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

Abridged Prescribing Information

Metformin Hydrochloride Prolonged Release 1000mg and Glimepiride 1mg/2mg Tablets IP
Amaryl® M Forte 1mg and 2mg

COMPOSITION

Each uncoated bilayered tablet contains: Metformin hydrochloride IP (as prolonged release) 1000mg + Glimepiride IP 1mg / 2mg

THERAPEUTIC INDICATIONS

For the management of type 2 diabetes mellitus when diet, exercise and single agent (glimepiride or metformin alone) do not result in adequate glycaemic control.

DOSAGE AND ADMINISTRATION

Initial dose: 1 tablet of Amaryl M Forte 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 age > 65 years, 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 Amaryl M Forte; 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. 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 an increased risk of lactic acidosis. 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. *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), Amaryl® M Forte 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 Amaryl® M Forte, treatment with Amaryl® M Forte should be withdrawn immediately and prompt diagnostic evaluation should be performed. **Precautions:** Risk of hypoglycemia. 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

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