SCHEDULING STATUS

S1

1. NAME OF THE MEDICINE

Pollofex 120, 120 mg film-coated tablets

Pollofex 180, 180 mg film-coated tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Pollofex 120: Each film-coated tablet contains 120 mg fexofenadine hydrochloride.

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

Excipient with known effect:

Each 120 mg tablet contains 156,00 mg lactose monohydrate.

Each 180 mg tablet contains 234,00 mg lactose monohydrate.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Film-coated tablets.

Pollofex 120: Peach colour, film-coated, capsule-shaped tablets, plain on both sides, thickness of approximately 4,2 mm.

Pollofex 180: Peach colour, film-coated, capsule-shaped tablets, plain on both sides, thickness of approximately 5,4 mm.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

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

Pollofex 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:

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

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

Children under 12 years of age:

The efficacy and safety of Pollofex have not been studied in children under 12.

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.

4.3 Contraindications

Pollofex is contraindicated in patients with known hypersensitivity to fexofenadine hydrochloride or to any of the excipients of Pollofex (see section 6.1).

Safety in pregnancy and lactation has not been established. Pollofex should not be taken during pregnancy or lactation (see section 4.6).

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

4.4 Special warnings and precautions for use

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

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

Lactose intolerance

Patients with the rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take Pollofex.

4.5 Interactions with other medicines and other forms of interactions

Pollofex does not undergo hepatic biotransformation.

Fexofenadine as contained in Pollofex is a P-glycoprotein (P-gp) and organic-anion-transporting polypeptide (OATP) substrate. Concomitant use of Pollofex with P-gp inhibitors or inducers can affect the exposure to Pollofex. Co-administration of Pollofex with P-gp inhibitors, erythromycin or ketoconazole has been found to result in 2 to 3 times increase in the level of Pollofex 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. A clinical medicine-medicine interaction study showed that co-administration of apalutamide (a weak inducer of P-gp) and a single oral dose of 30 mg fexofenadine as contained in Pollofex resulted in a 30 % decrease in AUC of fexofenadine.

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

4.6 Fertility, pregnancy and lactation

Pregnancy

Safety in pregnancy has not been established.

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

Breastfeeding

Safety in lactation has not been established. Pollofex has been detected in breast milk.

Pollofex should not be taken during lactation (see section 4.3).

4.7 Effects on ability to drive and use machines

Pollofex 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.

The effect may be compounded by simultaneous intake of alcohol or other central nervous system depressants.

4.8 Undesirable effects

System Organ Class	**Frequency**	
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	Headaches, drowsiness, dizziness
Eye disorders	Frequency unknown	Blurred vision
Cardiac disorders	Frequency unknown	Tachycardia, palpitations

Respiratory, thoracic and mediastinal disorders	Less frequent	Sinusitis and viral infections such as cold or flu
Gastrointestinal disorders	Frequent	Nausea
	Less frequent	Dyspepsia
Skin and subcutaneous tissue disorders	Less frequent	Rash, urticaria, 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. Healthcare 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

Most reports of Pollofex 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 Pollofex from blood.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacological classification: A.5.7.1 Antihistaminics

Pharmacotherapeutic group: other antihistamines for systemic use.

ATC code: R06A X28.

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

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. The volume of distribution is 5,4 to 5,8 l/kg. Fexofenadine does not cross the blood brain barrier.

Distribution

Fexofenadine is 60 to 70 % plasma protein bound.

Biotransformation and elimination

Fexofenadine undergoes negligible metabolism, (about 5 % of the total dose is metabolised, 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 animals and man. The plasma concentration profiles of fexofenadine follows 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 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 to 80 ml/min) to severe (creatinine clearance 11 to 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

Tablet cores:

Lactose monohydrate

Hydroxypropyl cellulose

Magnesium stearate

Maize starch

Tablet coating:

Opadry Pink 03B54819 consisting of:

Hypromellose (6cP)

Iron oxide yellow (E172)

Iron oxide red (E172)

Macrogol 400

Titanium dioxide (E171)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Store in the original pack at or below 25 ˚C. Protect from light. Keep the blisters in the carton until required for use.

6.5 Nature and contents of container

White opaque PVC/PVDC/Alu blister strips of 10 tablets, packed into cartons with pack sizes of 30 tablets.

White to slightly yellow polypropylene container with LDPE lid with pack sizes of 30 tablets.

Not all packaging types may always be marketed.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Biotech Laboratories (Pty) Ltd

Block K West, Central Park

400 16th Street, Road, Halfway House

Johannesburg, South Africa,

1685

8. REGISTRATION NUMBER

Pollofex 120: A40/5.7.1/0590

Pollofex 180: A40/5.7.1/0591

9. DATE OF FIRST AUTHORISATION

23 May 2006

10. DATE OF REVISION OF THE TEXT

29 November 2023