DIAMICRON® MR 60
Gliclazide
Scored Tablets
YOUR TRUSTED PARTNER

Up to 2 tablets daily
at breakfast

EFFECTIVENESS OF DIAMICRON® MR VS SITAGLIPTIN IN REAL WORLD EVIDENCE[1]

Comparative effectiveness of DIAMICRON® MR vs sitagliptin as second-line treatment after metformin monotherapy in patients with uncontrolled type 2 diabetes

AIM

- To compare the effectiveness and safety of DIAMICRON® MR to sitagliptin as type 2 diabetes (T2D) treatments in a real-world patient population.

METHODS

- A retrospective cohort study used records from the UK Clinical Practice Research Datalink (CPRD)
- The cohort consisted of adult patients with T2D and glycated hemoglobin (HbA1c) level of ≥7.0%
- Newly treated with either DIAMICRON® MR or sitagliptin as 2nd-line treatment added to metformin

1986
patients included

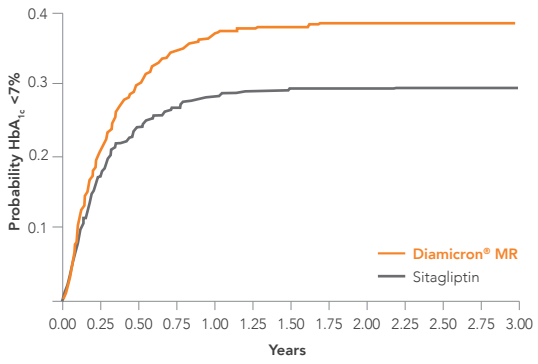
n=993
Diamicron® MR

n=993
Sitagliptin

RESULTS

Primary outcome:

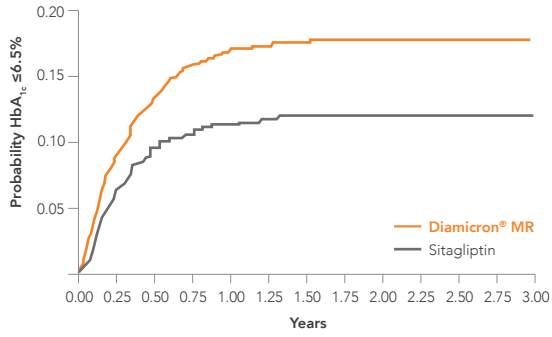
Time to HbA1c <7%



35% more likely to reach HbA1c <7%
HR [95% CI]: 1.35 [1.15-1.57]

Secondary outcome:

Time to HbA1c ≤6.5%



51% more likely to reach HbA1c ≤6.5%
HR [95% CI]: 1.51 [1.19-1.92]

- A rapid separation of probability curves, with patients in the DIAMICRON® MR group more likely to achieve HbA1c control starting at approximately 3 months

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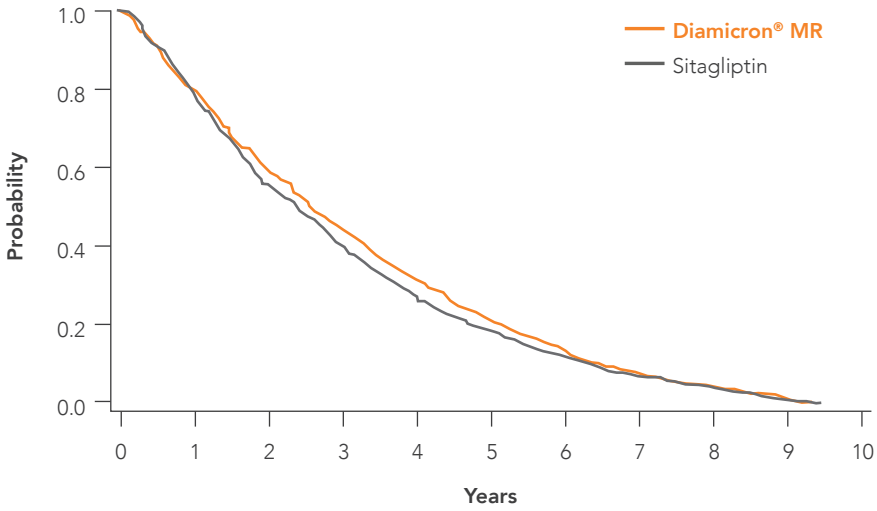
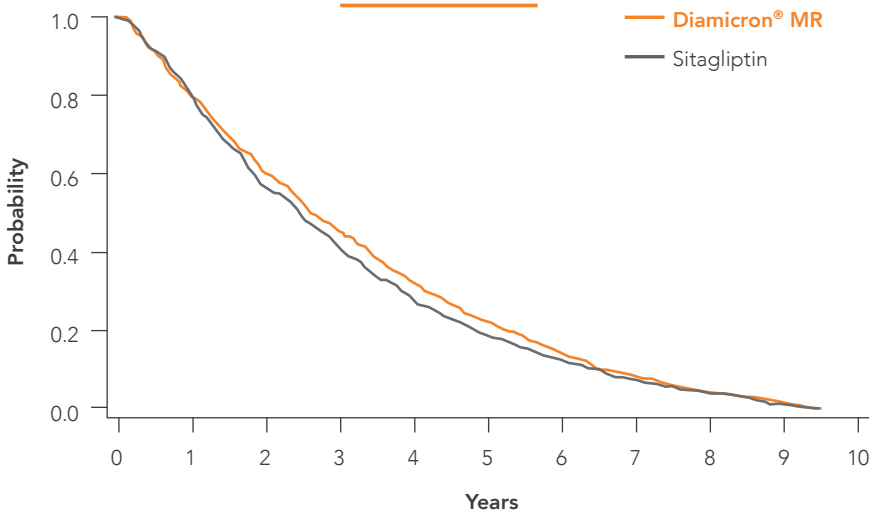
CI, confidence interval; HbA1c, glycated hemoglobin; HR, hazard ratio; MR, modified release.

DURABILITY AND PERSISTENCE WERE SIMILAR BETWEEN DIAMICRON MR AND SITAGLIPTIN

Durability*



Persistence**



* Durability defined as the treatment duration until stop, switch or add-on of a new glucose-lowering drug

** Persistence defined as the treatment duration until stop or switch, regardless of add-on glucose-lowering drug

Log-rank test: durability p=0.135; persistence p=0.119. MR, modified release.

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VERY LOW RATE OF HYPOGLYCEMIC EVENTS

	Rate (per 1,000 patient years)	
	DIAMICRON® MR	Sitagliptin
Total number of hypoglycemia events	4.7	2.6

Hypoglycemic events were uncommon (total 23 events; incidence rate, 3.7 events per 1,000 patient years), 4.7 and 2.6 events per 1,000 patient years with DIAMICRON® MR and sitagliptin treatments respectively

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MR, modified release.

Reference: 1. Zaccardi F, et al. Diabetes Obes Metab. 2020 Dec;22(12):2417-2426.

COMPOSITION*: Diamicron MR 60 mg, modified release tablet containing 60 mg of Diamicron®, 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 Diamicron® 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, MAOIs, 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. **PROPERTIES*** 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. **LES LABORATOIRES SERVIER**, 50 rue Carnot, 92284 Suresnes cedex France. **www.servier.com**

For healthcare professional only. **For complete information, please refer to the complete summary of product characteristics.*

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