FEXO M

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

Abbreviated Prescribing information for FEXO M [Fexofenadine Hydrochloride 120 mg & Montelukast sodium 10 mg]

[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: ***Fexofenadine hydrochloride:*** is a non-sedating H1 antihistamine. Fexofenadine is a pharmacologically active metabolite of terfenadine. ***Montelukast:*** is an orally active compound that binds with high affinity and selectivity to the CysLT1 receptor (in preference to other pharmacologically important airway receptors, such as the prostanoid, cholinergic, or β-adrenergic receptor). Montelukast inhibits physiologic actions of LTD4 at the CysLT1 receptor without any agonist activity.

INDICATIONS: FEXO M is indicated for treatment of allergic rhinitis in adults only.

DOSAGE AND ADMINISTRATION: The recommended dose of fexofenadine hydrochloride for adults is 120 mg once daily taken before a meal. The recommended dose of fexofenadine hydrochloride for children aged 12 years and over is 120 mg once daily taken before a meal. In children from 6 to 11 years of age: fexofenadine hydrochloride 30 mg tablet is the appropriate formulation for administration and dosing in this population. The dosage for adults 15 years of age and older with seasonal allergic rhinitis, is one 10 mg tablet daily to be taken in the evening. Montelukast may be taken with or without food. FEXO M should not be used concomitantly with other products containing the same active ingredient, montelukast.

CONTRAINDICATION: Hypersensitivity to the active substance or to any of the excipients.

WARNINGS & PRECAUTIONS: ***Fexofenadine Hydrochloride:*** Patients with a history of or ongoing cardiovascular disease should be warned that antihistamines as a medicine class have been associated with the adverse reactions, tachycardia and palpitations. ***Montelukast Sodium:*** 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. If an acute attack occurs, a short-acting inhaled β-agonist should be used. Patients should seek their doctor's advice as soon as possible if they need more inhalations of short-acting β-agonists than usual. Montelukast should not be substituted abruptly for inhaled or oral corticosteroids. In rare cases, patients on therapy with anti-asthma agents including montelukast may present with systemic eosinophilia, sometimes presenting with clinical features of vasculitis consistent with Churg-Strauss syndrome, a condition which is often treated with systemic corticosteroid therapy. Physicians should be alert to eosinophilia, vasculitic rash, worsening pulmonary symptoms, cardiac complications, and/or neuropathy presenting in their patients. Patients who develop these symptoms should be reassessed and their treatment regimens evaluated. Treatment with montelukast does not alter the need for patients with aspirin-sensitive asthma to avoid taking aspirin and other non-steroidal anti-inflammatory drugs.

DRUG INTERACTIONS: ***Fexofenadine Hydrochloride:*** Fexofenadine does not undergo hepatic biotransformation and therefore will not interact with other medicinal products through hepatic mechanisms. Coadministration of fexofenadine hydrochloride with erythromycin or ketoconazole has been found to result in 2-3 times increase in the level of fexofenadine in plasma. The administration of an antacid containing aluminium and magnesium hydroxide gels 15 minutes prior to fexofenadine hydrochloride caused a reduction in bioavailability, most likely due to binding in the gastrointestinal tract. It is advisable to leave 2 hours between administration of fexofenadine hydrochloride and aluminium and magnesium hydroxide containing antacids. ***Montelukast Sodium:*** The area under the plasma concentration curve (AUC) for montelukast was decreased approximately 40% in subjects with co-administration of phenobarbital. Since montelukast is metabolised by CYP 3A4, 2C8, and 2C9, caution should be exercised, particularly in children, when montelukast is co-administered with inducers of CYP 3A4, 2C8, and 2C9, such as phenytoin, phenobarbital and rifampicin. In a clinical drug-drug

interaction study involving montelukast and gemfibrozil (an inhibitor of both CYP 2C8 and 2C9) gemfibrozil increased the systemic exposure of montelukast by 4.4-fold. No routine dosage adjustment of montelukast is required upon co-administration with gemfibrozil or other potent inhibitors of CYP 2C8, but the physician should be aware of the potential for an increase in adverse reactions. Co-administration of montelukast with itraconazole, a strong inhibitor of CYP 3A4, resulted in no significant increase in the systemic exposure of montelukast.

ADVERSE REACTIONS: ***Fexofenadine Hydrochloride:*** Headache, drowsiness, dizziness, nausea, fatigue, Immune system disorders, hypersensitivity reactions with manifestations such as angioedema, chest tightness, dyspnoea, flushing and systemic anaphylaxis, insomnia, nervousness, sleep disorders or nightmares/excessive dreaming (paroniria), tachycardia, palpitations, diarrhoea, Skin and subcutaneous tissue disorders rash, urticaria, and pruritus. ***Montelukast Sodium:*** Headache, abdominal pain, upper respiratory infection, increased bleeding tendency, hypersensitivity reactions including anaphylaxis, hepatic eosiniophilic infiltration, dream abnormalities including nightmares, insomnia, somnambulism, anxiety, agitation including aggressive behaviour or hostility, depression, psychomotor hyperactivity (including irritability, restlessness, tremor), disturbance in attention, memory impairment, hallucinations, disorientation, suicidal thinking and behaviour (suicidality), dizziness, drowsiness paraesthesia/hypoesthesia, seizure, palpitations, epistaxis, Churg-Strauss Syndrome (CSS) and pulmonary eosinophilia, diarrhoea, nausea, vomiting, dry mouth, dyspepsia, elevated levels of serum transaminases (ALT, AST), hepatitis (including cholestatic, hepatocellular, and mixed-pattern liver injury), rash, bruising, urticaria, pruritus, angioedema, erythema nodosum, erythema multiforme, arthralgia, myalgia including muscle, cramps, pyrexia, asthenia/fatigue, malaise, and oedema.

MARKETED BY:

Torrent Pharmaceuticals Limited.

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(Additional information is available on request)