Fexofenadine

Core Safety Proflie

This CSP is combining safety information from the three existing pharmaceutical forms : 30 mg film-coated tablets, 120 mg film-coated tablets and 180 mg film-coated tablets. Information that is specific to one pharmaceutical form is identified by a subheading. No subheading indicates that information is valid for all three pharmaceutical forms.

4.3 Contraindications

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

4.4 Special warnings and precautions for use

Patients with a history of or ongoing cardiovascular disease should be warned that, antihistamines as a drug class have been associated with the adverse events tachycardia and palpitations (see section 4.8).

For 120 mg film-coated tablets and 180 mg film-coated tablets
As with most new drugs 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.

For 30 mg film-coated tablets
The safety and efficacy of fexofenadine hydrochloride in renally or hepatically impaired children have not been established (see section 4.2). Fexofenadine hydrochloride should be administered with caution in these patients.

4.5 Interaction with other medicinal products and other forms of interaction

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 events 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 hydrochloride 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.

For 30 mg film-coated tablets
Interaction studies have only been performed in adults.

4.6 Pregnancy and lactation

Pregnancy
There are no adequate data from the use of fexofenadine hydrochloride in pregnant women. Limited animal studies do not indicate direct or indirect harmful effects with respect to effects on pregnancy, embryonal/foetal development, parturition or postnatal development (see section 5.3). Fexofenadine hydrochloride should not be used during pregnancy unless clearly necessary.

Lactation
There are no data on the content of human milk after administering Fexofenadine hydrochloride. However, when terfenadine was administered to nursing mothers fexofenadine was found to cross into human breast milk. Therefore fexofenadine hydrochloride is not recommended for mothers breast-feeding their babies.

4.7 Effects on ability to drive and use machines

On the basis of the pharmacodynamic profile and reported adverse events it is unlikely that Fexofenadine hydrochloride tablets will produce an effect on the ability to drive or use machines.
In objective tests, Telfast has been shown to have no significant effects on central nervous system function. This means that patients may drive or perform tasks that require concentration. However, in order to identify sensitive people who have an unusual reaction to drugs, it is advisable to check the individual response before driving or performing complicated tasks.

4.8 Undesirable effects

In adults, the following undesirable effects have been reported in clinical trials, with an incidence similar to that observed with placebo:
Nervous system disorders
Common (≥1/100, <1/10): headache, drowsiness, dizziness

Gastrointestinal disorders
Common (≥1/100, <1/10): nausea

General disorders and administration site conditions
Uncommon (≥1/1000, <1/100): fatigue

In adults, the following undesirable effects have been reported in postmarketing surveillance. The frequency with which they occur is not known (cannot be estimated from available data):

Immune system disorders
hypersensitivity reactions with manifestations such as angioedema, chest tightness, dyspnoea, flushing and systemic anaphylaxis

Psychiatric disorders

insomnia, nervousness, sleep disorders or nightmares/excessive dreaming (paroniria),

Cardiac disorders
tachycardia, palpitations

Gastrointestinal disorders
diarrhoea

Skin and subcutaneous tissue disorders
rash, urticaria, pruritus

For 30 mg film-coated tablets
In controlled clinical trials in children aged 6 to 11 years, the most commonly reported adverse reaction considered at least possibly related to fexofenadine hydrochloride by the investigator was headache. The incidence of headache in pooled data from clinical trials was 1.0% for patients taking fexofenadine hydrochloride 30 mg (673 children) and for patients taking placebo (700 children). There are no clinical safety data in children treated with fexofenadine hydrochloride for periods longer than two weeks
In controlled clinical trials in 845 children aged 6 months to 5 years with allergic rhinitis, 415 children were administered 15 mg or 30 mg of fexofenadine hydrochloride (capsule content sprinkled onto dosing vehicle) and 430 children were administered placebo. There were no unexpected adverse events in the children treated with fexofenadine and the adverse event profile was similar to that of older children and adults (see section 4.2).

4.9 Overdose

Dizziness, drowsiness, fatigue and dry mouth have been reported with overdose of fexofenadine hydrochloride. Doses up to 60 mg twice daily for two weeks have been administered to children, and single doses up to 800 mg and doses up to 690 mg twice daily for 1 month or 240 mg once daily for 1 year have been administered to healthy adult subjects without the development of clinically significant adverse events as compared with placebo. The maximum tolerated dose of fexofenadine hydrochloride has not been established.
Standard measures should be considered to remove any unabsorbed drug. Symptomatic and supportive treatment is recommended. Haemodialysis does not effectively remove fexofenadine hydrochloride from blood.