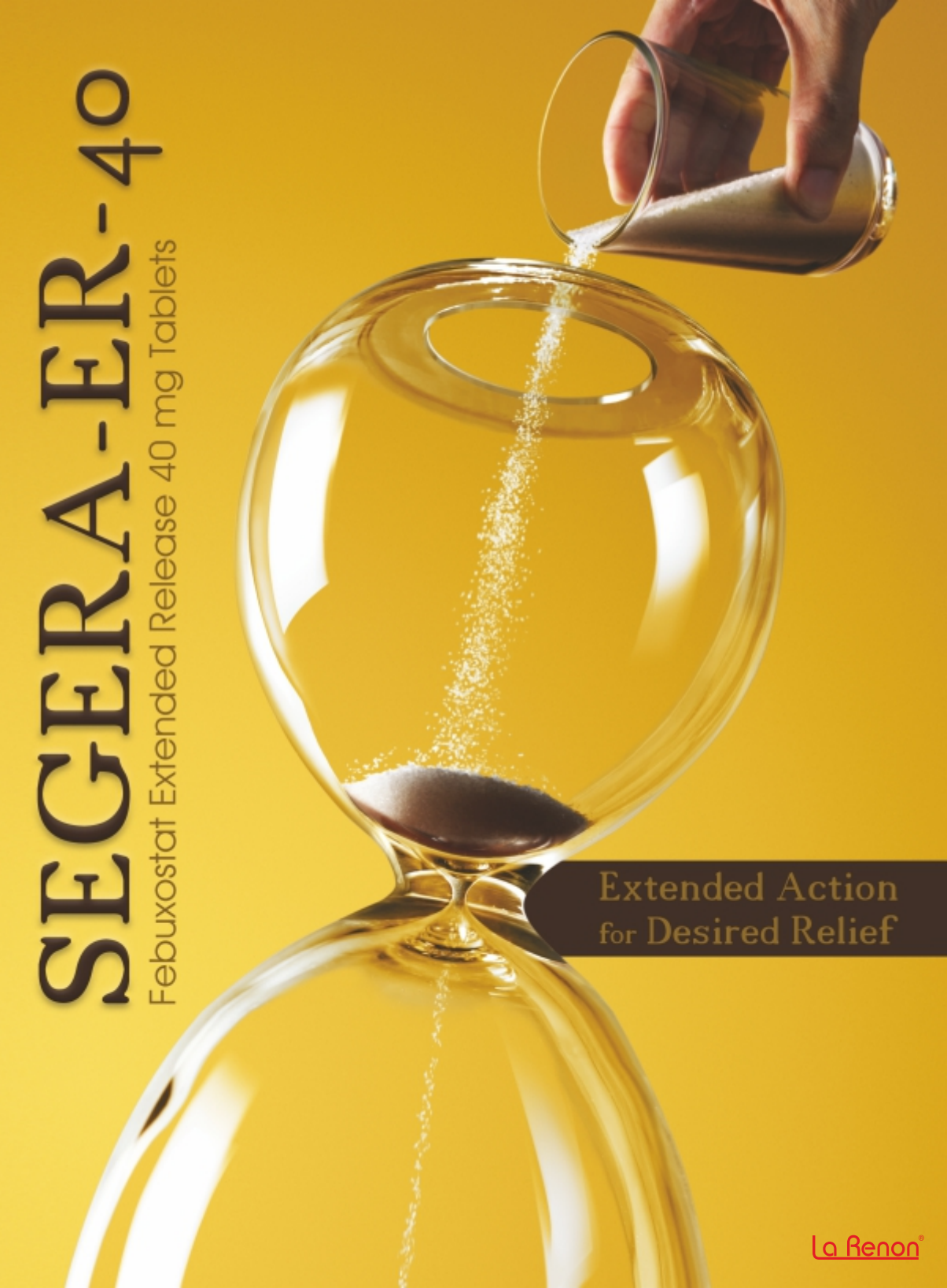


SEGERA-ER-40

Febuxostat Extended Release 40 mg Tablets



Extended Action
for Desired Relief

La Renon®

SEGERA-ER-40

Febuxostat Extended Release 40 mg Tablets

Background¹:

Gout and hyperuricemia are important disorders because they are highly prevalent and have treatment implications beyond the care of inflamed joints. In addition, these disorders are of great interest for investigators and clinicians because of the newly recognized pathogenic mechanisms underlying the disorders, and for the development of newer therapeutic modalities.

Therapeutic management of Hyperuricemia¹:

Management aims to reduce serum uric acid (sUA) below 6.0 mg/dl (357 mmol/l). At present, three classes of drug are approved for lowering urate levels: xanthine oxidase inhibitors, uricosuric agents, and uricase agents.

Febuxostat: Febuxostat, a non-purine analogue XO inhibitor, used for the treatment of hyperuricemia in gout patients, that is found to be more **efficacious and safer** than conventional **xanthine oxidase inhibitors**.

Preclinical studies demonstrated that Febuxostat was more potent than allopurinol in inhibiting xanthine oxidase and decreasing sUA levels. Febuxostat is well absorbed after oral administration, with an estimated 80% absorption, and no clinically relevant effect has been found for food or antacids on its absorption.

Febuxostat vs Allopurinol:

Sr. no	Parameters	Febuxostat	Allopurinol
1	Class of Drug ¹	Xanthine Oxidase Inhibitors	Xanthine Oxidase Inhibitors
2	MOA ¹	Unlike Allopurinol, Febuxostat is non-purine analog, inhibits only xanthine oxidase/ dehydrogenase, but not other enzymes.	Allopurinol is an purine analogue inhibits xanthine oxidase/ dehydrogenase and other enzymes in metabolic pathways.
3	Types of Xanthine Oxidase Inhibition ²	Inhibits both Oxidized and reduced types Xanthine Oxidase	Inhibit only selective xanthine oxidase
4	Adverse Effect ²	Fewer as compared to Allopurinol	Comparably higher as compared to Febuxostat

Reference:

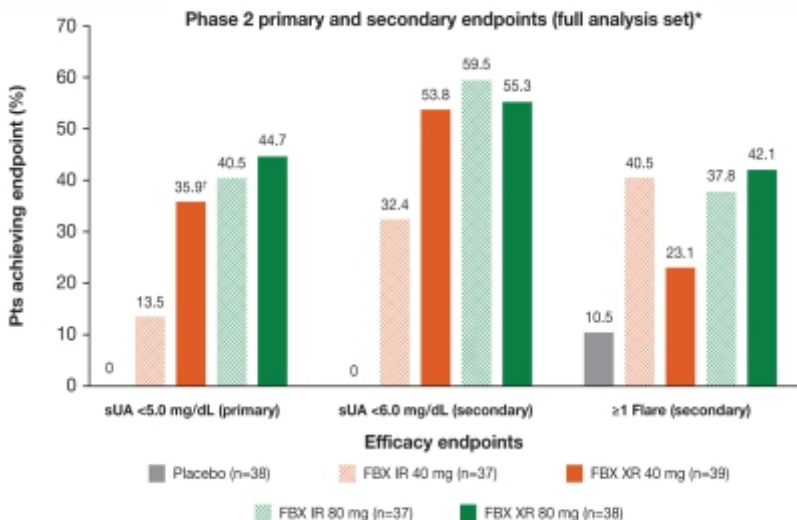
1. Ther Adv Musculoskel Dis;2011
2. Journal of Rheumatic Diseases Vol. 23, No. 1, February, 2016
3. Metabolic & Crystal Arthropathies;2016

Febuxostat vs Allopurinol:

Sr. no	Study	Design	Subjects	Outcomes
1	Metabolic & Crystal Arthropathies; 2016	Randomized Controlled Double blinded study	This Phase 2 study was conducted to evaluate the efficacy and safety of Febuxostat ER compared with Febuxostat IR in patients with gout and moderate renal impairment.	Significantly more patients receiving Febuxostat ER 40 mg achieved the primary endpoint of sUA reduction to <5.0 mg/dL at the Month 3 visit compared with Febuxostat IR 40 mg.
2	Becker et al. Arthritis Research & Therapy 2010	Randomized Controlled Trial	The purpose of this study was to compare urate-lowering (UL) efficacy and safety of daily febuxostat and allopurinol in subjects with gout and serum urate (sUA) ≥ 8.0 mg/dL in a six-month trial.	Urate-lowering efficacy of Febuxostat doses were more efficacious than allopurinol and equally safe.
3	Jackson et al. BMC Geriatrics 2012	Randomized Controlled Trial	The objective of this post hoc analysis was to examine the efficacy and safety of ULT with Febuxostat or allopurinol in a subset of elderly subjects enrolled in the CONFIRMS trial	Febuxostat is superior to commonly prescribed fixed doses of Allopurinol in subjects ≥ 65 years of age with high rates of renal dysfunction.
4	Clinical Interventions in Aging 2014:	Randomized Controlled Trial	The aim of this study was to assess the efficacy and safety of Febuxostat in elderly female patients. Evaluation done on 82 elderly patients (Group 1 Male 53 & Group 2 Female 29).	The efficacy of Febuxostat in elderly female patients is superior to that in elderly male patients and that the safety is equivalent.

Why Febuxostat ER³?

As per the Phase 2, multicentre, randomized, placebo-controlled, study conducted on **189 patients of hyperuricemia**, higher proportion of patients receiving Febuxostat XR 40 mg achieved sUA <5.0 mg/dL versus (vs) Febuxostat IR 40 mg at Month 3 (**35.9% vs 13.5%**).



SEGERA-ER-40

Febuxostat Extended Release 40 mg Tablets

Indication:

Chronic Management of Hyperuricemia in patients with Gout.

Composition:

Each film coated Extended Release Tablet Contains:

Febuxostat 40 mg

Excipients: q.s.

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 of xanthine oxidase. Xanthine oxidase is needed successively to oxidize both hypoxanthine and xanthine into uric acid. Hence, febuxostat inhibits xanthine oxidase, therefore reducing production of uric acid.

Advantages:

- ✓ More potent and more selective than allopurinol.
- ✓ Hypoallergenic.

Dosage:

The recommended starting dose is 40 mg once a daily. Segera ER can be taken without food or antacid use.

Description	SEGERA	Allopurinol
How often to take medication	1 x a Day	Upto 4 X a day
When to take medication	Anytime	Generally better tolerated after meals

Presentation:

SEGERA-ER-40 comes in a strip of 10 tablets.

Storage:

Store at a temperature not exceeding 30°C.

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