

TORKAST-FX

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

Abbreviated Prescribing information for TORKAST-FX [Fexofenadine hydrochloride 120mg & Montelukast 10mg Tablets] [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: Fexofenadine hydrochloride is a non-sedating H₁ antihistamine. Montelukast is an orally active compound that binds with high affinity and selectivity to the CysLT₁ receptor and inhibits physiologic actions of LTD₄ at the CysLT₁ receptor without any agonist activity.

INDICATION: Indicated for the treatment of allergic rhinitis in adults only.

DOSAGE AND ADMINISTRATION: The recommended dose is one tablet daily in the evening before a meal.

CONTRAINDICATION: In patients with hypersensitivity to the active substance or to any of the excipients.

WARNINGS & PRECAUTIONS: Fexofenadine hydrochloride should be administered with care in special groups such as older people and renally or hepatically impaired patients. Risk of tachycardia and palpitations in patients with a history of or ongoing cardiovascular disease. Patients should be advised never to use oral montelukast to treat acute asthma attacks and to keep their usual appropriate rescue medication for this purpose readily available. Montelukast should not be substituted abruptly for inhaled or oral corticosteroids. Physicians should be alert to clinical features of Churg-Strauss syndrome such as eosinophilia, vasculitic rash, worsening of pulmonary symptoms, cardiac complications, and/or neuropathy and should reassess treatment regimen. Patients with aspirin-sensitive asthma should avoid taking aspirin and other non-steroidal anti-inflammatory drugs.

DRUG INTERACTIONS: Interacts with aluminium and magnesium hydroxide containing antacids, enzyme inducers of CYP 3A4, 2C8, and 2C9, such as phenytoin, phenobarbital and rifampicin.

ADVERSE REACTIONS: headache, drowsiness, dizziness, nausea, hypersensitivity reactions with manifestations such as angioedema, chest tightness, dyspnoea, flushing and systemic anaphylaxis, insomnia, nervousness, sleep disorders or nightmares/excessive dreaming (paroniria), diarrhea, rash, urticaria, pruritus, abdominal pain, upper respiratory infection, increased bleeding tendency, hepatic eosinophilic infiltration, dream abnormalities including nightmares, insomnia, somnambulism, anxiety, agitation including aggressive behaviour or hostility, depression, psychomotor hyperactivity, disturbance in attention, memory impairment, hallucinations, disorientation, suicidal thinking and behaviour (suicidality), paraesthesia/hypoesthesia, seizure, epistaxis, Churg-Strauss Syndrome (CSS), vomiting, dry mouth, dyspepsia, elevated levels of serum transaminases (ALT, AST), hepatitis, erythema nodosum, erythema multiforme, arthralgia, myalgia, pyrexia, asthenia/fatigue, malaise and oedema.

MARKETED BY:



TORRENT PHARMACEUTICALS LTD.

Torrent House, Off Ashram Road,
Ahmedabad-380 009, INDIA

IN/ TORKAST-FX /120,10mg/Mar-2015/01/AbPI

(Additional information is available on request)