

## MASTOWELL M

Abbreviated Prescribing information for Mastowell M (20/10 mg) [Please refer the complete prescribing information available at [www.torrentpharma.com](http://www.torrentpharma.com)]

**PHARMACOLOGICAL PROPERTIES:** Mastowell M contains bilastine and montelukast.

Montelukast is an orally active compound which binds with high affinity and selectivity to the CysLT1 receptor. The cysteinyl leukotrienes (LTC<sub>4</sub>, LTD<sub>4</sub>, LTE<sub>4</sub>) are potent inflammatory eicosanoids released from various cells including mast cells and eosinophils. These important pro-asthmatic mediators bind to cysteinyl leukotriene (CysLT) receptors. The CysLT type-1 (CysLT1) receptor is found in the human airway (including airway smooth muscle cells and airway macrophages) and on other pro-inflammatory cells (including eosinophils and certain myeloid stem cells). CysLTs have been correlated with the pathophysiology of asthma and allergic rhinitis.

Bilastine is an antihistamine; its principal effects are mediated via selective inhibition of peripheral H<sub>1</sub> receptors. The anti-histaminic activity of bilastine has been documented in a variety of animal and human models. It shows moderate bilastine is a non-sedating, long-acting histamine antagonist with selective peripheral H<sub>1</sub> receptor antagonist affinity and no affinity for muscarinic receptors.

**INDICATIONS:** For the treatment of allergic rhinitis in adults.

**DOSAGE AND ADMINISTRATION:** One tablet once daily for the relief of symptoms of allergic rhinitis in adults. The tablet is to be swallowed with water. It is recommended to take the daily dose in one single intake.

**WARNINGS & PRECAUTIONS:** Churg-Strauss syndrome; Neuropsychiatric events; children aged 2-5 years of age; in patients with moderate or severe renal impairment coadministration of bilastine with P-glycoprotein inhibitors, such as e.g, ketoconazole, erythromycin, cyclosporine, ritonavir or diltiazem, may increase plasmatic levels of bilastine and therefore increase the risk of adverse effects of bilastine.

**ADVERSE REACTIONS:** Increased bleeding tendency, thrombocytopenia, upper respiratory infection, oral herpes, hypersensitivity reactions (such as anaphylaxis, angioedema, dyspnoea, rash, localized oedema/local swelling, and erythema), increased appetite, 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, tic, hallucinations, disorientation, suicidal thinking and behaviour (suicidality), dysphemia, tinnitus, vertigo, right bundle branch block, sinus arrhythmia, other ECG abnormalities, electrocardiogram QT prolonged, tachycardia, palpitation, somnolence, headache, dizziness, drowsiness paraesthesia/hypoesthesia, seizure, dyspnea, nasal discomfort, nasal dryness, epistaxis, Churg-Strauss Syndrome (CSS), pulmonary eosinophilia, upper abdominal pain, nausea, vomiting, stomach discomfort, diarrhea, dry mouth, dyspepsia and gastritis, hepatitis (including cholestatic, hepatocellular, and mixed-pattern liver injury), pruritus, rash, bruising, urticaria, pruritus, angioedema, erythema nodosum, erythema

multiforme, arthralgia, myalgia including muscle cramps, increased gamma-glutamyl transferase, alanine aminotransferase increased, aspartate aminotransferase increased, blood creatinine increased, blood triglycerides increased and increased weight.

**MARKETED BY:**



**TORRENT PHARMACEUTICALS LTD.**

Torrent House, Off Ashram Road,  
Ahmedabad-380 009, INDIA  
Torrent Pharmaceuticals Ltd.

**IN/ MASTOWELL M 20+10mg/AUG-20/01/ABPI**

(Additional information is available on request)