APPROVED PROFESSIONAL INFORMATION

SCHEDULING STATUS: S1

1. NAME OF THE MEDICINE

FENOFEX 120 Tablets

FENOFEX 180 Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

FENOFEX 120

Each film coated tablet contains:

Fexofenadine hydrochloride 120 mg

FENOFEX 180

Each film coated tablet contains:

Fexofenadine hydrochloride 180 mg

Sugar free.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Fenofex 120: Pink coloured, capsule shaped, coated tablets imprinted with '**F1**' in black ink on one side and plain on the other side.

Fenofex 180: Pink coloured, capsule shaped, coated tablets imprinted with '**F2**' in black ink on one side and plain on the other side.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

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

FENOFEX 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): 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 **FENOFEX** has not been studied in children under 12 years of age.

Special risk groups: (See section 4.4).

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.

Method of administration

Oral

4.3 Contraindications

- Hypersensitivity to fexofenadine or to any of the excipients listed in section 6.1.
- Safety in pregnancy and lactation has not been established (See section 4.6).
- The safety and efficacy of **FENOFEX** has not been studied in children under the age of 12 years.

4.4 Special warnings and precautions for use

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

Patients with a history of ongoing cardiovascular disease should be warned that, **FENOFEX** has been associated with adverse reactions, tachycardia and palpitations (see section 4.8).

4.5 Interaction with other medicines and other forms of interaction

FENOFEX does not undergo hepatic biotransformation. Co-administration of **FENOFEX** with erythromycin or ketoconazole has been found to result in a 2-3 times increase in the level of **FENOFEX** 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 **FENOFEX** observed after co-administration of erythromycin or ketoconazole appears to be due to an increase in gastro-intestinal absorption and either a decrease in biliary excretion or gastro-intestinal secretion, respectively.

No interaction between **FENOFEX** and omeprazole was observed. However, the administration of an antacid containing aluminium and magnesium hydroxide gels 15 minutes prior to **FENOFEX** caused a reduction in bioavailability, most likely due to binding in the gastro-intestinal tract. It is advisable to leave 2 hours between administration of **FENOFEX** and aluminium and magnesium hydroxide containing antacids.

4.6 Fertility, pregnancy and lactation

Pregnancy

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

FENOFEX should not be taken during pregnancy (see section 4.3).

Breastfeeding

FENOFEX has been detected in breast milk.

FENOFEX should not be taken during breastfeeding (see section 4.3).

4.7 Effects on ability to drive and use machines

FENOFEX may affect the ability to drive or operate machinery.

FENOFEX 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 section 5.2).

4.8 Undesirable effects

Tabulated list of adverse reactions

MedDRA System organ class	**Frequency**	**Adverse reactions**
Infections and infestations	Less frequent	Sinusitis and 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	Insomnia, nervousness and sleep disorders or nightmares/excessive dreaming (paroniria)
Nervous system disorders	Frequent	Headache, drowsiness and dizziness.
Cardiac disorders	Frequency unknown	Tachycardia, palpitations
Gastrointestinal disorders	Frequent	Nausea
	Less frequent	Dyspepsia
	Frequency unknown	Diarrhoea
Hepatobiliary disorders	Less frequent	Hepatitis either cytolytic or cholestatic.
Skin and subcutaneous tissue disorders	Less frequent	Rash, urticaria and pruritus.
Reproductive system and breast disorders	Less frequent	Dysmenorrhoea.
General disorders and administration site conditions	Less Frequent	Fatigue

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 "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

4.9 Overdose

See section 4.8.

Symptoms of overdose

Most reports of **FENOFEX** overdose contain limited information. However, dizziness, drowsiness and dry mouth have been reported.

Treatment of overdose

Standard measures should be considered to remove any unabsorbed drug. Haemodialysis does not effectively remove **FENOFEX** from blood.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

A 5.7.1 Antihistaminics.

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.

5.2 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 427 ng/ml and 494 ng/ml following the administration of a 120 mg and 180 mg once daily dose, respectively.

Distribution

Fexofenadine does not cross the blood brain barrier.

Biotransformation and elimination

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.

Special populations

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Croscarmellose sodium,

Magnesium stearate,

Microcrystalline cellulose,

Opadry brown

Opacode S-1-27794

Povidone.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months.

6.4 Special precautions for storage

Store at or below 25 °C in the original package, protected from moisture.

6.5 Nature and contents of container

Fenofex 120

Tablets are packed in white, opaque, PVC/PVDC blister strips with an aluminium foil backing. Cartons contain 10 or 30 tablets.

Fenofex 180

Tablets are packed in white, opaque, PVC/PVDC blister strips with an aluminium foil backing. Cartons contain 10 or 30 tablets.

7. HOLDER OF CERTIFICATE OF REGISTRATION

RANBAXY PHARMACEUTICALS (PTY) LTD

a Sun Pharma company

14 Lautre Road, Stormill Ext 1

Roodepoort, 1724

South Africa

8. REGISTRATION NUMBER:

Fenofex 120: A38/5.7.1/0407

Fenofex 180: A38/5.7.1/0408

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

07 July 2006

10. DATE OF REVISION OF THE TEXT

08 August 2022