Laformin GP-1 / GP-2

Glimepiride 1mg/2mg + Metformin 500 mg (SR) + Pioglitazone 15mg Tablets

Description:

Laformin GP-1 and GP-2 is a Triple drug Combination consists of Glimepiride, Pioglitazone and Metformin Extended Release for the treatment and management of type-2 diabetes mellitus in adults.

Indication:

LAFORMIN GP-1/GP-2 Tablets are indicated once daily, as an adjunct to diet and exercise, to lower blood glucose. It is indicated as second-line therapy when diet, exercise, and the single agents or dual therapy do not result in adequate glycemic control in patients with type-2 diabetes.

Mechanism of Action:

Glimepiride:

The primary mechanism of action of glimepiride in lowering blood glucose appears to be dependent on stimulating the release of insulin from functioning pancreatic beta cells.

Metformin:

Metformin improves glucose tolerance in patients with type-2 diabetes (NIDDM), lowering both basal and postprandial plasma glucose. Metformin decreases hepatic glucose production, decreases intestinal absorption of glucose, and improves insulin sensitivity by increasing peripheral glucose uptake and utilization.

Pioglitazone:

It selectively stimulates the nuclear receptor peroxisome proliferator activated receptor gamma (PPAR-γ). It modulates the transcription of the insulin-sensitive genes involved in the control of glucose and lipid metabolism in the muscle, adipose tissue, and the liver. As a result, pioglitazone reduces insulin resistance in the liver and peripheral tissues; increases the expense of insulin-dependent glucose; decreases withdrawal of glucose from the liver; reduces quantity of glucose, insulin and glycated hemoglobin in the bloodstream.

Dosage and Administration:

- LAFORMIN GP 1 / GP 2 should be given once daily with the first meal of the day.
- There is no fixed dose regimen for the management of hyperglycemia in patients with type 2 diabetes with this combination or any other pharmacological agent.
- Dose should be individualized on the basis of both effectiveness and tolerance, while no exceeding the maximum recommended daily dose.
- The maximum recommended daily dose of this combination in adults should not exceed 3 tablets.

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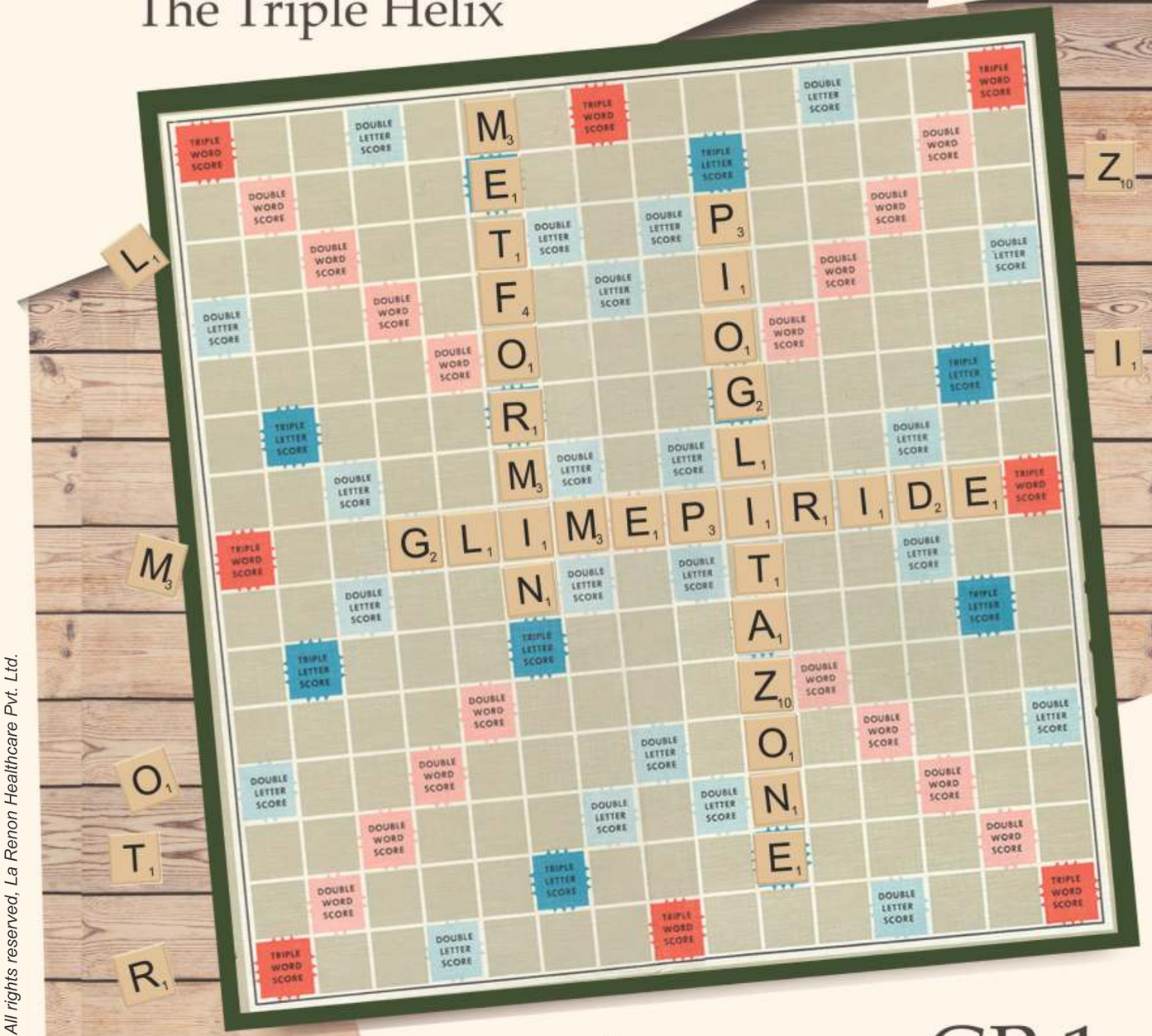
La Renon®

The Triple Helix



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Clinical Study 1

Triple oral fixed dose combination of glimepiride, metformin and low dose pioglitazone in the treatment of uncontrolled type 2 diabetes

Total Patients: 75 patients with type 2 diabetes and were randomized into the three treatment groups

Group A: FDC of Glimepiride 1mg + Metformin 500 mg SR + Pioglitazone 7.5 mg (n=25)
Group B: FDC of Glimepiride 2mg + Metformin 500 mg SR + Pioglitazone 7.5 mg (n=25)
Group C: Insulin 70/30 Mix + Metformin 500mg SR (n=25)

Duration of Study: 180 Days

End Points: Reduction in HbA1c at 180 days, Reduction in fasting plasma glucose (FPG), postprandial plasma glucose (PPG), Change in lipid parameters and weight

Results:

	Duration in days	Group A	Group B	Group C
Mean HbA1c	Baseline Reduction at day 180	9.40 ± 0.89 -1.49 ± 0.72	9.57 ± 079 -1.51 ± 0.69	9.46 ± 0.99 -1.11 ± 0.76
Mean FPG	Baseline Reduction at day 180	181.76 ± 29.98 -66.72 ± 27.12	181.24 ± 28.44 -79.68 ± 23.87	184.92 ± 29.46 -69.6 ± 25.34
LDLc (mg/dl)	Baseline Reduction at day 180	152.52 ± 12.42 128.28 ±9.03	153.52 ± 10.40 129.00 ± 08.79	158.88 ± 08.83 136.28 ± 07.78
TG (mg/dl)	Baseline Reduction at day 180	157.76 ± 35.10 120.92 ± 27.55	158.16 ± 31.98 119.84 ± 19.02	149.16 ± 32.26 115.12 ± 17.16
HDLc (mg/dl)	Baseline Reduction at day 180	36.92 ± 5.73 40.32 ± 2.95	37.04 ± 4.36 40.32 ± 4.18	36.88 ± 5.17 39.64 ± 3.39

Conclusion:
An anti-diabetic fixed dose combination of glimepiride, metformin and pioglitazone achieved similar glycemic control to insulin plus metformin combination and resulted in a trend towards lower HbA1c levels as compared to insulin plus metformin therapy. This combination may help in postponing insulin therapy.

Reference:
IJBMS, Ananad Mose, Rahul Balip, August 17, 2015

Clinical Study 2

Triple therapy with glimepiride in patients with type 2 diabetes mellitus inadequately controlled by metformin and a thiazolidinedione: results of a 30-week, randomized, double-blind, placebo-controlled, parallel-group study

- A multicenter, randomized, double-blind, placebo-controlled Study
- Study Duration: 30 weeks
- Of 170 randomized patients, 159 were included in the efficacy analysis and 168 were included in the safety analysis.
- Patients with a diagnosis of type 2 diabetes for a minimum of 1 year received glimepiride or placebo in combination with an established regimen of immediate- or extended release metformin and rosiglitazone or pioglitazone.

End Points:
The primary efficacy outcome was the change in glycosylated hemoglobin (HbA(1c)) from baseline.
The safety analysis was based on the incidence of hypoglycemia, adverse events, and laboratory abnormalities.
Changes in lipid levels (high-density lipoprotein cholesterol, total cholesterol, low-density lipoprotein cholesterol, very low density lipoprotein cholesterol, and triglycerides) were evaluated.

Results:
HbA(1c) was significantly improved at end point with glimepiride combination therapy compared with placebo.
The majority of patients (62.2%) who received glimepiride achieved an HbA(1c) value of < or =7%, compared with 26.0% of patients receiving placebo.
At end point, the adjusted mean differences between treatments significantly favored the glimepiride combination in terms of fasting plasma glucose, fasting insulin, and C-peptide.
The overall incidence of hypoglycemia, however, was 51.2% in the glimepiride group and 8.3% in the placebo group.

Conclusions:
In these patients with type 2 diabetes that was not adequately controlled by dual combination therapy with metformin and a thiazolidinedione, the addition of glimepiride improved glycemic control compared with placebo with an acceptable tolerability profile.

Reference:
ClinTher.2005Oct;27(10):1535-47

The Triple Helix