European Grade API

DIAMICRON® XR MEX 500

Gliclazide and metformin hydrochloride extended release tablets

1 ➡ 1½ ➡ 2

Original breakable tablet 

Trusted Partner

Rapid & Powerful glycemic control

Patients with type 2 diabetes...

Newly diagnosed | **Uncontrolled on Metformin**

Rapid & Powerful glycemic control[1,2]

HbA1c reduction of ≥1% within 3 months

Assurance of safety[2,3]

70% less risk of hypoglycemia

Life free of complications[3,4]

70% less risk of hospitalization for heart failure

API: Active pharmaceutical ingredient

1. Zaccardi et al. Diabetes Obesity & Metabolism 2020;1-10. 2. Schernthaner G et al. Eur J Clin Invest. 2004;34:535-542. 3. Tian J et al. Diabetes Care 2020;43:1293-1299. 4. Pedersen O et al. Diabetologia 2018;61:1724-1733.

DIAMICRON® XR MEX 500 is an extended release preparation containing gliclazide 60 mg and Metformin 500 mg in a Fixed Dose Combination. **COMPOSITION***: Each uncoated bi-layered scored tablet contains gliclazide I.P. (as extended release)… 60 mg; metformin hydrochloride I.P. (as extended release)… 500 mg; excipients. q.s. color: lake ponceau 4R **INDICATIONS***: DIAMICRON® XR MEX 500 is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. **DOSAGE AND METHOD OF ADMINISTRATION***: Dosage: The starting dose for DIAMICRON® XR MEX 500 is 1 tablet daily and should be increased to a maximum dose of 2 tablets daily only on the consultation of the doctor. DIAMICRON® XR MEX 500 tablet is a scored tablet and can be broken for sequential incremental increase in the dose to achieve the desired glycemic control. **Method and route of administration:** Oral route. The tablets must be taken whole, with half a glass of water just before breakfast. **CONTRAINDICATIONS***: Gliclazide and Metformin: Hypersensitivity to gliclazide, metformin or to any of the excipients, other sulfonylurea or sulphonamide; 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); cardiac failure, severe impairment of thyroid function acute and chronic alcoholism; disease which may cause tissue hypoxia; pregnancy and lactation (see fertility, pregnancy and lactation section). **WARNINGS***: Gliclazide Hypoglycemia 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, 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. Metformin: Metformin accumulation occurs with acute worsening of renal function and increases the risk of lactic acidosis. In patient with stable chronic heart failure, metformin should be used with a regular monitoring of cardiac and renal function. GFR should be assessed before treatment initiation and regularly thereafter. If eGFR < 30 mL/min/ 1.73m^2, discontinue metformin. Metformin should be discontinued temporarily prior to the administration of intravenous contrast media and prior to any surgical procedure and should not be re-administered any sooner than 48 hours after such procedures and should be withheld until renal function is determined to be normal. Metformin alone does not cause hypoglycaemia, but caution is advised when it is used in combination with insulin or other oral anti-diabetic treatment (sulfonylureas or meglitinides). **INTERACTION(S)***: Gliclazide Risk of hypoglycaemia- contraindicated: combination with miconazole; not recommended: phenylbutazone; alcohol; use with caution: other antidiabetic agents, beta-blockers, fluconazole, ACE inhibitors (captopril, enalapril), H2-receptor antagonists, MAOIs, sulfonamides, clarithromycin, NSAIDs. Risk of hyperglycemia not recommended: danazol; use with caution: chlorpromazine at high doses; glucocorticoids; ritodrine; salbutamol; terbutaline, St John's Wort (Hypericum Perforatum) preparations. Risk of dysglycaemia- use with caution: fluoroquinolones. Potentiation of anticoagulant therapy (e.g. warfarin), adjustment of the anticoagulant may be necessary. Metformin Concomitant use of metformin with specific drugs like ACE inhibitors, di-isopyramide, MAOIs and Cimetidine may increase the risk of metformin-associated lactic acidosis: those that impair renal function, result in significant hemodynamic change, interfere with acid-base balance, or increase metformin accumulation. Consider more frequent monitoring of patients. **PREGNANCY***: Gliclazide Change to insulin before a pregnancy is attempted, or as soon as pregnancy is discovered. Metformin The use of metformin in pregnant women does not indicate an increased risk of congenital abnormalities and switch to insulin to maintain blood glucose level as close to normal as possible. **BREASTFEEDING***: Gliclazide Contraindicated. Metformin No adverse effect were observed in breastfed newborns/infants DIAMICRON® XR MEX 500 mg should not be used during pregnancy and lactation. **FERTILITY***: Gliclazide/Metformin No effect on fertility or reproductive performance in male and female rats. **DRIVE AND USE MACHINES***: Possible symptoms of hypoglycemia to be taken into account especially at the beginning of the treatment. **UNDESIRABLE EFECTS***: Gliclazide Hypoglycemia, abdominal pain, nausea, vomiting, dyspepsia, diarrhea, constipation. Rare: changes in hematology 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 state of treatment. More rarely: rash, pruritus, urticaria, angioedema, erythema, maculopapular rashes, bullous reactions such as Stevens-Johnson syndrome and toxic epidermal necrolysis, 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. Metformin Very rare effect like Lactic acidosis, decrease of vitamin B12 absorption with decrease of serum levels, isolated reports of liver function tests abnormalities or hepatitis resolving upon metformin discontinuation and Skin reactions such as erythema, pruritus, urticarial and megaloblastic anaemia. Very common effect like taste disturbance, gastrointestinal disorders such as nausea, vomiting, diarrhoea, abdominal pain and loss of appetite are observed. **OVERDOSE***: Gliclazide Possible severe hypoglycemia requiring urgent IV glucose, immediate hospitalization and monitoring. Metformin Lactic acidosis may occur. Accumulated drug needs to be removed by hemodialysis.

DIAMICRON® XR MEX 500: June 2021.

*For complete information, including other special warnings and precautions for use, please refer to the full prescribing information (available on request).

Disclaimer: The people shown in this document are being used for illustrative purposes only and are professional models

For the use of a registered medical practitioner, hospital, nursing home or laboratory only.

SERVIER

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