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

DAONIL® M
Glibenclamide and Metformin Hydrochloride Sustained Release Tablets

Abridged Prescribing Information

COMPOSITION
Daonil® M: Each tablet contains Glibenclamide IP 5mg + Metformin Hydrochloride IP 500mg (in sustained release form)

THERAPEUTIC INDICATIONS
For the management of type II diabetes mellitus when diet, exercise and single drug therapy do not result in adequate glycemic control.

DOSAGE AND ADMINISTRATION
Initial dose: 1 tablet of Daonil M should be administered once daily with meals. Maximum Dosing: For once daily administration maximum 2 tablets of Daonil M can be given. For higher doses, it may be necessary to administer in 2 doses. Upto 4 tablets of Daonil M can be given per day. 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: Daonil®M must not be used in patients with known hypersensitivity to glibenclamide or metformin or any excipients, in patients with insulin-dependent (type 1) diabetes mellitus, any type of acute metabolic acidosis (such as lactic acidosis, diabetic ketoacidosis, diabetic pre-coma or coma), acute conditions with the potential to alter renal function such as dehydration, severe infection, shock), disease which may cause tissue hypoxia (especially acute disease, or worsening of chronic disease) such as: decompensated heart failure, respiratory failure, recent myocardial infarction, shock, in patients with severe renal failure (GFR <30 mL/min), in patients with serious hepatic dysfunction, alcoholism (acute, chronic), in pregnant women, in breast feeding women, in patients treated with bosentan.
Warnings: Glibenclamide may be associated with an increased risk of cardiovascular mortality, when compared to treatment with metformin or gliclazide. This risk was especially observed in patients with diagnosed coronary diseases. The patient should be trained to recognize the first signs of hyperglycaemia so as to be able to inform the doctor in good time. In exceptional stress situations blood glucose regulation may deteriorate, and a temporary change to insulin may be necessary. Persons allergic to other sulfonamide derivatives may develop an allergic reaction. Metformin accumulation occurs at acute worsening of renal function and increases the risk of lactic acidosis. In case of dehydration metformin should be temporarily discontinued, Medicinal products that can acutely impair renal function should be initiated with caution. Other risk factors associated lactic acidosis are excessive alcohol intake, hepatic insufficiency, inadequately controlled diabetes, ketosis, prolonged fasting and any conditions associated with hypoxia, as well as concomitant use of medicinal products that may cause lactic acidosis. In case of suspected symptoms, the patient should stop taking metformin and seek immediate medical attention. Diagnostic laboratory findings are decreased blood pH (< 7.35), increased plasma lactate levels (>5 mmol/l) and an increased anion gap and lactate/pyruvate ratio. Patients with heart failure are at higher risk of hypoxia and renal insufficiency. In patients with stable chronic heart failure, metformin may be used with a regular monitoring of cardiac and renal functions. For patients with acute or unstable heart failure, metformin is contraindicated. GFR should be assessed before treatment initiation and regularly thereafter. Intravascular administration of iodinated contrast agents may lead to contrast induced nephropathy, resulting in metformin accumulation and an increased risk of lactic acidosis. Metformin should be discontinued prior to or at the time of the imaging procedure and not restarted until at least 48 hours after. Metformin must be discontinued at the time of surgery under general, spinal or epidural anesthesia. Therapy may be restarted no earlier than 48 hours following surgery or resumption of oral nutrition.
Precautions : To achieve the goal of treatment with Daonil®M - optimal control of blood glucose, adherence to correct diet, regular and sufficient physical exercise and, if necessary, reduction of body weight are just as necessary as regular ingestion of Daonil®M. Glucose levels in blood and urine must be measured regularly. Regular determinations of the proportion of glycated haemoglobin may be carried out. Patient and the physician must be aware of the risk of hypoglycaemia. If risk factors for hypoglycaemia are present, it may be necessary to adjust the dosage of Daonil®M or the entire therapy. Elderly patients are particularly susceptible to hypoglycemic action of glucose-lowering drugs. Hypoglycaemia can, almost always, be promptly controlled by immediate intake of carbohydrates. Treatment of patients with G6PD-deficiency with sulfonylurea agents can lead to hemolytic anaemia. Caution is advised when metformin is used in combination with insulin or other oral antidiabetics. 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
Pregnancy & Lactation: Contraindicated in pregnancy and lactation; patients must switch to insulin during pregnancy or when planning pregnancy. Patients may change over to insulin when breast feeding or must stop breast feeding.
Adverse Reactions: Very common and common adverse reactions : Nausea, vomiting, abdominal pain, diarrhoea, rashes. Hypoglycaemia, sometimes prolonged and even life-threatening, may occur. The clinical picture of a severe hypoglycemic attack may resemble that of a stroke. Like all sulfonylureas glibenclamide can cause weight gain. Loss of appetite (very common) and metallic taste (common frequency).

For full prescribing information write to Sanofi India Ltd, Sanofi House, CT Survey No 117-B, L&T Business Park, Saki Vihar Road, Powai, Mumbai 400072
Updated: July 2022
Sources: Metformin and Glibenclamide combination CCSI Version 3 dated 31st May 2018