LOURIC Tablets
(FEBUXOSTAT)

لویورک گولیاں
(فی بیکسوسٹیٹ)

COMPOSITION:
Louric 40mg Tablet
Each film coated tablet contains:
Febuxostat……..40mg
Louric 80mg Tablet
Each film coated tablet contains:
Febuxostat……..80mg

CLINICAL PHARMACOLOGY
Pharmacokinetics:
Absorption: *Atleast 49% absorbed tmax is 1 to 1.5 hrs. Cmax is approx. 1.6 mcg/ml.*
Distribution: *Volume of distribution is 50 L. Plasma protein binding is approx. 99%., (primarily to albumin).*
Metabolism: *Extensively metabolized by both conjugation via uridine diphosphate glucuronosyltransferase enzymes and oxidation via CYP enzymes, including CYP 1A2, 2C8 & 2C9, as well as non-P450 isozymes.*
Elimination: *Mean terminal elimination half –life is approx. 5 to 8 hours. Approx. 49% is recovered in the urine and approx. 45% is recovered in feces*

INDICATIONS AND USAGE:
Febuxostat is a xanthine oxidase (XO) inhibitor indicated for the chronic management of hyperuricemia in patients with gout. Febuxostat is not recommended for the treatment of asymptomatic hyperuricemia.

DOSAGE AND ADMINISTRATION:
Recommended Dose:
For treatment of hyperuricemia in patients with gout, Febuxostat is recommended at 40 mg or 80 mg once daily.
The recommended starting dose of Febuxostat is 40 mg once daily. For patients who do not achieve a serum uric acid (sUA) less than 6 mg per dL after 2 weeks with 40 mg, Febuxostat 80 mg is recommended. Febuxostat can be taken without regard to food or antacid use.
Special Populations:
No dose adjustment is necessary when administering Febuxostat in patients with mild to moderate renal impairment.

CONTRAINDICATIONS:
Febuxostat is contraindicated in patients being treated with azathioprine, mercaptopurine, or theophylline.

WARNINGS AND PRECAUTIONS:
Gout Flare
After initiation of Febuxostat, an increase in gout flares is frequently observed. This increase is due to reduction in serum uric acid levels resulting in mobilization of urate from tissue deposits. In order to prevent gout flares when Febuxostat is initiated, concurrent prophylactic treatment with an NSAID or colchicine is recommended.

Cardiovascular Events:
In the randomized controlled studies, there was a higher rate of cardiovascular thrombo embolic events (cardiovascular deaths, non-fatal myocardial infarctions, and non-fatal strokes) in patients treated with Febuxostat [0.74 per 100 P-Y(95% CI 0.36-1.37)] than allopurinol [0.60 per 100 P-Y (95% CI 0.16-1.53). A causal relationship with Febuxostat has not been established. Monitor for signs and symptoms of myocardial infarction (MI)and stroke.

Liver Enzyme Elevations:
During randomized controlled studies, transaminase elevations greater than 3 times the upper limit of normal (ULN) were observed (AST: 2%, 2%, and ALT: 3%, 2% in Febuxostat and allopurinol-treated patients, respectively). No dose-effect relationship for these transaminase elevations was noted. Laboratory assessment of liver function is recommended at, for example, 2 and 4 months following initiation of Febuxostat and periodically thereafter.

ADVERSE REACTIONS :
Most Common Adverse Reactions
In three randomized, controlled clinical studies, which were 6 to 12 months in duration, the
- *Liver functions abnormalities 6.6%*
- *Nausea 1.1%*
- *Arthralgia Rash 0.5%*

The most common adverse reaction leading to discontinuation from therapy was liver function abnormalities in 1.8% of Febuxostat 40 mg, 1.2% of Febuxostat 80.
In addition to the above adverse reactions, dizziness was reported in more than 1% of Febuxostat-treated subjects although not at a rate more than 0.5% greater than placebo.
Less Common Adverse Reactions Less common side effects include stroke,heart attack, anemia, hepatitis, hypersensitivity & weight loss.

DRUG INTERACTIONS:
Xanthine Oxidase Substrate Drugs Febuxostat is an XO inhibitor. Drug interaction studies of Febuxostat with drugs that are metabolized by XO (e.g., theophylline, mercaptopurine, azathioprine) have not been conducted. Inhibition of XO by Febuxostat may cause increased plasma concentrations of these drugs leading to toxicity [see Clinical Pharmacology]. Febuxostat is contraindicated in patients being treated with azathioprine, mercaptopurine, or theophylline [see Contraindications].
Cytotoxic Chemotherapy Drugs
Drug interaction studies of Febuxostat with cytotoxic chemotherapy have not been conducted. No data are available regarding the safety of Febuxostat during cytotoxic chemotherapy.

USE IN SPECIFIC POPULATIONS:
Pregnancy
Pregnancy Category C: There are no adequate and well-controlled studies in pregnant women. Febuxostat should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.
Nursing Mothers
Febuxostat is excreted in the milk of rats. It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Febuxostat is administered to nursing women.
Pediatric Use
Safety and effectiveness in pediatric patients under 18 years of age have not been established.
Geriatric Use
No dose adjustment is necessary in elderly patients. Of the total number of subjects in clinical studies of Febuxostat, 16 percent were 65 and over, while 4
percent were 75 and over.
Renal Impairment
No dose adjustment is necessary in patients with mild or moderate renal impairment (Clcr 30-89 mL per min). The recommended starting dose of Febuxostat is 40 mg once daily.
Hepatic Impairment
No dose adjustment is necessary in patients with mild or moderate hepatic impairment (Child-Pugh Class A or B).

OVERDOSAGE:
Febuxostat was studied in healthy subjects in doses up to 300 mg daily for seven days without evidence of dose-limiting toxicities. No overdose of Febuxostat was reported in clinical studies. In case of over dosage patients should be managed by symptomatic and supportive care.

STORAGE CONDITIONS:
Store in a dry place below below 30°C and protect from sunlight.
Keep all medicines out of reach of children.
To be sold on the prescription of a registered medical practitioner only.

Presentations:
Louric Tablets 40 mg :
2x10's film coated tablets in Alu Alu blister pack.
Louric Tablets 80 mg :
2x10's film coated tablets in Alu Alu blister pack.

خوراک:
ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

ہدایات:
خشک جگہ پر ۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر محفوظ کریں۔
بچوں کی دسترس سے دُور رکھیں۔
سورج کی روشنی سے بچائیں۔
صرف مستند ڈاکٹر کے نسخے پر فروخت کریں۔

Manufactured by:
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