



# Fexanto-ER-40

Febuxostat Extended Release 40 mg Tablets

### Description:

- Hyperuricemia is a very common condition, being usually caused by an unhealthy lifestyle that is mainly represented by a poor diet exceeding in purine nucleotides, protein, alcohol, and carbohydrates intake.
- Febuxostat is a new oral non-purine xanthine oxidase (XO) inhibitor effective for the treatment of chronic hyperuricaemia and gout. It is a more selective and potent inhibitor of XO than allopurinol and has no effect on other enzymes involved in purine or pyrimidine metabolism.

### Composition:

- Each Tablet of **FEXANTO-ER-40** contains 40 mg of Febuxostat.

### Indication:

- FEXANTO-ER-40** is indicated for the chronic management of hyperuricemia in patients having over production of uric acid.

### Mechanism of Action:

- Febuxostat is a non-purine selective inhibitor of xanthine oxidase. It works by non-competitively blocking the channel leading to the active site on xanthine oxidase.
- Xanthine oxidase is needed to successively oxidize both hypoxanthine and xanthine to uric acid.
- Hence, febuxostat inhibits xanthine oxidase, therefore reducing production of uric acid. It does not inhibit other enzymes involved in purine or pyrimidine metabolism.

### Dosage:

The recommended starting dose of **FEXANTO-ER-40** is 40 mg once daily without regard to food or antacid use.

### Presentation:

**FEXANTO-ER-40** is available as a strip of 10 tablets.

### La Renon Healthcare Pvt. Ltd.

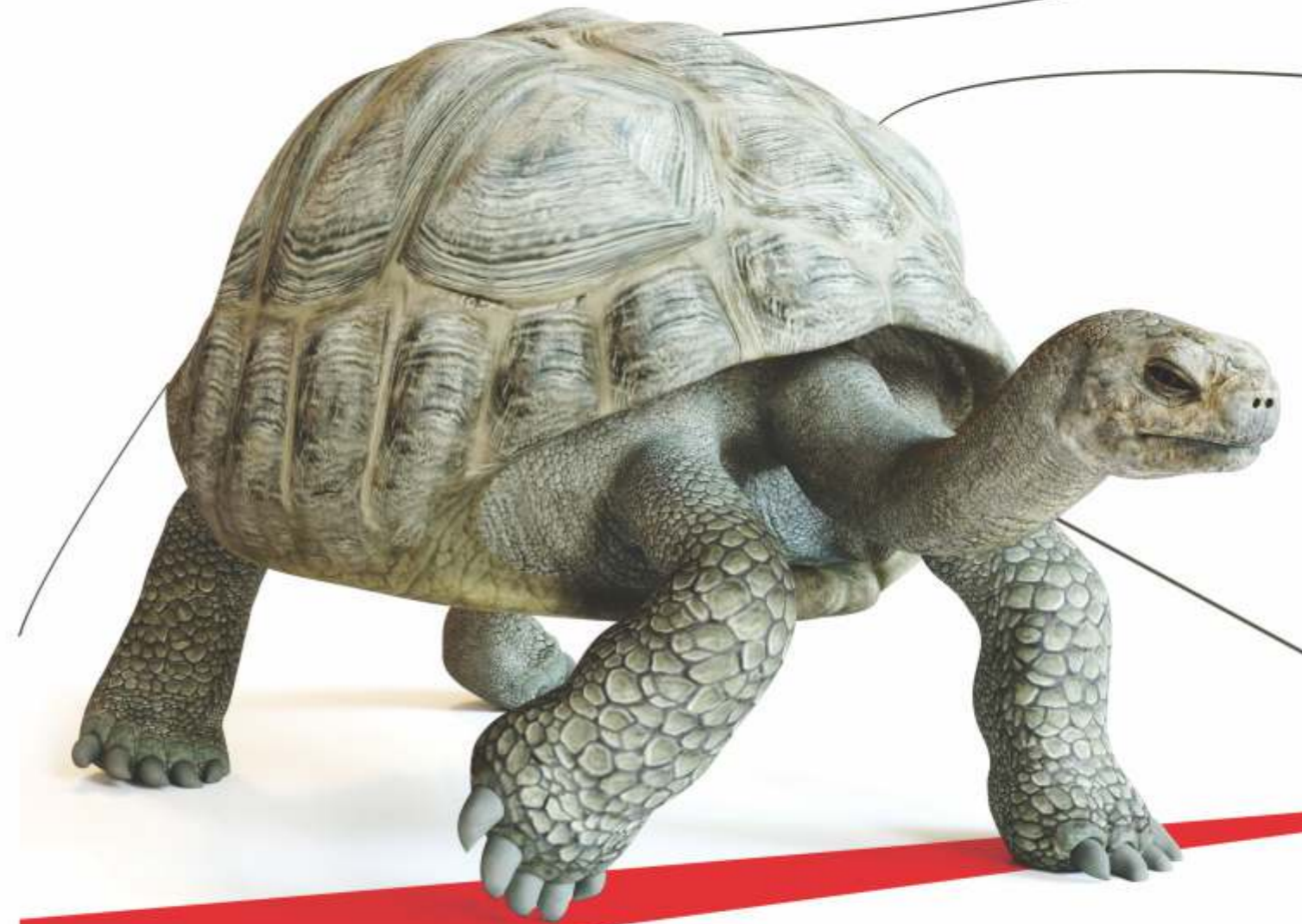
207-208 Iscon Elegance, Circle P, Prahlad Nagar Cross Roads,  
S.G.Highway, Ahmedabad-380015, Gujarat, India.  
Phone: +91-79-3046-1000 (30 Lines) , Fax: +91-79-3046-1001  
E-mail: info@larenon.com, Web: www.larenon.com

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Achievement Of

**ENDURANCE**



# Fexanto-ER-40

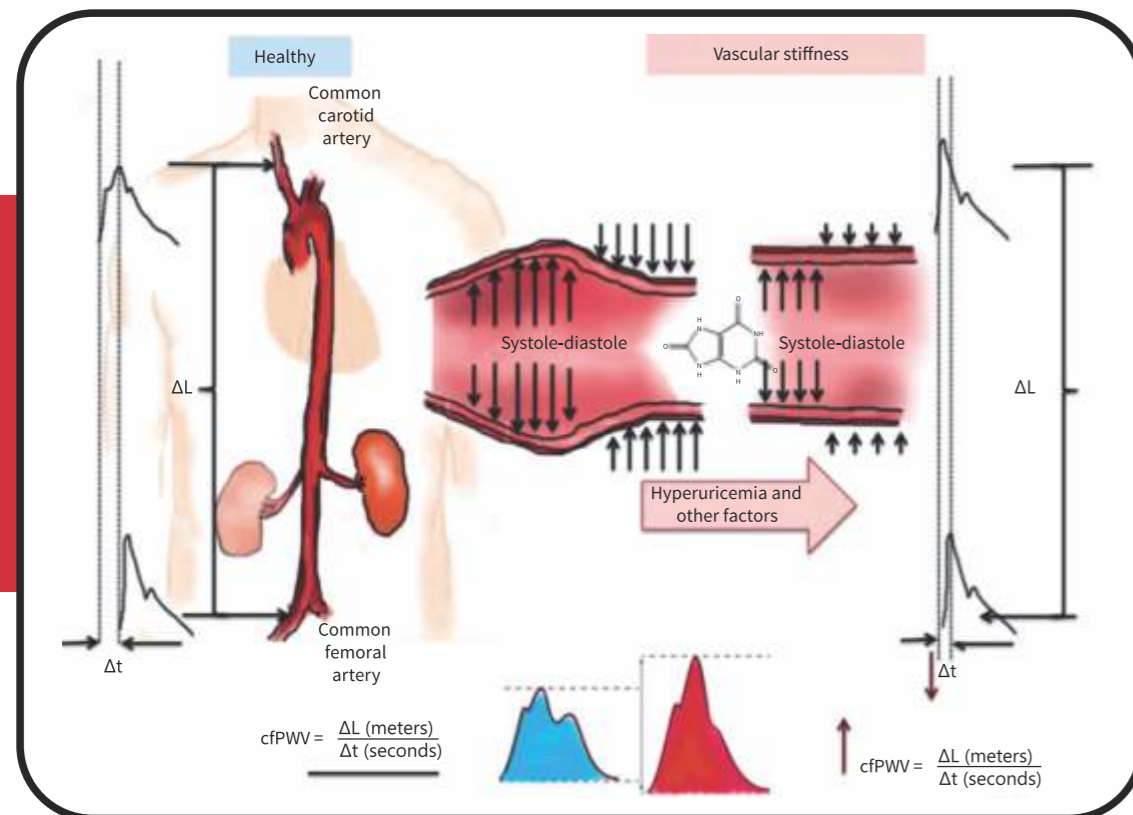
Febuxostat Extended Release 40 mg Tablets

La Renon®

## Uric Acid, Vascular Stiffness & Chronic Kidney Disease: Is There a Link ?

- Hyperuricemia is defined as a level of serum uric acid greater than or equal to 70 mg/l (420 μmol/l) in men and 60 mg/l (360 μmol/l) in women.
- Hyperuricemia is a very common biochemical finding associated with aging, hypertension, chronic kidney disease (CKD), and cardiovascular disease (CVD).
- Several studies have shown that hyperuricemia in persons with CKD appears to be associated with an increased risk for cardiovascular and all-cause-mortality.
- Recent experimental and epidemiological data correlate the association of hyperuricemia with chronic kidney disease (CKD), arterial hypertension, vascular stiffness, cardiovascular diseases and possible links to the pathogenesis and progression of CKD.

## Estimation of Arterial pulse wave velocity (aPWV) in healthy individuals and in those who have hyperuricemia - induced vascular stiffness

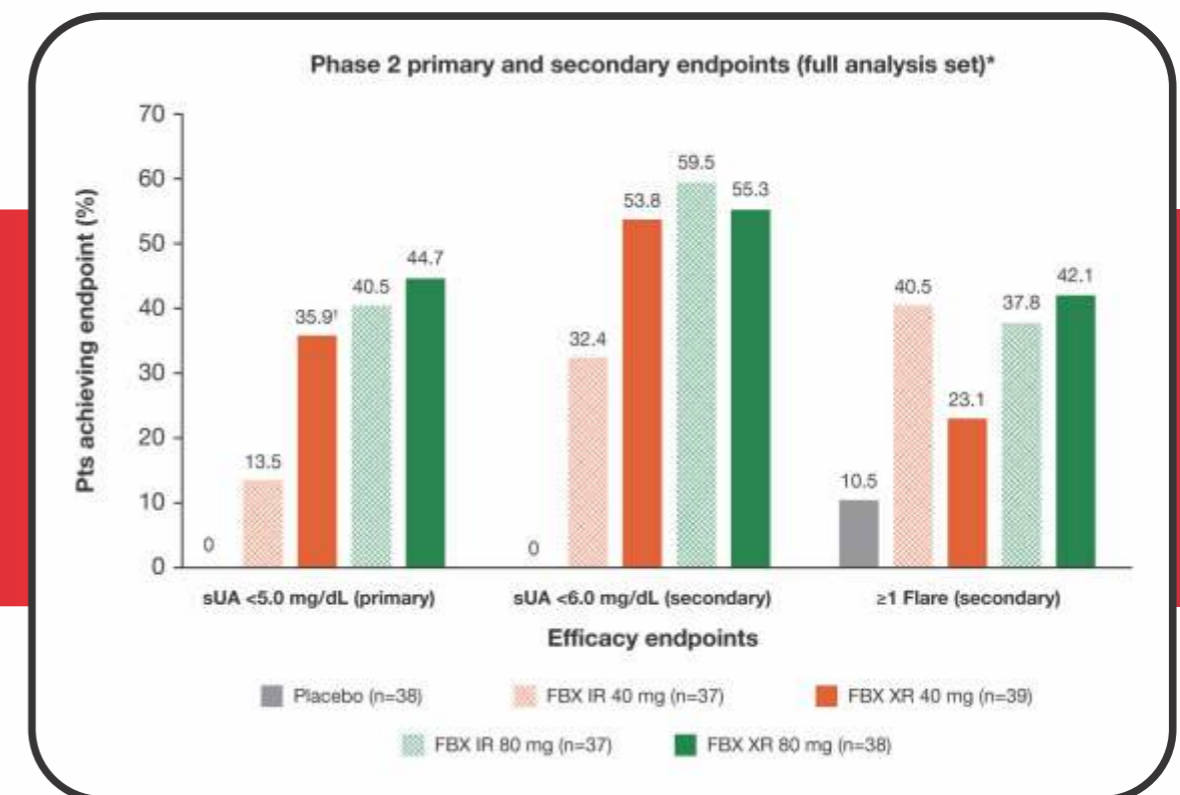


In conclusion, vascular stiffness provides a better understanding of the relationship between SUA, CKD and CVD.

**Reference:**  
Blood Purif 2017;43:189–195

## A Phase 2 Study to Evaluate the Efficacy and Safety of Febuxostat Extended- Versus Immediate-Release Formulations in Patients with Gout and Moderate Renal Impairment

- A Multicenter, randomized, placebo-controlled, double-blind study was performed on Patients with gout and Moderate Renal Impairment.
- A total of 189 patients received treatment with placebo (n=38), FBX XR 40 mg (n=39), FBX XR 80 mg (n=38), FBX IR 40 mg (n=37), or FBX IR 80 mg (n=37).
- The primary endpoint was the proportion of patients with Serum Urate level (sUA) <5.0 mg/dL at Month 3.
- Secondary endpoints were proportions of patients with at least 1 flare requiring treatment during the 3-month treatment period and of patients with sUA <6.0 mg/dL at Month 3.



## Conclusion:

Significantly more patients receiving FBX XR 40 mg achieved the primary endpoint of sUA reduction to <5.0 mg/dL at the Month 3 visit compared with FBX IR 40 mg. There was a trend toward lower flare rates in the FBX XR 40 mg vs the IR 40 mg group.

**Reference:**  
American College of Rheumatology, Abstract Number-198, September 28, 2016