FEXOFEN

Fexofenadine Hydrochloride
Tablet & Suspension

FEXOFEN (Fexofenadine Hydrochloride) is a non-sedating antihistamine with selective peripheral H_1 receptor antagonist activity.

COMPOSITION

FEXOFEN 120 Tablet: Each film coated tablet contains Fexofenadine Hydrochloride USP 120 mg.

FEXOFEN 180 Tablet: Each film coated tablet contains Fexofenadine Hydrochloride USP 180 mg.

FEXOFEN Suspension: Each 5 ml suspension contains Fexofenadine Hydrochloride USP 30 mg.

INDICATION

FEXOFEN (Fexofenadine Hydrochloride) is indicated for the relief of symptoms associated with allergic rhinitis e.g. sneezing, rhinorrhea and allergic skin conditions e.g. chronic idiopathic urticaria.

DOSAGE AND ADMINISTRATION

Adults : **Allergic Rhinitis** : 120 mg once daily.
Urticaria : 180 mg once daily.
Children: ***2-11 years*** : 30 mg or 5 ml (1 teaspoonful) twice daily.
6 months - 2 years : 15 mg or 2.5 ml ($^1/_2$ teaspoonful) twice daily.

PREGNANCY & LACTATION

FEXOFEN should be used in pregnancy only if the potential benefit outweighs the potential risk to the fetus. Because many drugs are excreted in human milk, caution should be exercised when **FEXOFEN** is administered to nursing women.

SIDE EFFECT

Adverse events reported with fexofenadine include :
Common : Headache.
Uncommon : Fatigue, drowsiness, nausea, tachycardia, palpitations, dry mouth and gastrointestinal disturbances (like dyspepsia, diarrhoea).

CONTRAINDICATION

FEXOFEN is contraindicated in patients with known hypersensitivity to any of its ingredients.

PRECAUTION

FEXOFEN should not be taken closely in time with aluminium and magnesium containing antacids.

DRUG INTERACTION

Fexofenadine does not undergo hepatic bio-transformation and is therefore unlikely to interact with drugs that rely upon hepatic metabolism. Fexofenadine hydrochloride at doses of 120 mg twice daily has been safely co-administered with erythromycin (500 mg three times daily) and ketoconazole (400 mg once daily) under steady state conditions in healthy volunteers. An increase in the level of fexofenadine in plasma of two times was observed after co-administration of erythromycin or ketoconazole but this was not associated with any increase in adverse events or effects on the QT interval, compared to that seen when the drugs were given singly.

OVERDOSE

Single dose up to 800 mg and dose up to 690 mg b.i.d. for 1 month or 240 mg q.i.d for 1 year were studied in healthy subjects without the development of clinically significant adverse events as compared to placebo. However, dizziness, drowsiness, and dry mouth have been reported.

STORAGE INSTRUCTION

Store below 25°C. Protect from light. Keep out of reach of children.

PACKAGING

FEXOFEN 120 Tablet: Each box contains 5x10's tablet in blister pack.
FEXOFEN 180 Tablet: Each box contains 3x10's tablet in blister pack.
FEXOFEN Suspension: Each bottle contains 50ml, 70ml Suspension.

Manufactured by
SOMATEC PHARMACEUTICALS LTD.
SARULIA, DEMRA, DHAKA, BANGLADESH