

Metformin Hydrochloride Prolonged Release 500 mg And Glimepiride 0.5 mg Tablets I.P. Semi-Amaryl[®] M

Abridged Prescribing Information

COMPOSITION

Semi-Amaryl M : Each uncoated bilayered tablet contains glimepiride I.P. 0.5 mg and metformin hydrochloride I.P. (as prolonged release form) 500mg.

THERAPEUTIC INDICATIONS : As an adjunct to diet and exercise in Type 2 diabetes mellitus when monotherapy, is not able to achieve glycemic control.

DOSAGE AND ADMINISTRATION

Initial dose : 1 tablet of Semi-Amaryl M should be administered once daily during breakfast or the first main meal. Maximum dosing : 8mg of glimepiride and 2000mg of metformin Do not crush or chew the tablet.

Renal impairment

A GFR should be assessed before initiation of treatment with metformin containing products and at least annually thereafter. In patients at 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.

SAFETY-RELATED INFORMATION

CONTRAINDICATIONS: Hypersensitivity to glimepiride, other sulfonylureas, other sulfonamides, metformin, or any of the excipients of Semi-Amaryl M; pregnant women; breast-feeding women; 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 or respiratory failure, recent myocardial infarction, shock); hepatic insufficiency; acute alcohol intoxication; alcoholism.

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 increases the risk of lactic acidosis. In case of suspected symptoms, the patient should stop taking metformin and seek immediate medical attention. GFR should be assessed regularly. Intravascular administration of iodinated contrast agents may lead to contrast induced nephropathy, resulting in an increased risk of lactic acidosis. Semi-Amaryl M to be discontinued under conditions that alter renal function, at the time of imaging procedure, surgery with general, spinal or epidural anaesthesia and not restarted until at least 48 hours after provided that renal function is stable.

PRECAUTIONS: Risk of hypoglycaemia. Treatment of patients with G6PD can lead to hemolytic anaemia. 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. Overweight patients should continue their energy-restricted diet usual laboratory tests for diabetes monitoring should be performed regularly. Metformin used in combination with insulin or sulfonylureas may cause hypoglycaemia.

PREGNANCY AND LACTATION: Contraindicated in pregnancy and lactation; switch to insulin recommended. Data insufficient to recommend use in paediatric patients.

ADVERSE REACTIONS: *For glimepiride* - Hypoglycaemia may occur and may also be prolonged; temporary visual impairment; gastrointestinal symptoms (e.g., nausea, vomiting, abdominal pain, sensation of fullness in epigastrium, diarrhoea) may occur; hepatitis, elevation of liver enzymes, cholestasis and jaundice may occur; change in blood picture may occur; allergic reactions or pseudo allergic reactions may occur occasionally. Like all sulfonylureas, it can cause weight gain. *For metformin* – GI symptoms, metallic taste, mild erythema, decrease in Vit B12 absorption, very rarely lactic acidosis, hemolytic anemia, reduction of thyrotropin level in patients with hypothyroidism, hypomagnesemia in the context of diarrhea, encephalopathy, photosensitivity, hepatobiliary disorders.

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 : 8th March 2019

Reference : CCDS Version 11 dated 17th October 2017 for (Glimepiride plus Metformin Fixed Dose Combination)