

**SCHEDULING STATUS:** S2**PROPRIETARY NAME (AND DOSAGE FORM):****FEXO 120 (Tablets)****FEXO 180 (Tablets)****COMPOSITION:****FEXO 120 Tablets:** Each coated tablet contains 120 mg fexofenadine hydrochloride.**FEXO 180 Tablets:** Each coated tablet contains 180 mg fexofenadine hydrochloride.**PHARMACOLOGICAL CLASSIFICATION:**

A 5.7.1 Antihistaminics.

**PHARMACOLOGICAL ACTION:**Fexofenadine hydrochloride is a non-sedating selective histamine H<sub>1</sub>-receptor antagonist. It is the major active metabolite of terfenadine. The antihistaminic effect of fexofenadine starts within one hour post dose, reaches maximum effect at 6 hours and lasts for 24 hours.**Pharmacokinetics:**Following oral administration, fexofenadine is absorbed into the body. T<sub>max</sub> is reached approximately 1 - 3 hours after administration. After a single once daily dose of 120 mg or 180 mg, mean C<sub>max</sub> values of approximately 427 ng/ml and 494 ng/ml, respectively, are obtained. Fexofenadine has a volume of distribution of 5.4 - 5.8 L/kg body weight. Fexofenadine does not transfer across the blood-brain barrier.

Sixty to seventy percent of fexofenadine is plasma protein bound. Studies in animals and humans reveal that fexofenadine undergoes negligible metabolism, as it is the only major molecule detected in urine and faeces. The intestinal mucosa metabolises about 5 % of the total dose, while only 0.5 - 1.5 % of the dose undergoes hepatic biotransformation. After multiple dosing, the plasma concentration profiles of fexofenadine show a bi-exponential decline and a terminal elimination half-life of 11 - 15 hours. Daily administration of between 40 mg and 240 mg fexofenadine shows linear single and multiple dose pharmacokinetics. Biliary excretion (faeces) seems to be the major route of elimination with up to 10% of the ingested dose being eliminated unchanged through urinary excretion.

**Effect of age:**

Peak plasma levels of fexofenadine are 99 % greater in older subjects (≥ 65 years of age), compared to those observed in younger volunteers (&lt; 65 years of age). Similar mean elimination half-lives are observed in the two age groups.

**Renal impairment:**

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

**INDICATIONS:****FEXO 120** is indicated for the relief of seasonal allergic rhinitis (SAR) symptoms.**FEXO 180** is indicated for the relief of chronic idiopathic urticaria (CIU) symptoms.**CONTRA-INDICATIONS:**

The safety in pregnancy and lactation has not been established (see "WARNINGS").

There are no studies on the safety and efficacy of **FEXO** in children under the age of 12 years.Hypersensitivity to **FEXO** or any of its ingredients.**WARNINGS:**Data on the use in the elderly and in renally or hepatically impaired patients is limited. Use **FEXO** with care in these special risk groups. **FEXO** is excreted in breast milk.The ability to drive or operate machinery may be affected by **FEXO**.**INTERACTIONS:****FEXO** is not metabolised in the liver. A two to three fold increase in the plasma levels of **FEXO** result from co-administration of **FEXO** with erythromycin or ketoconazole. These changes do not coincide with changes in the QT-interval and are not accompanied by any increase in adverse reactions compared to the drugs administered individually. An increase in gastrointestinal absorption together with either a decrease in biliary excretion or a decrease in gastrointestinal secretion, appears to be responsible for the increase in plasma levels of **FEXO** following co-administration with either erythromycin or ketoconazole.There is no interaction between **FEXO** and omeprazole. However, the bioavailability of **FEXO** is reduced when an antacid containing aluminium and magnesium hydroxide gels is administered 15 minutes prior to **FEXO**. This most likely results from binding in the gastrointestinal tract. Therefore the administration of **FEXO** and aluminium and magnesium hydroxide containing antacids should be spaced two hours apart.**PREGNANCY AND LACTATION:**There is no data on the use of **FEXO** in pregnant women.Do not take **FEXO** during pregnancy or lactation.**DOSAGE AND DIRECTIONS FOR USE:****Adults and children aged 12 years and older:**

Chronic idiopathic urticaria (CIU): Take one 180 mg tablet once a day.

Seasonal allergic rhinitis (SAR): Take one 120 mg tablet once a day.

**Children younger than 12 years of age:**The safety and efficacy of **FEXO** in children younger than 12 years has not been studied.**Special risk groups: (see "WARNINGS")**

Because of the increases in bioavailability and half-life, a single dose of 60 mg daily is recommended as the starting dose in patients with renal impairment.

**SIDE-EFFECTS AND SPECIAL PRECAUTIONS:****Side-effects:**

The following side-effects can occur:

**General disorders:****Less Frequent:** Fatigue.**Central nervous system disorders:****Frequent:** Drowsiness, dizziness, headache**Less Frequent:** Sleep disorders or paranoia, insomnia, nervousness.**Gastrointestinal system disorders:****Frequent:** Nausea.**Less Frequent:** Dyspepsia.**Hypersensitivity reactions:****Less Frequent:** Chest tightness, dyspnoea, angioedema, flushing, systemic anaphylaxis, urticaria, pruritus, rash.**Respiratory system disorders:****Less Frequent:** Viral infections such as cold or flu and sinusitis.**Reproductive system disorders:****Less Frequent:** Dysmenorrhoea.

No cardiovascular, haematological, hepatobiliary, musculoskeletal or renal side-effects have been reported.

**Special Precautions:****FEXO** has no sedative effects but since a small number of individuals may experience sedation, patients should be warned of this. Each individual's response to the medication should therefore be determined prior to driving or performing complicated tasks.

The sedative effects may be enhanced by the concomitant intake of other central nervous system depressants or alcohol (see "Pharmacokinetics", "INTERACTIONS" and "WARNINGS").

**KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:**There is limited information on **FEXO** overdoses. However, available data have reported drowsiness, dizziness and a dry mouth. Any unabsorbed drug should be removed by standard measures. Haemodialysis is not an effective measure to remove **FEXO** from the circulation.**IDENTIFICATION:****FEXO 120:** Peach coloured, oblong, biconvex, film-coated tablets, plain on one side with a central breakline on the other.**FEXO 180:** Yellow coloured, oblong, biconvex, film-coated tablets, plain on one side with a central breakline on the other.**PRESENTATION:**

Both strengths are packed in transparent PVC and aluminium foil blister strips with 5, 10 or 15 tablets, packed in cartons of 5, 10 or 30 tablets.

**STORAGE INSTRUCTIONS:**

Store below 25°C. Keep the blister strips in the carton until required for use.

KEEP OUT OF REACH OF CHILDREN.

**REGISTRATION NUMBERS:****FEXO 120:** A38/5.7.1/0414**FEXO 180:** A38/5.7.1/0415**NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:**CIPLA MEDPRO (PTY) LTD  
Rosen Heights, Pasita Street,  
Rosen Park, Bellville, 7530, RSA.**DATE OF PUBLICATION OF THIS PACKAGE INSERT:**

March 2006

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