

SCHEDULING STATUS

S2

PROPRIETARY NAME (AND DOSAGE FORM)

FASTWAY 120 (tablets)

FASTWAY 180 (tablets)

COMPOSITION

FASTWAY 120: Each tablet contains fexofenadine hydrochloride 120 mg

FASTWAY 180: Each tablet contains fexofenadine hydrochloride 180 mg

Contains sugar (mannitol).

The excipients are croscarmellose sodium, FD&C Red #40/Allura Red AC Aluminium Lake, hypromellose, iron oxide Black JPE, isopropyl alcohol, macrogol/PEG 400, magnesium stearate, maize starch, mannitol, powdered cellulose, purified water, silica colloidal anhydrous, titanium dioxide.

PHARMACOLOGICAL CLASSIFICATION

A 5.7.1 Antihistaminics

PHARMACOLOGICAL ACTION

Pharmacodynamics Properties:

Fexofenadine hydrochloride is a pharmacologically active metabolite of terfenadine and is a non-sedating, selective histamine H₁-receptor antagonist. Fexofenadine exhibits an antihistaminic effect beginning within one hour, achieving maximum effect at 6 hours and lasting 24 hours.

Pharmacokinetic Properties:

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 427 ng/ml and 494 ng/ml following the administration of a 120 mg and 180 mg dose once daily, respectively. The volume of distribution is 5,4 – 5,8 l/kg. Fexofenadine does not cross the blood brain barrier.

Fexofenadine is 60 - 70 % plasma protein bound. Fexofenadine undergoes negligible metabolism (about 5 % of the total dose is metabolised, mostly by the intestinal mucosa, with only 0,5 – 1,5 % of the dose undergoing hepatic biotransformation), 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 (faeces), while up to 10 % of the 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.

Renal impairment

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.

INDICATIONS

FASTWAY 120 is indicated for the relief of symptoms associated with seasonal allergic rhinitis (SAR).

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

CONTRAINDICATIONS

Patients with known hypersensitivity to fexofenadine hydrochloride or to any of the ingredients of **FASTWAY**.

Safety in pregnancy and lactation has not been established. (See “**PREGNANCY AND LACTATION**”).

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

WARNINGS AND SPECIAL PRECAUTIONS

Exacerbation of psoriasis has been reported with the use of **FASTWAY**.

Patients with a history of, or ongoing cardiovascular disease should be warned that antihistamines, as a class of medicines, have been associated with adverse reactions such as tachycardia and palpitations.

There is only limited data for the use in elderly and renally or hepatically impaired patients. **FASTWAY** should be administered with care in these special risk groups.

Effect on ability to drive or use of machinery

FASTWAY may affect the ability to drive or operate machinery.

FASTWAY 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. (See “**INTERACTIONS**”).

FASTWAY contains mannitol which, on rare occasions, may cause hypersensitivity reactions.

INTERACTIONS

Interaction with other medicaments and other forms of interaction

FASTWAY does not undergo hepatic biotransformation. Co-administration of **FASTWAY** with erythromycin or ketoconazole has been found to result in a 2 - 3 times increase in the level of **FASTWAY** 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 individually. The increase in plasma levels of **FASTWAY** 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 **FASTWAY** and omeprazole was observed. However, the administration of an antacid containing aluminium and magnesium hydroxide gels 15 minutes prior to **FASTWAY**, causes a reduction in bioavailability, most likely due to binding in the gastrointestinal tract. It is advisable to leave 2 hours between administration of **FASTWAY** and aluminium and magnesium hydroxide containing antacids.

PREGNANCY AND LACTATION

PREGNANCY

There is no experience with **FASTWAY** in pregnant women.

LACTATION

FASTWAY has been detected in breast milk.

Mothers on **FASTWAY** should not breastfeed.

FASTWAY should not be taken during pregnancy or lactation.

DOSAGE AND DIRECTIONS FOR USE

Adults and children aged 12 years and over

Chronic idiopathic urticaria (CIU): One 180 mg tablet daily.

Seasonal allergic rhinitis (SAR): One 120 mg tablet daily.

Children under 12 years of age

The efficacy and safety of **FASTWAY** has not been studied in children below 12 years of age.

Special risk groups (See “**WARNINGS AND SPECIAL PRECAUTIONS**”)

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.

SIDE- EFFECTS

Infections and infestations

Frequent: Viral infections such as cold or flu

Immune system disorders

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

Psychiatric disorders

Less frequent: Paranoia

Nervous system disorders

Frequent: Fatigue , headache, drowsiness, dizziness

Less frequent: Insomnia, nervousness, sleep disorders

Respiratory, thoracic and mediastinal disorders

Frequent: Sinusitis

Gastrointestinal disorders

Frequent: Nausea, dyspepsia

Skin and subcutaneous tissue disorders

Less frequent: Rash, urticaria, pruritus

Reproductive system and breast disorders

Frequent: Dysmenorrhoea

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

In overdose side effects will be exacerbated and exaggerated (see **SIDE EFFECTS**).

Dizziness, drowsiness and dry mouth have been reported. Standard measures should be considered to remove any unabsorbed fexofenadine. Haemodialysis does not effectively remove **FASTWAY** from blood.

Treatment is symptomatic and supportive.

IDENTIFICATION

FASTWAY 120: Pink coloured, oval shaped, biconvex film coated tablets debossed with 'FXF' on one side and '120' on other side

FASTWAY 180: Pink coloured, oval shaped, biconvex film coated tablets debossed with 'FXF' on one side and '180' on other side

PRESENTATION

FASTWAY 120: White opaque PVC/PE/PVDC blisters of 10 tablets are packed in to cartons of 10 or 30 tablets.

FASTWAY 180: White opaque PVC/PE/PVDC blisters of 10 tablets are packed in to cartons of 10 or 30 tablets.

STORAGE INSTRUCTIONS

Store at or below 25 °C. Protect from light. Keep blisters in carton until required for use.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBERS

FASTWAY 120: 41/5.7.1/0319

FASTWAY 180: 41/5.7.1/0320

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE REGISTRATION CERTIFICATE

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