

Unsiatem 40mg & 80mg Film coated tablet

Febuxostat 40mg&80mg

2/9/2019

1 INDICATIONS AND USAGE

UNSIATEM is a xanthine oxidase (XO) inhibitor indicated for the chronic management of hyperuricemia in adult patients with gout who have an inadequate response to a maximally titrated dose of allopurinol, who are intolerant to allopurinol, or for whom treatment with allopurinol is not advisable.

For the safe and effective use of allopurinol, see allopurinol prescribing information.

Limitations of Use:

UNSIATEM is not recommended for the treatment of asymptomatic hyperuricemia.

2 DOSAGE AND ADMINISTRATION**2.1 Recommended Dose**

The recommended UNSIATEM dosage is 40 mg or 80 mg once daily.

The recommended starting dosage of UNSIATEM is 40 mg once daily. For patients who do not achieve a serum uric acid (sUA) less than 6 mg/dL after two weeks, the recommended UNSIATEM dosage is 80 mg once daily.

UNSIATEM can be taken without regard to food or antacid use [see *Clinical Pharmacology (12.3)*].

2.2 Dosage Recommendations in Patients with Renal Impairment and Hepatic Impairment

No dose adjustment is necessary when administering UNSIATEM in patients with mild or moderate renal impairment.

The recommended dosage of UNSIATEM is limited to 40 mg once daily in patients with severe renal impairment [see *Use in Specific Populations (8.6)* and *Clinical Pharmacology (12.3)*].

No dose adjustment is necessary in patients with mild to moderate hepatic impairment [see *Use in Specific Populations (8.7)* and *Clinical Pharmacology (12.3)*].

2.3 Uric Acid Level

Testing for the target serum uric acid level of less than 6 mg/dL may be performed as early as two weeks after initiating UNSIATEM therapy.

2.4 Recommended Prophylaxis for Gout Flares

Gout flares may occur after initiation of UNSIATEM due to changing serum uric acid levels resulting in mobilization of urate from tissue deposits. Flare prophylaxis with a non-steroidal anti-inflammatory drug (NSAID) or colchicine is recommended upon initiation of UNSIATEM.

Prophylactic therapy may be beneficial for up to six months [see *Clinical Studies (14.1)*].

If a gout flare occurs during UNSIATEM treatment, UNSIATEM need not be discontinued. The gout flare should be managed concurrently, as appropriate for the individual patient [see *Warnings and Precautions (5.2)*].

3 DOSAGE FORMS AND STRENGTHS

- 40 mg tablets, Green(light green to dark green), round, biconvex unscored film coated tablet
- 80 mg tablets, Green(light green to dark green), round, biconvex unscored film coated tablet

4 CONTRAINDICATIONS

UNSIATEM is contraindicated in patients being treated with azathioprine or mercaptopurine [see *Drug Interactions (7)*].

- patients with rare hereditary problems of galactose intolerance, the lactose deficiency or glucose-galactose malabsorption should not take this medicine as it contains Lactose. *مريضين*