FEBUGOOD

For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory

Abbreviated Prescribing information for Febugood (Febuxostat Tablets 40, 80 and 120 mg) [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: Febuxostat is xanthine oxidase (XO) inhibitor and shows its action by decreasing serum uric acid level.

INDICATION: It is indicated for the treatment of chronic hyperuricemia in conditions where urate deposition has already occurred (including a history, or presence of tophus and / or gouty arthritis).

DOSAGE AND ADMINISTRATION: *For hyperuricemia in patients with gout:* recommended dose is 40 mg or 80 mg once daily. The maximum recommended dose is 120mg daily.

CONTRAINDICATION: It is contraindicated in patients being treated with azathioprine, mercaptopurine, or theophylline. Also in patients with hypersensitivity to the active substance or to any of the excipients.

WARNINGS & PRECAUTIONS: Treatment with febuxostat in patients with ischemic heart disease or congestive heart failure is not recommended. It may cause increase in frequency of gout flares and elevate the transaminase. Long term treatment of febuxostat may increase TSH values (>5.5 µIU/ml). Not recommended for patients in whom rate of urate formation is greatly increased.

DRUG INTERACTION: Febuxostat may interact with xanthine oxidase substrate drugs like azathioprine, mercaptopurine and theophylline. Febuxostat neither inhibit nor induce cytochrome P450 enzymes. It is metabolized by conjugation and oxidation via multiple metabolizing enzymes hence drug interaction between febuxostat and a drug that inhibits or induces one particular enzyme isoform is in general not expected. No dose adjustment is necessary for colchicine, naproxen, indomethacin, hydrochlorothiazide, warfarin and desipramine when prescribed with febuxostat.

ADVERSE REACTIONS: Liver function abnormality, nausea, diarrhea, arthralgia, rash, and dizziness, anemia, idiopathic thrombocytopenic purpura, angina pectoris, ECG abnormal, vertigo, vision blurred, abdominal distention, abdominal pain, constipation, dry mouth, dyspepsia, flatulence, frequent stools, asthenia, edema, cholelithiasis/cholecystitis, hepatic steatosis, hepatitis, hypersensitivity, herpes zoster infection, appetite decreased/increased, muscle spasms/twitching/tightness/weakness, musculoskeletal pain/stiffness, myalgia, altered taste, cerebrovascular accident, Guillain-Barré syndrome, anxiety, depression, renal failure, renal insufficiency, gynecomastia, bronchitis, cough, urticarial, hypertension, activated partial thromboplastin time prolonged, creatine increased, bicarbonate decreased, sodium increased and glucose increased.

MARKETED BY:

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(Additional information is available on request)