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

Glimepiride Tablets IP

Semi-Amaryl® 0.5mg / Amaryl® 1mg/2mg/3mg

Abridged Prescribing Information

COMPOSITION
Tablets with 0.5mg, 1mg, 2mg, 3mg glimepiride. Oral antidiabetic agent of the sulphonylurea group.

THERAPEUTIC INDICATION
Non-insulin dependent (type 2) diabetes mellitus, whenever blood sugar levels cannot be controlled adequately by diet, physical exercise or weight reduction alone. Semi-Amaryl® / Amaryl® is not suitable for insulin-dependent (type 1) diabetes mellitus, diabetic ketoacidosis; diabetic precoma or coma. Semi-Amaryl® / Amaryl® may be combined with other non-betacytotropic oral anti-diabetic agents and may also be used with insulin.

DOSAGE AND ADMINISTRATION
Dosage is governed by desired blood glucose level. Dosage must be lowest which is sufficient to achieve the desired metabolic control. Regularly measure glucose levels in blood and urine. Mistakes like forgetting dose should not be corrected by subsequently taking larger dose. Usual initial dose is 0.5mg to 1mg once daily, usual daily dose is 1mg to 4mg in well-controlled patients. Daily dose of more than 6mg are more effective only in minority of patients. Not recommended in children.

SAFETY-RELATED INFORMATION
Contraindications : Hypersensitivity to glimepiride or other sulphonylureas or sulphonamides or any of its excipients; pregnant women; breast feeding women. No experience gained in patients with severe impairment of liver function and in dialysis patient.
Warnings: Temporary changeover to insulin may be necessary in exceptional stress situations (e.g., trauma, surgery, febrile infections).
Precautions : Risk of hypoglycaemia may be increased in initial weeks of treatment. Hypoglycaemia may be controlled by intake of carbohydrates. Symptoms of hypoglycaemia may be milder or absent in elderly patients and where there is autonomic neuropathy or patients receiving concurrent treatment with beta blockers, clonidine, reserpine, guanethidine or other sympatholytic drugs. Severe hypoglycaemia requires immediate treatment. Treatment of patients with G6PD deficiency with sulfonylurea agents can lead to haemolytic anemia. Non-sulfonyl urea alternative should be considered.
Pregnancy and Lactation : Contraindicated.
Adverse Reactions : Hypoglycaemia may occur and may also be prolonged; temporary visual impairment; gastrointestinal symptoms (e.g., nausea, vomiting, abdominal pain, sensation of fullness in epigastrum, 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 full prescribing information, please contact : Sanofi India Ltd., Sanofi House, CT Survey No 117-B, L&T Business Park, Saki Vihar Road, Powai, Mumbai 400072

Updated : April 2021

Source : CCDS Version 14 dated 12th May 2016