AZZa
17/12/2019

1. NAME OF THE MEDICINAL PRODUCT

UNSIATEM 120 mg film-coated tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 120 mg of febuxostat. Excipient(s) with known effects:
Each tablet contains 246.15 mg of lactose (as monohydrate)

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Film-coated tablet (tablets).

Light Green to Dark Green, Oblong, unscored, biconvex Film coated tablets.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

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

UNSIATEM is indicated for the prevention and treatment of hyperuricaemia in adult patients undergoing chemotherapy for haematologic malignancies at intermediate to high risk of Tumor Lysis Syndrome (TLS).

UNSIATEM is indicated in adults.

4.2 Posology and method of administration

Posology
Gout: The recommended oral dose of febuxostat is 80 mg once daily without regard to food. If serum uric acid is > 6 mg/dL (357 µmol/L) after 2-4 weeks, UNSIATEM 120 mg once daily may be considered.

Febuxostat works sufficiently quickly to allow retesting of the serum uric acid after 2 weeks. The therapeutic target is to decrease and maintain serum uric acid below 6 mg/dL (357µmol/L).

Gout flare prophylaxis of at least 6 months is recommended (see section 4.4).

Tumor Lysis Syndrome: The recommended oral dose of UNSIATEM is 120 mg once daily without regard to food.
UNSIATEM should be started two days before the beginning of cytotoxic therapy and continued for a minimum of 7 days; however treatment may be prolonged up to 9 days according to chemotherapy duration as per clinical judgment.

Elderly
No dose adjustment is required in the elderly (see section 5.2).

Renal impairment