DAONIL® & SEMI-DAONIL®

Glibenclamide Tablets I.P.

THERAPEUTIC CATEGORY
Antidiabetic

COMPOSITION
DAONIL® - Each uncoated tablet contains Glibenclamide I.P. 5.0 mg.
SEMI-DAONIL® - Each uncoated tablet contains Glibenclamide I.P. 2.5 mg.

THERAPEUTIC INDICATIONS
Non-insulin-dependent (type 2) diabetes mellitus, whenever blood glucose levels cannot be controlled adequately by diet, physical exercise, and weight reduction alone. When the efficacy of Daonil/ Semi-Daonil decreases (partial secondary failure) it can be given together with insulin. Can be combined with other, non-betacytotropic oral antidiabetics.

DOSAGE AND ADMINISTRATION
Usual initial dose: ½ to 1 tablet Daonil 5 mg or 1 to 2 tablets Semi-Daonil 2.5 mg, respectively, once daily. If necessary, the daily dose can be raised gradually, i.e. in increments of no more than ½ tablet Daonil 5 mg or 1 tablet Semi-Daonil 2.5 mg, respectively, and at intervals of one to two weeks, and that the increase be guided by regular blood glucose monitoring.
As data on the safety and effectiveness in children is not available, Daonil/ Semi-Daonil is not recommended for this age group.

SAFETY-RELATED INFORMATION
Contraindications: Should not be used in patients with insulin-dependent (type 1) diabetes mellitus (for example diabetics with a history of ketoacidosis), in treatment of diabetic ketoacidosis , in treatment of diabetic precoma or coma, in patients with serious renal dysfunction, in patients with serious hepatic dysfunction, in patients hypersensitive to glibenclamide, in patients hypersensitive to any of the excipients, in patients treated with bosentan, in pregnant women and in breast feeding women.
Precautions & Warnings: Glibenclamide - Epidemiological studies suggest that the administration of glibenclamide is associated with an increased risk of cardiovascular mortality, when compared to treatment with metformin or gliclazide. especially observed in patients with diagnosed coronary diseases.Clinical signs of hyperglycaemia are: increased urinary frequency, intense thirst, dryness of the mouth, and dry skin. In exceptional stress situations (e.g. trauma, surgery, febrile infections), 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 to glibenclamide. During treatment glucose levels in blood and urine must be measured regularly. Regular determinations of the proportion of glycated haemoglobin to be carried out. The patient and the physician must be aware of the risk of hypoglycaemia. The initial and maintenance dosing should be conservative to avoid hypoglycemic reactions, especially in elderly patients who are particularly susceptible to hypoglycemic action of glucose-lowering drugs. Hypoglycaemia can be promptly controlled by immediate intake of carbohydrates. Caution should be used in patients with G6PD-deficiency and a nonsulfonylurea alternative should be considered.
Pregnancy & Lactation: Contraindicated in pregnancy and lactation; switch to insulin recommended.
Adverse Reactions: Metabolism and nutrition disorders: Hypoglycaemia, sometimes prolonged and even life-threatening, may occur. Clinical picture of a severe hypoglycaemic attack may resemble that of a stroke. The symptoms of hypoglycaemia nearly always subside when hypoglycaemia is corrected.In isolated cases, sodium concentration in the serum may decrease. Eye disorders: Especially at the start of treatment, there may be temporary visual impairment due to the change in blood glucose levels. Gastrointestinal disorders : Occasionally gastrointestinal symptoms such as nausea, vomiting, sensation of pressure or fullness in the epigastrium, abdominal pain and diarrhoea may occur.Isolated cases of hepatitis, elevation of liver enzyme levels and / or cholestasis and jaundice. Blood and lymphatic system disorders: Potentially life-threatening changes in the blood picture may occur.Immune system disorders: Hypersensitivity reactions,Allergic or pseudoallergic reactions may occur. . In isolated cases, mild reactions in the form of urticaria may develop into serious and even life-threatening reactions with dyspnoea and fall in blood pressure, sometimes progressing to shock. In the event of urticaria, a physician must therefore be notified immediately. Skin and subcutaneous disorders: Itching,rashes,bullous reactions,erythema multiforme,dermatitis exfoliative have been observed. In isolated cases,hypersensitivity of the skin to light, may occur.Glibenclamide, like all sulfonylureas can cause weight gain.

For full prescribing information please write to : Sanofi House, CT Survey No 117-B, L&T Business Park, Saki Vihar Road, Powai, Mumbai 400072
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