Barif®

Febuxostat

COMPOSITION
Barif® 40 tablet: Each film coated tablet contains Febuxostat INN 40 mg

PHARMACOLOGY
Barif® (Febuxostat) decreases serum uric acid level by inhibiting xanthine oxidase , an enzyme responsible for the production of uric acid.The absorption of febuxostat following oral dose administration was estimated to be at least 49%. Maximum plasma concentrations of febuxostat occurred between 1 to 1.5 hours post-dose. After multiple oral 40 mg and 80 mg once daily doses, Cmax is approximately 1.6 ± 0.6 mcg per mL and 2.6 ± 1.7 mcg per mL, respectively. The plasma protein binding of febuxostat is approximately 99.2%, (primarily to albumin). The apparent mean terminal elimination half-life (t1/2) of febuxostat is approximately 5 to 8 hours.

INDICATION
Barif® is indicated for the chronic management of hyperuricemia in patients with gout. Barif® is not recommended for the treatment of asymptomatic hyperuricemia.

DOSAGE AND ADMINISTRATION
Barif® is recommended at 40 mg or 80 mg once daily. The recommended starting dose of Barif® is 40 mg once daily. For patients who do not achieve a serum uric acid less than 6 mg /dL after 2 weeks with 40 mg then 80 mg is recommended. Barif® can be administered without regard to food or antacid use. No dose adjustment is necessary when administering Febuxostat to patients with mild to moderate renal or hepatic impairment.

PRECAUTION:
Gout Flare: An increase in gout flares is frequently observed during initiation of anti-hyperuricemic agents, including Febuxostat. If a gout flare occurs during treatment, Febuxostat need not be discontinued. Prophylactic therapy (i.e., non-steroidal anti-inflammatory drug (NSAID) or colchicine upon initiation of treatment) may be beneficial for up to six months. Cardiovascular Events: A higher rate of cardiovascular thromboembolic events was observed in patients treated with febuxostat than allopurinol in clinical trials. Monitor for signs and symptoms of MI and stroke. Liver Enzyme Elevation: Transaminase elevations have been observed in febuxostat -treated patients. Monitor liver function tests periodically.

SIDE EFFECT
The most common adverse events associated with the use of Febuxostat may include liver function abnormalities, nausea, arthralgia, and rash.

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

DRUG INTERACTION
Concomitant administration of Febuxostat with azathioprine, mercaptopurine or theophylline could
increase plasma concentrations of these drugs resulting in severe toxicity.

USE IN PREGNANCY & LACTATION
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. It is not known whether this drug is excreted in human milk. Caution should be exercised when Febuxostat is administered to a nursing woman.

USE IN CHILDREN
The safety and efficacy of Febuxostat in children (under 18 years of age) has not been established.

STORAGE CONDITION
Store in a cool and dry place. Protect from light and moisture. Keep the medicine out of the reach of children.

HOW SUPPLIED
Barif® 40 tablet: Each box contains 30 tablets in alu-alu blister pack.

Manufactured by
SQUARE
PHARMACEUTICALS LTD.
BANGLADESH