APPROVED PROFESSIONAL INFORMATION FOR TELFAST 180 TABLETS

SCHEDULING STATUS: S1

PROPRIETARY NAME AND DOSAGE FORM:

TELFAST 180 tablets

COMPOSITION:

TELFAST 180:

Fexofenadine base 168 mg (as fexofenadine hydrochloride 180 mg) per tablet.

Inactive ingredients:

Colloidal anhydrous silica, croscarmellose sodium, hypromellose, macrogol, magnesium stearate, microcrystalline cellulose, pregelatinised maize starch, povidone, titanium dioxide, pink and yellow iron oxide.

Sugar free.

CATEGORY AND CLASS:

A 5.7.1 Antihistaminics

PHARMACOLOGICAL ACTION:

Pharmacodynamic properties:

Fexofenadine hydrochloride is a pharmacologically active metabolite of terfenadine and is a non-sedating selective histamine H_1-receptor antagonist.

Fexofenadine exhibits an antihistaminic effect beginning within one hour, achieving maximum effect at 6 hours and lasting 24 hours. There was no evidence of tolerance to these effects after 28 days of dosing.

Pharmacokinetic properties:

Absorption:

Fexofenadine is absorbed into the body following oral administration, with T_{max} occurring at approximately 1 - 3 hours post dose. The mean C_{max} value was approximately 494 ng/ml following the administration of a 180 mg dose once daily.

Distribution:

Fexofenadine is 60 – 70 % plasma protein bound.

Biotransformation and elimination:

Fexofenadine undergoes negligible metabolism, as it was the only major compound identified in urine and faeces of animals and man. The plasma concentration profiles of fexofenadine follow a bi-exponential decline with a terminal elimination half-life ranging from 11 to 15 hours after multiple dosing. The single and multiple dose pharmacokinetics of fexofenadine are linear between 40 mg and 240 mg taken daily. The major route of elimination is believed to be via biliary excretion while up to 10 % of ingested dose is excreted unchanged through the urine.

Effect of age:

In older subjects (≥ 65 years old), peak plasma levels of fexofenadine were 99 % greater than those observed in normal volunteers (< 65 years old). Mean elimination half-lives were similar to those observed in normal volunteers.

Renally impaired:

In patients with mild (creatinine clearance 41-80 mL/min) to severe (creatinine clearance 11-40 mL/min) renal impairment, peak plasma levels of fexofenadine were 87 % and 111 % greater, respectively, and mean elimination half-lives were 59 % and 72 % longer, respectively, than observed in normal volunteers. Peak plasma levels in patients on dialysis (creatinine clearance ≤ 10 mL/min) were 82 % greater and half-life was 31 % longer than observed in normal volunteers.

Based on increases of bioavailability and half-life, a dose of 60 mg once daily is recommended as the starting dose in patients with decreased renal function. (See Dosage and Directions for use).

INDICATIONS:

TELFAST 180 is indicated for the relief of symptoms associated with chronic idiopathic urticaria (CIU).

TELFAST 180 is indicated for the relief of symptoms associated with

Seasonal allergic rhinitis (SAR), where TELFAST 120 has been

Insufficient to control the symptoms.

CONTRAINDICATIONS:

TELFAST 180 is contraindicated in patients with known hypersensitivity to fexofenadine hydrochloride or any of its inactive ingredients (see COMPOSITION).

There is no experience with TELFAST 180 in pregnant women. TELFAST 180 should not be taken during pregnancy or by mothers breastfeeding their babies (see HUMAN REPRODUCTION).

WARNINGS AND SPECIAL PRECAUTIONS:

There is only limited data for the use in elderly and renally or hepatically impaired patients. TELFAST 180 should be administered with care in these special risk 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 (see section 4.8).

Effects on the ability to drive and use machines:

Fexofenadine lacks sedative effects. Patients should, however, be warned that a small number of individuals may experience sedation. It is therefore advisable to determine individual response before driving or performing complicated tasks. This effect may be compounded by simultaneous intake of alcohol or other central nervous system depressants

INTERACTIONS:

Fexofenadine does not undergo hepatic biotransformation.

Coadministration of TELFAST 180 with erythromycin or ketoconazole has been found to result in 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 medicines given singly.

Animal studies have shown that the increase in plasma levels of fexofenadine observed after coadministration 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] TELFAST 180 and omeprazole was observed. However, the administration of an antacid containing aluminium and magnesium hydroxide gels 15 minutes prior to TELFAST 180 caused a reduction in bioavailability, most likely due to binding in the gastrointestinal tract. It is advisable to leave 2 hours between administration of TELFAST 180 and aluminium and magnesium hydroxide containing antacids.

The efficacy and safety of TELFAST 180 has not been studied in children under the age of 12 years.

HUMAN REPRODUCTION:

There is no experience with **TELFAST 180** in pregnant women. **TELFAST 180** should not be taken during pregnancy or by mothers breastfeeding their babies.

DOSAGE AND DIRECTIONS FOR USE

Adults and children aged 12 years and over:

One 180 mg tablet daily.

Children under 12 years of age:

The efficacy and safety of TELFAST 180 has not been studied in children under 12.

Special risk groups: (See Pharmacokinetics and Warnings)

SIDE-EFFECTS

The following frequency rating has been used, where relevant:

Very common (>1/10); common (>1/100, <1/10); uncommon (> 1/1 000, <1/100); rare (> 1/10 000, <1/1 000); very rare (<1/10 000), including 'isolated reports'.

Nervous system disorders:

Common: Headache, drowsiness, dizziness.

Gastrointestinal disorders:

Common: Nausea.

General disorders and administration site conditions:

Uncommon: Fatigue.

Immune system disorders:

Uncommon: Hypersensitivity reactions with manifestations such as angioedema, chest tightness, dyspnoea, flushing and systemic anaphylaxis.

Psychiatric disorders:

Uncommon: Insomnia, nervousness and sleep disorders.

Nervous system disorders:

Uncommon: Paroniria.

Skin and subcutaneous tissue disorders:

Uncommon: Rash, urticaria, pruritus.

In adults, the following adverse reactions have been reported in post-marketing surveillance. The frequency with which they occur is not known (cannot be estimated from available data):

Uncommon: Cardiac disorders

Tachycardia, palpitations

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

Most reports of TELFAST 180 overdose contain limited information. However, dizziness, drowsiness and dry mouth have been reported. Standard measures should be considered to remove any unabsorbed medicine. Haemodialysis does not effectively remove fexofenadine hydrochloride from blood.

IDENTIFICATION:

Peach coloured, capsule-shaped, film-coated tablets. One face is debossed “018”, the other face with an “e”.

Diameter approximately 7,6 mm x 17,3 mm.

Thickness: approximately 5,3 mm.

STORAGE INSTRUCTIONS:

Store in a well-closed container at or below 25 °C.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

32/5.7.1/0447

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

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