PROFESSIONAL INFORMATION

SCHEDULING STATUS

S2

1 NAME OF THE MEDICINE

POLLENTYME FC 5 mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 5 mg desloratadine.

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablets.

Blue, round, biconvex film coated tablets.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

POLLENTYME FC is used in the symptomatic relief of allergic conditions including: Rhinitis: POLLENTYME FC tablets are indicated for the relief of symptoms of seasonal allergic rhinitis in patients 12 years of age and older.
Chronic urticaria: POLLENTYME FC tablets are indicated for the symptomatic relief of chronic urticaria in patients 12 years of age and older.

4.2 Posology and method of administration

Posology

Pollentyme FC 5 mg film-coated tablets should be taken once daily with or without food.

Adults and children 12 years of age and older: One tablet daily.
Pollentyme FC 5 mg film-coated tablets has an effect within 1 to 2 hours after administration.

Safety and efficacy have not been established for treatment periods in excess of 4 weeks.

Special populations

Hepatic and Renal impairment

Patients with mild to moderate hepatic impairment or renal impairment should receive 5 mg every other day as a starting dose.

Peadiatric Population

The safety and efficacy of Pollentyme FC 5 mg film-coated tablets in children below the age of 12 years have not been established. No data are available.

Method of administration

For oral use.

4.3 Contraindications

- Hypersensitivity to desloratadine, cross sensitivity to other antihistamines or to any of the excipients (see section 6.1).
- Pregnancy and lactation (see section 4.6).

4.4 Special warnings and precautions for use

Renal and hepatic impairment

Pollentyme FC 5 mg film-coated tablets should be used with caution in patients with hepatic function and/or renal impairment. Dosage adjustment is recommended for patients with hepatic or renal function impairment.

Impaired metabolism of desloratadine

Patients that are slow metabolisers of Pollentyme FC 5 mg film-coated tablets may be more susceptible to dose-related adverse events. (see section 4.5).

Epilepsy

There have been occasional reports of convulsions in patients taking antihistamines such as Pollentyme FC 5 mg film-coated tablets and caution is therefore suggested in patients with epilepsy.

Use in the elderly

In general, dose selection for an elderly patient should be cautious, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or with concomitant medicines.

Paediatric patients

Pollentyme FC 5 mg film-coated tablets is not recommended for use in children under 12 years as safety is not established.

Weight gain

The use of Pollentyme FC 5 mg film-coated tablets has been associated with the risk of weight gain.

Skin test:

Pollentyme FC 5 mg film-coated tablets should be discontinued prior to skin tests using allergen extracts as it may inhibit the cutaneous histamine response, thus producing false-negative results.

Desloratadine should be discontinued at least 48 hours before skin test

Pollentyme FC 5 mg film-coated tablets should be used with caution when the following medical conditions exists (below) and/or patients using other medication metabolised by the cytochrome P-450 system such as:

- emphysema
- prostatic hypertrophy
- narrow angle glaucoma
- cardiovascular disorder
- epilepsy or
- during acute attacks of asthma

4.5 Interaction with other medicines and other forms of interaction

Concomitant use of Pollentyme FC 5 mg film-coated tablets with ketoconazole, clarithromycin, erythromycin, fluoxetine, azithromycin and cimetidine may increase the plasma concentrations of Pollentyme FC 5 mg film-coated tablets.

Neither food nor grapefruit juice had an effect on the bioavailability of Pollentyme FC 5 mg film-coated tablets.

Concomitant administration of Pollentyme FC 5 mg film-coated tablets and azithromycin, may increase the Cmax and AUC of azitromycin.

The Cmax and AUC of fluoxetine may be decreased when administered with Pollentyme FC 5 mg film-coated tablets, but the corresponding mean parameters of norfluoxetine may be increased**.**

In a clinical pharmacological trial, desloratadine tablets taken concomitantly with alcohol did not potentiate the performance- impairing effects of alcohol (see section 5.1). However, cases of alcohol intolerance and intoxication have been reported during post-marketing use. Therefore, caution is recommended if alcohol is taken concomitantly.

4.6 Fertility, pregnancy and lactation

Pregnancy

Pollentyme FC 5 mg film-coated tablets should not be used during pregnancy and lactation. Safety and efficacy in pregnancy and lactation have not been established. (see section 4.3).

Breastfeeding

Desloratadine and its metabolites have been detected in breast milk. (see section 4.3).

Fertility

There are no clinical data on fertility.

4.7 Effects on ability to drive and use machines

POLLENTYME FC lacks significant sedative effects. Patients should however be warned that individuals may experience sedation, dizziness and blurred vision. It is therefore advisable to determine individual response before driving or performing complicated tasks. (see section 4.8).

4.8 Undesirable effects

a. Summary of the safety profile

The most frequent adverse reactions reported were somnolence, headache, fatigue, asthenia, dry mouth and dizziness.

b. Tabulated summary of adverse reactions

System Organ Class	Frequency	Side Effects
Vascular disorders	Frequency unknown	Hypotension

System Organ Class	Frequency	Side Effects
Immune system disorders	Less frequent	Anaphylaxis, angioedema, urticaria, pruritus, oedema
Blood and lymphatic system disorders	Less Frequent	Blood disorders including agranulocytosis, leucopenia, haemolytic anaemia, thrombocytopenia.
Psychiatric disorders	Less frequent	Depression, confusion, hallucinations
Nervous system disorders	Frequent	Headache
	Less frequent	Dizziness, somnolence, insomnia, psychomotor hyperactivity, seizures
Eye disorders	Less Frequent	Blurred vision
Cardiac disorders	Frequency unknown	Tachycardia and palpitations, QT prolongation
Respiratory, thoracic and mediastinal disorders	Frequent	Pharyngitis
	Frequency unknown	Dyspnoea
Gastrointestinal disorders	Less frequent	Abdominal or stomach pain; dyspepsia (heartburn); nausea,

System Organ Class	Frequency	Side Effects
		vomiting,diarrhoea, dry mouth, anorexia.
Skin and subcutaneous tissue disorders	Less frequent	Rash, alopecia
	Frequency unknown	Photosensitivity
Musculoskeletal, connective tissue and bone disorders	Less frequent	Myalgia
General disorders and administration site conditions	Less frequent	Fatigue, Hypersensitivity reactions (such as anaphylaxis, angioedema, dyspnoea, pruritus, rash, and urticaria
	Frequency unknown	Asthenia
Reproductive system and breast disorder	Less frequent	Dysmenorrhoea
Hepato-biliary disorders	Less frequent	Hepatitis, elevations in liver enzymes, increased bilirubin,
	Frequency unknown	Jaundice

Ear and labyrinth disorders	Frequency unknown	Tinnitus

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 SAHPRA website.

4.9 Overdose

Symptoms:

Increase in mean heart rate, tachycardia, somnolence.

Treatment:

Desloratadine and its metabolite 3-hydroxydesloratadine are not eliminated by haemodialysis. It is not known if desloratadine is eliminated by peritoneal dialysis.

Supportive care:

Treatment should be symptomatic and supportive. Patients in whom intentional overdose is confirmed or suspected should be referred for psychiatric consultation.

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

Desloratadine is a non-sedating long-acting tricyclic second generation histamine antagonist with selective H1-receptor histamine antagonist activity.

Desloratadine exerts its action by competing with histamine for H1-receptor sites on effector cells. It prevents, but does not reverse responses mediated by histamine. Desloratadine inhibited histamine release from human mast cells in vitro. Desloratadine does not cross the blood-brain barrier to any extent.

After oral administration, desloratadine selectively blocks peripheral histamine H1-receptors. It does not readily penetrate into the central nervous system. In addition to antihistaminic properties, desloratadine has demonstrated anti-allergic and anti-inflammatory activity from numerous *in vitro* (mainly conducted on cells of human origin) and *in vivo* studies. These studies have shown that desloratadine inhibits the broad cascade of events that initiate and propagate allergic inflammation.

5.2 Pharmacokinetic properties

Absorption and bioavailability

Desloratadine plasma concentrations can be detected within 30 minutes of administration. Desloratadine is well absorbed with maximum concentration achieved after approximately 3 hours; the terminal phase half-life is approximately 27 hours. The degree of accumulation of desloratadine was consistent with its half-life (approximately 27 hours) and a once daily dosing frequency. The bioavailability of desloratadine was dose proportional over the range of 5 mg to 20 mg.

Distribution

Desloratadine is moderately bound (83 % - 87 %) to plasma proteins. There is no evidence of clinically relevant medicine accumulation following once daily dosing of desloratadine (5 43 mg to 20 mg) for 14 days.

Biotransformation

The enzyme responsible for the metabolism of desloratadine has not been identified yet, and therefore, some interactions with other medicinal products

cannot be fully excluded. Desloratadine does not inhibit CYP3A4 in vivo, and in vitro studies have shown that the medicinal product does not inhibit CYP2D6 and is neither a substrate nor an inhibitor of P-50 glycoprotein.

In a single dose trial using a 7.5 mg dose of desloratadine, there was no effect of food (highfat, high caloric breakfast) on the disposition of desloratadine. In another study, grapefruit juice had no effect on the disposition of desloratadine.

Elimination

The mean elimination half-life of desloratadine is approximately 27 hours. Desloratadine is excreted equally in the faeces and the urine.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core:

Microcrystalline cellulose

Partially pregelatinised maize starch

Magnesium stearate

Colloidal anhydrous silica

Tablet coating:

Opadry blue (03A30735) consisting of:

Hypromellose 6cP

Titanium dioxide (E171)

Microcrystalline cellulose

Stearic acid

Indigo Carmine (E132), Indigotine

6.2 Incompatibilities

Not applicable

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store at or below 30 ºC.

Keep blister in original container to protect from light.

6.5 Nature and contents of container

Aluminium blisters of 15 tablets are packed in a carton in pack sizes of 15. 30 or 100 tablets.

6.6 Special precautions for disposal

No special requirements.

7 HOLDER OF CERTIFICATE OF REGISTRATION

Astral Pharma (Pty) Ltd

125 Meade Street

1st Floor, Beacon Place

George, 6529

8 REGISTRATION NUMBER

57/5.7.1/0363

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10 June 2025

10 DATE OF REVISION OF THE TEXT

10 June 2025