<u>la Renon</u>

# TRELAHENZ

Trelagliptin 50 mg & 100 mg Tablets



# ONCE A WEEK SOLUTION

FOR DIABETES MANAGEMENT

# **TRELAHENZ-50**

# Trelagliptin 50 mg Tablets

Efficacy and Safety of Once-weekly Oral Trelagliptin
Switched from once Daily Dipeptidyl Peptidase-4 Inhibitor
in Patients with Type 2 Diabetes Mellitus: An Open-label, Phase 3 Exploratory Study

Study Type : Single-center, open-label, phase 3 exploratory study.

Total Patients : 14 patients with type 2 diabetes mellitus.

Duration : 15 weeks

Dosage : Patients were transitioned from Sitagliptin 50 mg once daily to Trelagliptin 100 mg orally

once weekly, administered before breakfast.

End-Point : The primary endpoint: the change in blood glucose levels measured via standardized

meal tolerance tests (days -1 to 3, and day 7), secondary endpoints: HbA1c, fasting plasma glucose (FPG), glycoalbumin, DPP-4 activity, bodyweight, insulin, glucagon,

active GLP-1 concentration.

Results :

Table 1: Changes in blood glucose measured during the meal tolerance test

Accoment	Day 1	Day 2	Day 3	
Assesment	Mean Change (SD)			
2 Hr After Post Breakfast (mg/dL)	-4.4	-1.6	7.0	
2 Hr After Post Lunch (mg/dL)	-10.6	-36.4	-28.1	
2 Hr After Post Dinner (mg/dL)	12.1	-16.4	-13.2	

Table 2: Changes from baseline at the end of the treatment period in efficacy measures

Variable	Summary Statistics		95% CI	
	Mean	SD	Lower	Upper
HbA1c (%)	0.04	0.36	-0.16	0.25
FPG (mg/dL)	-1.6	13.93	-9.61	6.47
Glycoalbumin(%)	1.01	1.78	-0.02	2.03
Weight (Kg)	0.39	1.14	-0.27	1.05

## The rate of compliance with Trelagliptin was 99.45% up to week 12.

Conclusion

- Switching from a daily DPP-4 inhibitor (Sitagliptin) to once-weekly Trelagliptin was feasible and did not negatively impact glycemic control or safety.
- The drug was well-tolerated, with no new safety concerns.

# **TRELAHENZ-100**

# Trelagliptin 100 mg Tablets

# Efficacy and Safety of Trelagliptin in Combination with Insulin Therapy in Patients with Type 2 Diabetes

Study Type : Phase IV, multicentre, randomized, double-blind, placebo-controlled study.

Total Patients : N= 240

Duration : 52 weeks

Dosage : Trelagliptin 100 mg with insulin (A/A group, n= 116) or a placebo with insulin

(P/A group n=124) once weekly.

End-Point : Change in HbA1c from baseline to the end of the study.

Results : • Change in HbA1c from baseline to the end of the double-blind phase was -0.56% for the A/A group and 0.07% for the P/A group.

More patients in the A/A group vs the P/A group achieved HbA1c levels <7.0%</li>

No severe hypoglycaemia was reported after initiation of Trelagliptin.

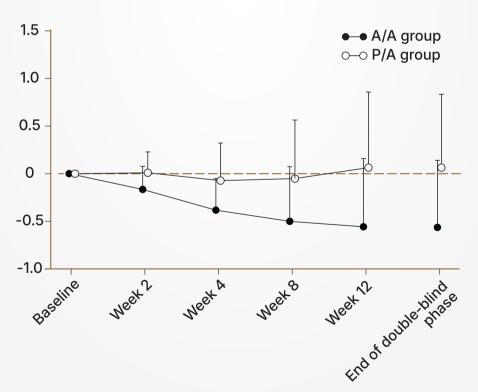


Fig.: Mean change in HbA1c from baseline in the double-blind phase. The error bars represent standard deviation (SD). Abbreviations: A/A group, Trelagliptin 100 mg with insulin; P/A group, placebo tablet with insulin; HbA1c, haemoglobin A1c; SD, standard deviation

Conclusion : Trelagliptin 100 mg in combination with insulin could be a potential therapeutic option,

with careful consideration for hypoglycaemia, in T2DM patients.



# Trelagliptin 50 mg & 100 mg Tablets

## **BACKGROUND**

Maintenance of long-term glycemic control in patients with type 2 diabetes is important to prevent or delay development of complications. However, adherence to treatment is often poor in patients with diseases such as type 2 diabetes reduced dosing frequency can improve compliance. DPP-4 inhibitors, commonly used for T2DM, are typically taken once or twice daily. Trelagliptin, a potent, selective, ultra-long-acting DPP-4 inhibitor, is the first approved for once-weekly use. Various study showed that a single dose of Trelagliptin provides sustained DPP-4 inhibition for 7 days, supporting its weekly dosing regimen. Therefore, the once-weekly administration regimen of Trelagliptin may lead to improved adherence compared with once-daily gliptins, with the potential for improved glycaemic control in patients with T2DM.

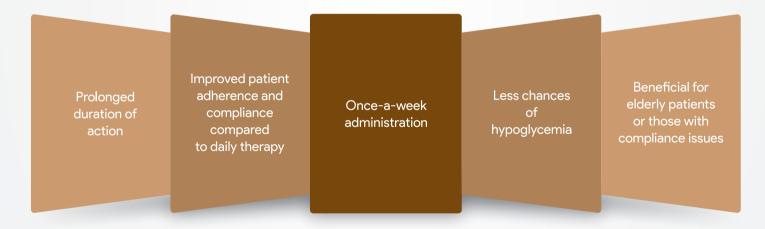
## INDICATION

Trelahenz is indicated as an adjunct to diet and exercise to improve glycemic control in patients with type-2 diabetes.

## **MECHANISM OF ACTION**

Trelagliptin-Trelagliptin selectively inhibits the action of DPP-4, the primary enzyme degrading the incretin hormones, allowing glucagon-like peptide-1 and glucose-dependent insulinotropic peptide to facilitate glucose regulation in response to a meal.

#### USP



## DOSAGE

Trelahenz-50,100: One Tablet a week orally or as prescribed by the doctor.

#### **PRESENTATION**

It is available as 4 tablets in a strip.



Scan QR for more Prescribing Information

References: 1.Lancet Diabetes Endocrinol. 2015 Mar;3(3):191-7. | 2.Drugs. 2015 Jul;75(10):1161-4.

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