PROFESSIONAL INFORMATION FOR

FEXO 120 TABLETS

FEXO 180 TABLETS

SCHEDULING STATUS

S1

1. NAME OF THE MEDICINE

FEXO 120 film coated tablets

FEXO 180 film coated tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

FEXO 120 : Each film-coated tablet contains 120 mg fexofenadine hydrochloride

FEXO 180: Each film-coated tablet contains 180 mg fexofenadine hydrochloride.

Sugar free.

For the full list of excipients, see **section 6.1**.

3. PHARMACEUTICAL FORM

Film-coated tablets.

FEXO 120: Peach coloured, oblong, biconvex, film-coated tablets with a breakline on one side and plain on the other side.

FEXO 180: Yellow coloured, oblong, biconvex, film-coated tablets, plain on one side and central breakline on the other.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

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

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

4.2 Posology and method of administration

Posology

Adults and children aged 12 years and over:

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 below 12 years of age:

The safety and efficacy of FEXO has not been studied in children under 12. (see **section 4.3** and **section 4.4**).

Special populations

(See **section 4.4**).

Renal impairment:

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.

Paediatric population

The safety and efficacy of FEXO in children younger than 12 years has not yet been established.

Method of administration

For oral administration.

4.3 Contraindications

FEXO is contraindicated in:

- Patients with known hypersensitivity to fexofenadine hydrochloride or to any of the excipients used in the formulation of FEXO (see **section 6.1**)
- FEXO should not be taken during pregnancy or by mothers breastfeeding their babies (see **section 4.6**)

4.4 Special warnings and precautions for use

Data on the use in the elderly and in renally or hepatically impaired patients is limited. FEXO should be administered with care in these special risk groups or special populations (see **section 4.2**).

FEXO is excreted in breast milk **(see section 4.6)**.

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

The ability to drive or operate machinery may be affected by FEXO.

Paediatric population:

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

4.5 Interaction with other medicinal products and other forms of interaction

FEXO is not metabolised in the liver. Fexofenadine is a P-glycoprotein (P-gp) and organic-anion-transporting polypeptide (OATP) substrate. Concomitant use of fexofenadine with P-gp inhibitors or inducers can affect the exposure to fexofenadine.

A two- or three-fold increase in plasma levels of FEXO result from co-administration of FEXO with P-gp inhibitors 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 medicines administered individually.

A drug-drug interaction study showed that co-administration of apalutamide (a weak inducer of P-gp) and a single oral dose of 30 mg fexofenadine resulted in a 30 % decrease in area under the curve (AUC) of fexofenadine.

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.

4.6 Fertility, pregnancy and lactation

Pregnancy:

There is no data on the use of FEXO in pregnant women. Therefore, FEXO should not be taken during pregnancy (see **section 4.3**).

Breastfeeding:

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, FEXO should not be taken by mothers breastfeeding their babies.

Fertility:

No human data on the effect of fexofenadine hydrochloride on fertility are available.

4.7 Effects on ability to drive and use machines

The ability to drive or operate machinery may be affected by FEXO. FEXO lacks significant sedative effects but since a small number of individuals may experience sedation, patients should be warned of this. Each individual's response to FEXO 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 **section 4.8**).

4.8 Undesirable effects

Tabulated summary of adverse reactions

The following adverse reactions have been classified according to the following categories, frequent, less frequent and frequency unknown.

MedDRA system organ class	Fequency	Side effects
General disorders and administration site conditions	**Less frequent**	Fatigue
Nervous system disorders	**Frequent**	Drowsiness, dizziness, headache
	Less frequent	Insomnia
Gastrointestinal disorders	**Frequent**	Nausea
	Frequency unknown	Diarrhea
Skin and subcutaneous tissue disorders	**Less frequent**	Rash, urticaria, pruritus
Immune system disorders	**Less frequent**	Hypersensitivity reactions with manifestations such as angioedema, chest tightness, dyspnoea, angioedema, flushing, systemic anaphylaxis
Cardiac disorders	**Frequency unknown**	Tachycardia, palpitations.

Psychiatric disorders	**Less frequent**	Nervousness, and sleep disorders or paranoia (nightmares/excessive dreaming)
Eye disorders	**Frequency unknown**	Blurred vision

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website, or to Cipla Medpro (Pty) Ltd. at drugsafetysa@cipla.com or telephone 080 222 6662 (toll free).

4.9 Overdose

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.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacological classification: A 5.7.1 Antihistaminics.

Pharmacotherapeutic group: Antihistamines for systemic use, ATC code: R06A X26

Mechanism of action

Fexofenadine hydrochloride is a non-sedating selective histamine H_1-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 24 hours. No evidence of tolerance to these effects after 28 days of dosing have been reported.

5.2 Pharmacokinetic properties

Absorption

Fexofenadine is absorbed into the body following oral administration, with T_{max} occurring at approximately 1 to 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.

Distribution

Fexofenadine has a volume of distribution of 5,4 to 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.

Biotransformation

Fexofenadine undergoes negligible metabolism (about 5 % of the total dose is metabolized, mostly by the intestinal mucosa, with only 0,5 % to 1,5 % of the dose undergoing hepatic biotransformation), as it was the only major compound identified in urine and faeces of man.

Elimination

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 billiary excretion (faeces), while up to 10 % of the ingested dose is excreted unchanged through the urine.

Elderly patients

Peak plasma levels of fexofenadine are 99 % greater in older subjects (≥ 65 years of age) compared to those observed in younger volunteers (< 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 to 80 mL/min) to severe (creatinine clearance 11 to 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. In patients with decreased renal function, a starting dose of 60 mg once daily is recommended based on increases in bioavailability and half-life (see **section 4.2**)

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Each tablet of FEXO 120 contains:

Croscarmellose sodium

Magnesium stearate

Maize starch

Microcrystalline cellulose

Opadry (03C54667) (containing Hypromellose, iron oxide red, iron oxide yellow, macrogol 400, macrogol-4000 and titanium dioxide)

Povidone

Each tablet of FEXO 180 contains:

Croscarmellose sodium

Magnesium stearate

Maize starch

Microcrystalline cellulose

Opadry (03C54667) (containing Hypromellose, iron oxide yellow, macrogol 400, Macrogol-4000 and titanium dioxide)

Povidone

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

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

6.5 Nature and contents of container

FEXO tablets 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.

Not all pack sizes may be marketed.

7. HOLDER OF CERTIFICATE OF REGISTRATION

CIPLA MEDPRO (PTY) LTD.

Building 9

Parc du Cap

Mispel Street

Bellville

7530

Customer Care: 080 222 6662

8. REGISTRATION NUMBER(S)

FEXO 120: A38/5.7.1/0414

FEXO 180: A38/5.7.1/0415

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

First authorisation: 07 April 2006

Latest renewal: Not applicable.

10. DATE OF REVISION OF THE TEXT

16 May 2025

Botswana: S2

FEXO 120 mg: BOT0801100

FEXO 180 mg: BOT0801099

Namibia: NS1

FEXO 120 mg: 09/5.7.1/0016

FEXO 180 mg: 09/5.7.1/0017