LAFORMIN G-1 / G-2

Glimepiride 1 mg / 2 mg & Metformin (SR) 500 mg Tablets

LAFORMIN G-1 Forte / G-2 Forte

Glimepiride 1 mg / 2 mg & Metformin (SR) 1000 mg Tablets

Background:

According to ADA & EASD consensus guidelines, many patients can be managed effectively with monotherapy, but disease is progressive. So they will require use of combination therapy in many, if not in most patients over time to maintain glycaemia in target range.

When adding second drug, synergy of particular combination and other interactions should be considered. Antihyperglycaemic agents with different mechanisms of action will have greatest synergy.

Description:

Laformin G-1/G-2 and **G-1 Forte/G-2 Forte** uncoated bilayer Tablet is Oral Anti hyperglycemic tablet containing Glimepiride and Metformin used in the management of Type 2 Diabetes Mellitus. **Laformin G-1/G-2** and **G-1 Forte/G-2 Forte** contain Metformin and Glimepiride used, in particular, in Overweight and Obese people.

Indication:

Laformin G-1/G-2 and **G-1 Forte/G-2 Forte** is indicated as an adjunct to diet and exercise to improve glycemic control in patients with type-2 diabetes whose diabetes is not adequately controlled with metformin alone, or for those patients who have initially responded to glimepiride alone and require additional glycemic control.

Key Features of Laformin G-1/G-2 and G1 Forte/G2 Forte

- Glimepiride and Metformin act complementary to each other.
- Both compounds have a synergistic antihyperglycaemic effect without increasing the adverse effects of either pharmacological class
- **Laformin G-1/G-2** and **G-1 Forte/G-2 Forte** provide Dosage Flexibility, hence Better compliance.
- **Laformin G-1/G-2** and **G-1 Forte/G-2 Forte** do not cause Hypoglycemia
- **Laformin G-1/G-2** and **G-1 Forte/G-2 Forte** is associated with less weight gain compared to other drug therapies.

Dosage:

Laformin G-1/G-2 and **G-1 Forte/G-2 Forte** should be given once daily with meals and should be started at a low dose. Dosage should be individualized on the basis of both effectiveness and tolerance.

The initial recommended dose is one tablet once daily with breakfast or first main meal of the day.

Presentation:

Laformin G-1/G-2 and **G-1 Forte/G-2 Forte** is available as a strip of 10 Tablets in ALU-PVDC Blister Packing.

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The combination of Glimepiride and Metformin addresses the 2 central defects of Type 2 diabetes in a complementary manner

Glimepiride improves beta cell function & increases insulin synthesis and release

Metformin has insulin sensitizing properties

Glimepiride reduces HGO through suppression of glucagon from alpha cells

Hepatic Glucose Overproduction (HGO)

Metformin decreases HGO by targeting the liver to decrease gluconeogenesis & glycogenolysis

Potential advantages of early combination therapy:

- Earlier achievement of therapeutic goals.
- Potential reduction in risk of side effects if you combine drugs at lower doses versus up-titration of single dose.
- Opportunity to combine oral antidiabetic drugs with complementary modes of action.
- Potential to delay disease progression.

Efficacy and safety of early combination therapy with glimepiride/metformin to metformin uptitration in reducing (HbA1c) levels in type 2 diabetic patients:

Group	n	Baseline Mean ± SD	End of study Mean ± SD	Change G/M FDC vs Met UP
HbA1c (%)				
G/M FDC	99	7.9 ± 0.8	6.6 ± 0.7	-0.4 (-0.6 to -0.3)
Met UP	103	7.8 ± 0.8	7.0 ± 0.7	
FBG (mg/dl)				
G/M FDC	98	156.7 ± 33.2	117.3 ± 21.0	-17.1 (-22.8 to -11.5)
Met UP	103	148.1 ± 26.9	133.0 ± 20.3	
PPBG (mg/dl)				
G/M FDC	97	233.6 ± 66.7	180.9 ± 57.3	-8.1 (-22.4 to -6.3)
Met UP	102	228.0 ± 69.0	187.4 ± 52.1	

- Glimepiride/metformin FDC was more effective in glycemic control and well tolerated in type 2 diabetic patients than metformin uptitration.

Reference: J Diabetes Investig. 2014 Nov;5(6):701-8.

Clinical Study

Efficacy and Tolerability of Glimepiride and Metformin Combination

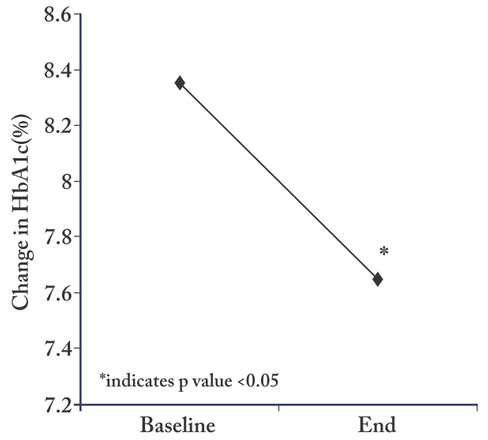
- A prospective, open-labeled, single-arm, Multicentric study was conducted, over a period of 12 weeks.
- A total of 177 patients were screened for the study, of which 84 patients were screening failures and the remaining 93 patients enrolled in this study. Out of 93 patients, 76 patients completed the 12 weeks' treatment period as outpatients.
- The primary efficacy endpoints HbA1c, Fasting Plasma Glucose (FPG) and post prandial glucose (PPG) were observed at the end of the study.

HbA1c (%), FPG, PPG (mg/dL) changes from baseline to end point :

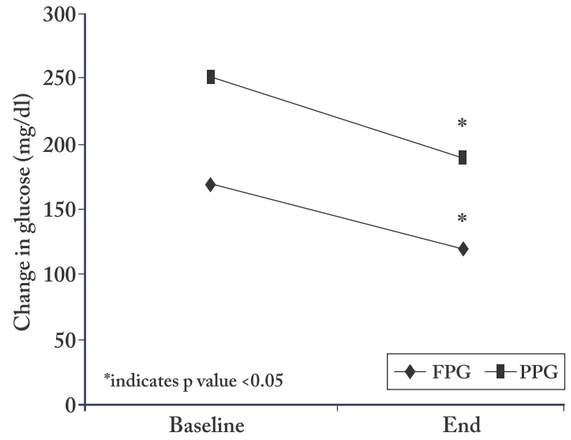
Parameters	HbA1c (%)	FPG (mg/dl)	PPPG (mg/dl)
Baseline	8.35 ± 0.93	168.76 ± 31.03	251.20 ± 60.05
Week 12	7.65 ± 1.70	119.59 ± 36.98	188.17 ± 56.49
Change from baseline	-0.70 ± 1.55	-49.17 ± 46.69	-63 ± 70.83

Mean changes in laboratory values at end of therapy from baseline

Parameters	Baseline (mean ± SD)	Day 90 (mean ± SD)	P value
LDL (mg/dL)	111.63 ± 28.64	103.05 ± 36.03	0.051
HDL (mg/dL)	43.41 ± 9.38	38.70 ± 12.89	0.016
TC (mg/dL)	189.65 ± 35.49	181.66 ± 36.86	0.069
TGs (mg/dL)	210.08 ± 114.29	178.55 ± 83.81	0.013



Change in HbA1c (%) from baseline to end (n=93).



Change in FPG and PPG values from baseline to end of the therapy.

HbA1c, FPG and PPPG level were significantly reduced and it showed the combination of glimepiride with metformin achieves good glycemic control with better tolerability profile.

Reference: Am J Ther. 2013 Jan;20(1):41-7