Amaryl® MV 1mg
Amaryl® MV 2mg

COMPOSITION
Amaryl® MV 1mg: Each uncoated bilayered tablet contains Metformin hydrochloride IP 500mg (in sustained release form) + Glimepiride IP 1mg + Voglibose IP 0.2mg
Amaryl® MV 2mg: Each uncoated bilayered tablet contains Metformin hydrochloride IP 500mg (in sustained release form) + Glimepiride IP 2mg + Voglibose IP 0.2mg

THERAPEUTIC INDICATION: As third line treatment of Type II diabetes mellitus in adult patients when diet, exercise and the single agents and second line therapy with two drugs do not result in adequate glycemic control.

DOSAGE AND ADMINISTRATION:
General: Usual recommended dose for adults: 1 tablet of Amaryl® MV twice a day before meals. Additionally, voglibose tablets may be taken before the remaining meal, as prescribed by the physician. Amaryl® MV must be swallowed whole and not crushed or chewed.
Children: Data insufficient to recommend pediatric use of Amaryl® MV

Renal impairment: A GFR should be assessed before initiation of treatment with metformin containing products and at least annually thereafter. The maximum daily dose of metformin should preferably be divided into 2-3 daily doses. Factors that may increase the risk of lactic acidosis (see section Warnings) should be reviewed before considering initiation of metformin in patients with GFR<60 mL/min. If no adequate strength of Amaryl® MV is available, individual monocomponents should be used instead of the fixed dose combination.

SAFETY RELATED INFORMATION
CONTRAINDICATIONS: In patients hypersensitive to glimepiride, other sulfonylureas, other sulfonamides, metformin, voglibose or any of the excipients; pregnant women; breast-feeding women. No experience in sever liver function impairment and in dialysis patient. Any type of acute metabolic acidosis (such as lactic acidosis, diabetic ketoacidosis, diabetic pre-coma), severe renal failure (GFR<30ml/min),acute conditions with the potential to alter renal function (dehydration, severe infection, shock, intravascular administration of iodinated contrast agents); acute or chronic disease which may cause tissue hypoxia (cardiac failure or respiratory failure, recent myocardial infarction, shock); hepatic insufficiency; acute alcohol intoxication; alcoholism; severe infections or trauma, gastrointestinal obstruction or predisposed to it.

WARNINGS: *For Glimepiride*: In exceptional stress situations (e.g. trauma, surgery, febrile infections) blood glucose regulation may deteriorate, switch to insulin may be required. *For Metformin*: Metformin accumulation occurs at acute worsening of renal function and increases the risk of lactic acidosis. In case of dehydration (severe diarrhoea or vomiting, fever or reduced fluid intake), metformin should be temporarily discontinued and contact with a health care professional is recommended. GFR should be assessed before treatment initiation and regularly thereafter. Metformin is contraindicated in patients with GFR<30 ml/min and should be temporarily discontinued. Postmarketing cases of metformin-associated lactic acidosis have resulted in death, hypothermia, hypotension, and resistant bradyarrhythmias. Symptoms included malaise, myalgias, respiratory distress, somnolence, and abdominal pain. Intravascular administration of iodinated contrast agents may lead to contrast induced nephropathy, resulting in metformin accumulation and an increased risk of lactic acidosis. Amaryl® MV to be discontinued at the time of imaging procedure and not restarted until at least 48 hours after provided that renal function is stable. Amaryl® MV must be discontinued at the time of surgery with general, spinal or epidural anaesthesia.
PRECAUTIONS: *For Glimepiride*: Risk of hypoglycaemia. Treatment of patients with G6PD-deficiency with sulfonylurea agents can lead to hemolytic anaemia. *For Metformin*: 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. *For Voglibose*: Voglibose tablets 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: Not be taken during pregnancy / lactation. Must change over to insulin.

ADVERSE REACTIONS: Some frequent adverse reactions include Hypoglycaemia, eye disorders, gastrointestinal disorders such as nausea, vomiting, diarrhoea, abdominal pain, heartburn and loss of appetite, blood & lymphatic disorders, metallic taste, abdominal distention, increased flatus and intestinal obstruction like symptoms.

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) CCDS 11 dated 17th October 2017 for Glimepiride plus Metformin Fixed Dose Combination
2) VOLICOSE - 0.2/0.3 mg Prescribing Information, Mfg by Biocon Ltd accessed on 6th Sept 2024.