

## ALLERFEX

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

Abbreviated Prescribing information for ALLERFEX (Fexofenadine Hydrochloride Tablets I.P.)

[Please refer the complete prescribing information available at [www.torrentpharma.com](http://www.torrentpharma.com)]

### **PHARMACOLOGICAL PROPERTIES:**

**MECHANISM OF ACTION:** Fexofenadine hydrochloride is a non-sedating H<sub>1</sub> antihistamine. Fexofenadine is a pharmacologically active metabolite of terfenadine.

**INDICATIONS:** In the treatment of relief of symptoms associated with seasonal allergic rhinitis and chronic idiopathic urticaria in adults only.

**DOSAGE AND ADMINISTRATION:** As directed by the Physician.

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

**WARNINGS & PRECAUTIONS:** As with most new medicinal products there is only limited data in the elderly and renally or hepatically impaired patients. Fexofenadine hydrochloride should be administered with care in these special groups, 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, Fexofenadine hydrochloride 180 mg Film-Coated Tablets also contain Allura Red AC Lake, which may cause allergic reactions.

**DRUG INTERACTIONS:** Fexofenadine does not undergo hepatic biotransformation and therefore will not interact with other medicinal products through hepatic mechanisms. Co-administration of fexofenadine hydrochloride with erythromycin or ketoconazole has been found to result in a 2-3 times increase in the level of fexofenadine in plasma. The changes were not accompanied by any effects on the QT interval and were not associated with any increase in adverse reactions compared to the medicinal products given singly. Animal studies have shown that the increase in plasma levels of fexofenadine observed after co-administration of erythromycin or ketoconazole, appears to be due to an increase in gastrointestinal absorption and either a decrease in biliary excretion or gastrointestinal secretion, respectively. No interaction between fexofenadine and omeprazole was observed. However, 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.

**ADVERSE REACTIONS:** Headache, Drowsiness, Dizziness, Nausea, Fatigue, Insomnia, Nervousness, Sleep disorders Or Nightmares/Excessive dreaming (Paroniria), Tachycardia, Palpitations, Diarrhea, Rash, Urticaria and Pruritus.

### **MARKETED BY:**



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**IN/ ALLERFEX 120,180mg /APR-19/01/ABPI**

(Additional information is available on request)