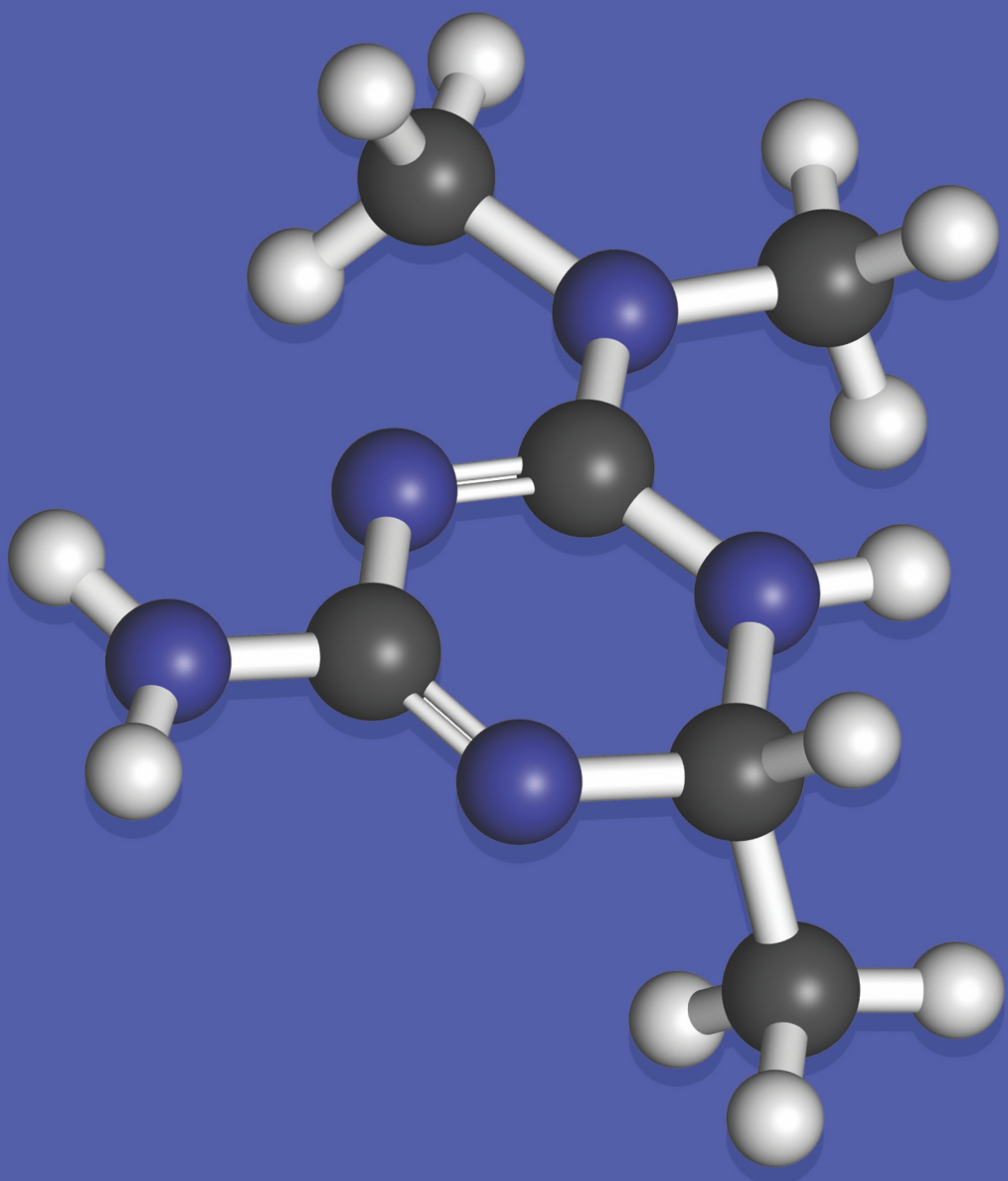
La Renon®

A CLASS APART



IMEG-CKD 500

Imeglimin Hydrochloride 500 mg Tablets

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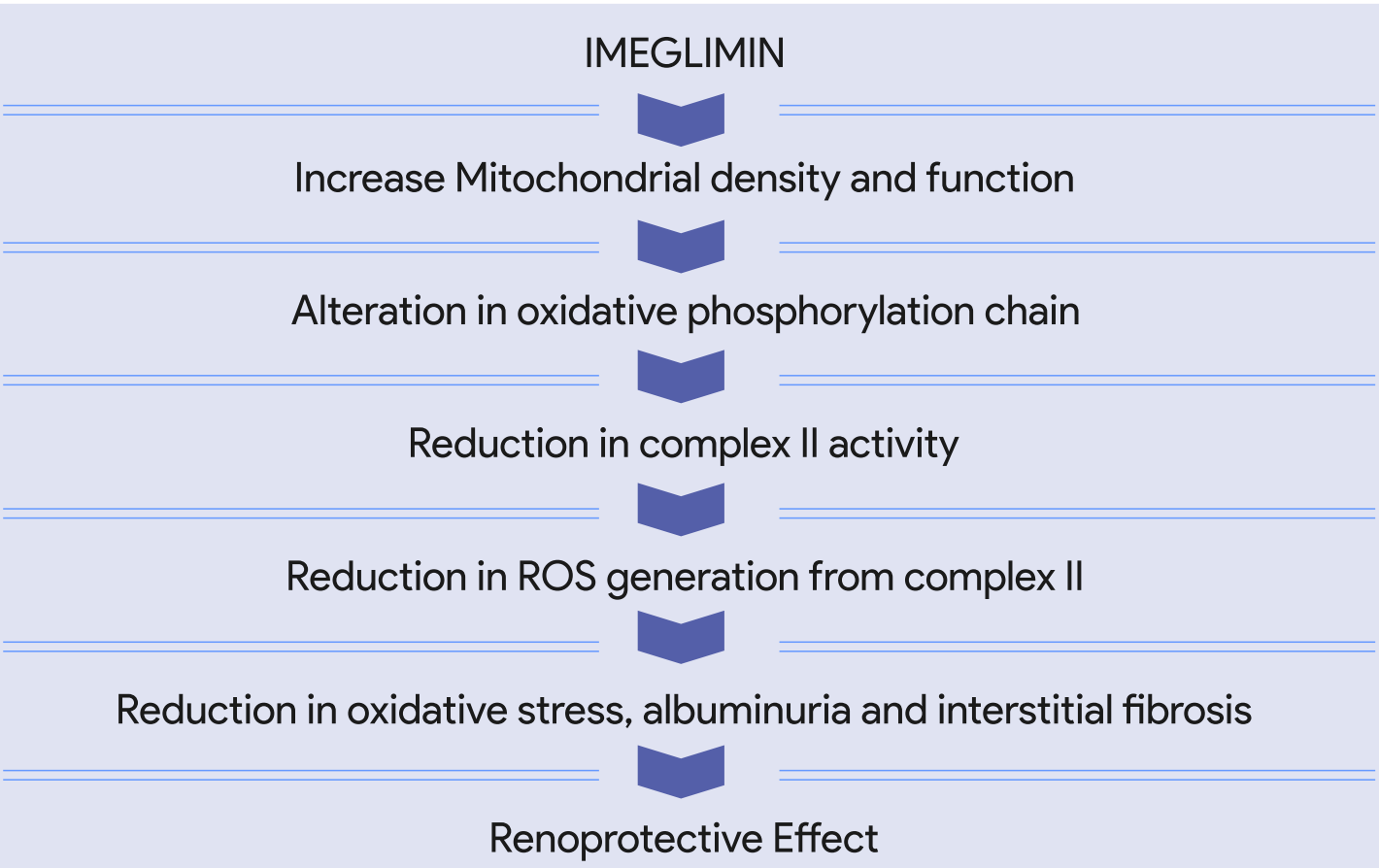
IMEGLIMIN – Renoprotective Effect Of Mitochondria Targeted Drug

- Imeglimin is a novel oral hypoglycemic agent that is being clinically tested as a monotherapy or an add-on therapy to reduce fasting blood glucose levels or hemoglobin A1c.
- Improved glucose tolerance has been reported in humans treated with imeglimin due to a variety of mechanisms, including decreased hepatic lipids, improved insulin signalling in the liver and muscle, and ameliorated β-cell function.
- More recent data indicate that imeglimin prevents endothelial death by decreasing the size of the mitochondrial permeability transition pore, which plays a pivotal role in cell death, without inhibiting mitochondrial respiration.
- Imeglimin reduces oxidative stress by acting on the liver, muscle, and pancreas, which are involved in the pathogenesis of type 2 diabetes, through a mechanism that targets the mitochondria.
- Imeglimin decreases glucose production in the liver and increases glucose uptake in the muscles. In addition, imeglimin has been reported to improve mitochondrial density and function.
- In vivo studies claimed that IMEGLIMIN decreases in albuminuria and interstitial fibrosis.

Renoprotective Mechanism of Imeglimin



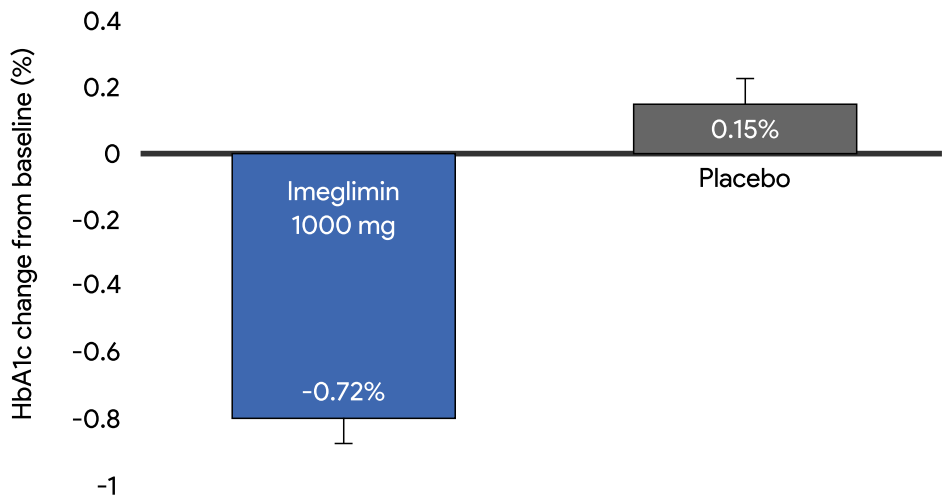
Reference: Heliyon. 2022 Feb 3;8(2):e08878

Clinical Evidence

Efficacy and Safety of Imeglimin Monotherapy Versus Placebo in Patients with Type 2 Diabetes

- A double-blind, randomized, parallel-group, placebo-controlled phase 3 trial
- Duration: 24 weeks
- Total Number of Patient: 213
  - Imeglimin Group: n=106
  - Placebo: n= 107
- Dose: 1000 mg Imeglimin Twice daily
- End Points: The primary end point was the change in mean HbA1c from baseline and the key secondary end point was the percentage of responders.

Results:



HbA1c reduction with imeglimin compared with placebo

- Compared with placebo, the adjusted mean difference in change from baseline HbA1c at week 24 was -0.87%. Forty-seven (44.3%) patients reported ≥1 adverse event in the Imeglimin group versus 48 adverse events (44.9%) in the placebo group.
- At week 24, HbA1c <7%, was achieved by significantly more patients in the imeglimin group (n=38 of 106 patients; 35.8%) compared with the placebo group (n = 8 of 106 patients; 7.5%).

Conclusion:

Imeglimin significantly improved HbA1c in patients with type 2 diabetes compared with placebo and had a similar safety profile to placebo. Imeglimin represents a potential new treatment option for this population.

Reference: Diabetes Care 2021;44:952–959

IMEG-CKD 500

Imeglimin Hydrochloride 500 mg Tablets

Background:

Recent advances in mitochondrial biology have provided a new understanding of mitochondrial dysfunction in Diabetes Kidney Disease. Studies have revealed impaired mitochondrial function in a variety of diabetic complications, including DKD; moreover, abnormal mitochondrial fission may be involved in the progression of DKD. It has been reported that metformin or sodium-glucose cotransporter 2 (SGLT2) inhibitors may provide renal protection by improving mitochondrial dynamics and reducing oxidative stress. Thus, drugs that target the restoration of mitochondrial function may become novel therapeutic agents for DKD.

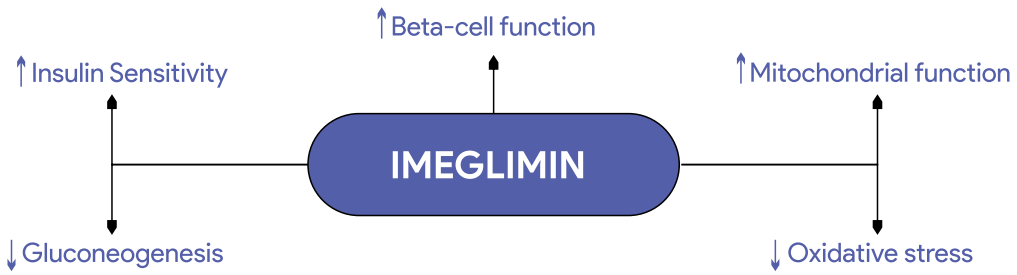
Description:

IMEG-CKD contains Imeglimin (500 mg) which is the first in a new class of oral antidiabetic drugs that can reduce reactive oxygen species production and increase mitochondrial DNA synthesis.

Indication:

IMEG-CKD is Indicated for the management of Type 2 Diabetes.

Mechanism of Action:



Dosage and administration:

The Dose of IMEG-CKD is 500 mg orally twice daily (b.i.d.) in the morning and evening.

USP:

- First of Its Class drug
- Decreases Albuminuria & Kidney Interstitial fibrosis
- Lower Risk of lactic acidosis compared with that associated with metformin
- Less Side Effects
- Displays a superior benefit: risk profile compared with metformin

References:
1.Clin Transl Sci. 2022;15:1014–1026
2.Heliyon. 2022 Feb 3;8(2):e08878.
3.Endokrynologia Polska 2022; 73 (2)
4.Diabetes Obes Metab. 2012 Sep;14(9):852-8.

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