

COMPOSITION*: Diamicron MR 60 mg, modified release tablet containing 60 mg of gliclazide, contains lactose as an excipient. **INDICATION***: Non insulin-dependent diabetes (type 2) in adults when dietary measures, physical exercise and weight loss alone are not sufficient to control blood glucose. **DOSAGE AND ADMINISTRATION***: One half to 2 tablets per day i.e. from 30 to 120 mg taken orally as a single intake at breakfast time, including in elderly patients and those with mild to moderate renal insufficiency with careful patient monitoring. One tablet of Diamicron MR 60 mg is equivalent to 2 tablets of Diamicron MR 30 mg. The breakability of Diamicron MR 60 mg enables flexibility of dosing to be achieved. In patients at risk of hypoglycaemia, daily starting dose of 30 mg is recommended. Combination with other antidiabetics: Diamicron MR 60 mg can be given in combination with biguanides, alpha glucosidase inhibitors or insulin (under close medical supervision). **CONTRAINDICATIONS***: Hypersensitivity to gliclazide or to any of the excipients, other sulfonylurea or sulphonamides; type 1 diabetes; diabetic pre-coma and coma, diabetic ketoacidosis; severe renal or hepatic insufficiency (in these cases the use of insulin is recommended); treatment with miconazole (see interactions section); lactation (see fertility, pregnancy and lactation section). **WARNINGS***: Hypoglycaemia may occur with all sulfonylurea drugs, in cases of accidental overdose, when calorie or glucose intake is deficient, following prolonged or strenuous exercise and in patients with severe hepatic or renal impairment. Hospitalization and glucose administration for several days may be necessary. Patient should be informed of the importance of following dietary advice, of taking regular exercise and of regular monitoring of blood glucose levels. To be prescribed only in patients with regular food intake. Use with caution in patients with G6PD-deficiency. Excipients: contains lactose. **INTERACTION(S)***: Risk of hypoglycaemia – contraindicated: miconazole; not recommended: phenylbutazone; alcohol; use with caution: other antidiabetic agents, beta-blockers, fluconazole, ACE inhibitors (captopril, enalapril), H2-receptor antagonists, MAOs, sulfonamides, clarithromycin, NSAIDs. Risk of hyperglycemia – not recommended: danazol; use with caution: chlorpromazine at high doses; glucocorticoids; ritodrine; salbutamol; terbutaline; Saint John's Wort (hypericum perforatum) preparations. Risk of dysglycemia – use with caution: fluoroquinolones. Potentiation of anticoagulant therapy (e.g. warfarin), adjustment of the anticoagulant may be necessary. **PREGNANCY***: Change to insulin before a pregnancy is attempted, or as soon as pregnancy is discovered. **BREASTFEEDING***: contraindicated. **DRIVE & USE MACHINES***: Possible symptoms of hypoglycaemia to be taken into account especially at the beginning of the treatment. **UNDESIRABLE EFFECTS***: Hypoglycaemia, abdominal pain, nausea, vomiting, dyspepsia, diarrhea, constipation. Rare: changes in haematology generally reversible (anaemia, leucopenia, thrombocytopenia, granulocytopenia). Raised hepatic enzymes levels (AST, ALT, alkaline phosphatase), hepatitis (isolated reports). If cholestatic jaundice: discontinuation of treatment. Transient visual disturbances at start of treatment. More rarely: rash, pruritus, urticaria, angioedema, erythema, maculopapular rashes, bullous reactions such as Stevens-Johnson syndrome and toxic epidermal necrolysis and autoimmune bullous disorders, and exceptionally, drug rash with eosinophilia and systemic symptoms (DRESS). As for other sulfonylureas: observed cases of erythrocytopenia, agranulocytosis, haemolytic anaemia, pancytopenia, allergic vasculitis, hyponatraemia, elevated liver enzymes, impairment of liver function (cholestasis, jaundice) and hepatitis which led to life-threatening liver failure in isolated cases. **OVERDOSE***: Possible severe hypoglycaemia requiring urgent IV glucose, immediate hospitalization and monitoring. **PROPER- TIES***: Diamicron MR 60 mg is a sulfonylurea reducing blood glucose levels by stimulating insulin secretion from beta cells in the islets of Langerhans, thereby restoring the first peak of insulin secretion and increasing the second phase of insulin secretion in response to a meal or intake of glucose. Independent haemovascular properties. **PRESENTATION***: Box of 30 tablets of Diamicron MR 60 mg in blister. **SERVIER HONG KONG LIMITED**, Flat 08-09, 43/F, Times Square Tower One, 1 Matheson Street, Causeway Bay, Hong Kong. www.servier.hk. *For complete information, please refer to the **Summary of Product Characteristics**.