1.3.1.1 PROFESSIONAL INFORMATION

POLLENTYME TABLETS AND POLLENTYME S

SCHEDULING STATUS: S1

1. NAME OF THE MEDICINE

POLLENTYME® TABLETS, 10 mg tablets

POLLENTYME® S, 5 mg/5 ml syrup

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

POLLENTYME TABLETS:

Each tablet contains 10 mg loratadine (micronised).

POLLENTYME TABLETS contain sugar (lactose monohydrate, 75 mg per tablet).

For a full list of excipients, see section 6.1.

POLLENTYME S:

Each 5 ml syrup contains 5 mg loratadine (micronised).

Excipients with known effect

Sodium benzoate 0,1 % *m/v* (equivalent to 1,0 mg/ml), as preservative.

Propylene glycol 550 mg in 5 ml, which is equivalent to 110 mg/ml.

POLLENTYME S contains sugar (sucrose, 3 g per 5 ml).

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablet

White or almost white, 8 mm round, flat-faced bevelled edge tablets with a break-line on the one side and plain on the other side.

Syrup

Clear or almost clear colourless solution with a taste and odour of peach.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

POLLENTYME is indicated for the relief of symptoms associated with allergic reactions including seasonal allergic rhinitis and chronic urticaria.

4.2 Posology and method of administration

Posology

POLLENTYME TABLETS:

Adults and children over the age of 12 years:

One tablet once a day.

POLLENTYME S:

Adults and children over the age of 12 years:

10 ml (2 medicine measures) once a day.

Children 2 to 12 years:

Body weight less than 30 kg: 5 ml (1 medicine measure) once a day.

Body weight more than 30 kg: 5 ml (1 medicine measure) twice a day.

Renal failure/decreased renal function:

In patients with renal failure or decreased renal function (creatinine clearance < 30 ml per minute), the initial dose should be 10 mg every other day.

Method of administration

Oral use.

4.3 Contraindications

- Hypersensitivity to loratadine or to any of the ingredients contained in POLLENTYME, listed in section 6.1.
- Cross-sensitivity to other antihistamines.
- Impaired hepatic function.
- Safety of POLLENTYME in the elderly has not been established.

4.4 Special warnings and precautions for use

- POLLENTYME lacks significant sedative effects. However, patients should be warned that a small number of individuals may experience sedation.
- The sedative effect may be compounded by the simultaneous intake of alcohol or other central nervous system depressants.
- Long-term use of POLLENTYME may decrease salivary flow and contribute to development of caries, periodontal disease, oral candidiasis, and discomfort.
- Patients should avoid alcoholic drinks.

Epilepsy: Use with caution in patients with epilepsy due to some reports of convulsions.

Weight gain: POLLENTYME use may cause an increase in weight.

Skin tests: POLLENTYME should be discontinued at least 48 hours before allergy skin tests since antihistamines may prevent or reduce otherwise positive reactions to dermal reactivity index (see section 4.5).

Special populations:

Elderly patients:

Elderly patients are especially susceptible to dizziness, sedation, confusion, hypotension and anticholinergic effects such as dry mouth and urinary retention.

Paediatric population:

POLLENTYME should not be given to neonates and children younger than 2 years of age as they are more susceptible to antimuscarinic effects.

POLLENTYME TABLETS contain lactose

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

POLLENTYME S contains sucrose

Patients with rare hereditary conditions such as fructose intolerance, glucose-galactose malabsorption or sucrose-isomaltase insufficiency should not take POLLENTYME S.

4.5 Interaction with other medicines and other forms of interaction

- POLLENTYME does not appear to potentiate the effects of alcohol, but it should be avoided in excess.
- Tricyclic antidepressants or maprotiline potentiate anticholinergic effects if taken with POLLENTYME.

- Monoamine oxidase inhibitors will potentiate both the drowsiness effect and the anticholinergic effects if taken with POLLENTYME. Concurrent use is not recommended.
- Anticholinergics or medicines with anticholinergic activity will be potentiated if used concurrently with POLLENTYME.
- Positive allergy skin tests may be suppressed by POLLENTYME; therefore treatment with POLLENTYME should be stopped several days before the test (see section 4.4).
- Inhibitors of the cytochrome P450 system (e.g. cimetidine, erythromycin, fluconazole, itraconazole, ketoconazole, quinidine, metronidazole or miconazole) may increase the plasma levels of loratadine.
- Concurrent use of ototoxic medicines with POLLENTYME may mask the symptoms of ototoxicity such as tinnitus, dizziness or vertigo.
- Concurrent use of photosensitising medicines with POLLENTYME may cause additive photosensitising effects.

4.6 Fertility, pregnancy and lactation

Pregnancy

Safety in pregnancy has not been established. The use of POLLENTYME during pregnancy is therefore not recommended.

Breastfeeding

Loratadine and its metabolites are distributed into breastmilk; therefore its administration during lactation is not advised.

Fertility

No data has been reported on male and female fertility.

4.7 Effects on ability to drive or use machines

POLLENTYME can cause side effects such as dizziness or drowsiness.

During POLLENTYME administration, patients should be cautioned about re-engaging in activities requiring rapid and precise responses such as driving an automobile or operating machinery until they know how POLLENTYME affects them.

4.8 Undesirable effects

a. Summary of the safety profile

Side effects with POLLENTYME vary in incidence and severity with each patient as much as with each medicine.

The most frequent of adverse reactions reported in excess of placebo were somnolence, headache, increased appetite and insomnia.

b. Tabulated summary of adverse reactions

Blood and the lymphatic system disorders

Frequency unknown: Leucopenia, agranulocytosis, thrombocytopenia, haemolytic anaemia

Immune system disorders

Less frequent: Anaphylaxis, angioedema

Metabolism and nutrition disorders

Frequency unknown: Increased appetite, loss of appetite

Psychiatric disorders

Frequency unknown: Confusion, depression, sleep disorders

Nervous system disorders

Frequent: Headache

Less frequent: Dizziness, convulsions

Frequency unknown:	Drowsiness, abnormal coordination, tremor, sweating

Eye disorders

Frequency unknown:	Blurred vision, change in vision

Ear and labyrinth disorders

Frequency unknown:	Ringing or buzzing in the ears

Cardiac disorders

Less frequent:	Palpitations, tachycardia
Frequency unknown:	Dysrhythmias

Vascular disorders

Less frequent:	Hypotension

Respiratory, thoracic and mediastinal disorders

Frequency unknown:	Dryness of nose or throat

Gastrointestinal disorders

Less frequent:	Dry mouth, nausea, gastritis
Frequency unknown:	Abdominal pain, vomiting, diarrhoea, epigastric pain

Hepatobiliary disorders

Less frequent:	Abnormal hepatic function
Frequency unknown:	Cholestasis, hepatitis

Skin and subcutaneous tissue disorders

Less frequent:	Rash, hair loss
Frequency unknown:	Photosensitivity, paraesthesia

Musculoskeletal, connective tissue and bone disorders

Less frequent: Myalgia

Renal and urinary disorders

Frequency unknown: Difficult or painful urination

General disorders and administrative site conditions

Less frequent: Fatigue

Investigations

Frequency unknown: Weight increase

Paediatric population

In children aged 2 through 12 years, common adverse reactions reported in excess of placebo were headache, nervousness and 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

Symptoms include drowsiness or paradoxical excitement, ataxia, tremors, athetosis, hallucinations, convulsions, fixed dilated pupils with a flushed face, sinus tachycardia, dyspnoea, urinary retention, dry mouth and fever. Terminally there may be deepening coma and cardiorespiratory collapse. Central excitatory effects constitute the greatest danger, particularly in children who are more likely to exhibit central nervous system stimulation.

Adults more frequently exhibit central nervous system depression and the aged are particularly prone to experience hypotension.

The stomach should be emptied by emesis or lavage. There is no specific antidote and treatment is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category and class: A.5.7.1 Antihistaminics

Pharmacotherapeutic group: antihistamines – H_1 antagonist,

ATC code: R06A X13

Loratadine is a long-acting, tricyclic antihistamine with highly selective peripheral H_1-receptor antagonistic activity and has no significant anticholinergic properties in the majority of the population and when used at the recommended dosage. During long-term treatment there may be no clinically significant changes in vital signs, laboratory test values, physical examinations or electrocardiograms. Loratadine has no significant H_2-receptor activity.

5.2 Pharmacokinetic properties

Absorption

Loratadine is rapidly absorbed from the gastrointestinal tract after oral administration. Peak plasma concentrations are attained in one hour. Bioavailability is increased and time to peak plasma concentrations is delayed when administered with food. The bioavailability parameters of loratadine and of the active metabolite are dose proportional.

Distribution

Loratadine is highly bound (97 % to 99 %) to plasma proteins; and its active major metabolite desloratadine (DL) is less extensively bound (73 % to 76 %).

In healthy subjects peak plasma concentrations of loratadine and its active metabolite are approximately 1 and 2 hours respectively.

Loratadine and its metabolites have been detected in breastmilk, but do not appear to cross the blood brain barrier to a significant extent.

Biotransformation

Loratadine undergoes an extensive first-pass metabolism, mainly by CYP3A4 and CYP2D6. The major metabolite, desloratadine (DL) is pharmacologically active and responsible for a large part of the clinical effect. Loratadine and DL achieve maximum plasma concentrations (T_{max}) between 1–1,5 hours and 1,5 – 3,7 hours after administration, respectively.

Elimination

Approximately 40 % of the dose is excreted in the urine and 42 % in the faeces over a 10 day period and mainly in the form of conjugated metabolites. Approximately 27 % of the dose is eliminated in the urine during the first 24 hours. Less than 1 % of the active substance is excreted unchanged in the active form, as loratadine or DL.

The mean elimination half-lives in healthy adult subjects were 8,4 hours (range = 3 to 20 hours) for loratadine and 28 hours (range = 8,8 to 92 hours) for the major active metabolite.

Characteristics in patient groups

Renal impairment

In patients with chronic renal impairment, both the AUC and peak plasma levels (C_{max}) increased for loratadine and its active metabolite as compared to the AUCs and peak plasma levels (C_{max}) of patients with normal renal function. The mean elimination half-lives of loratadine and its active metabolite were not significantly different from that observed in normal subjects. Haemodialysis does not have an effect on the pharmacokinetics of loratadine or its active metabolite in subjects with chronic renal impairment.

Hepatic impairment

In patients with chronic alcoholic liver disease, the AUC and peak plasma levels (C_{max}) of loratadine were double while the pharmacokinetic profile of the active metabolite was not significantly changed from that in patients with normal liver function. The elimination half-lives for loratadine and its metabolite were 24 hours and 37 hours, respectively, and increased with increasing severity of liver disease.

Elderly

The pharmacokinetic profile of loratadine and its active metabolite is comparable in healthy adult volunteers and in healthy geriatric volunteers.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

POLLENTYME TABLETS:

Lactose monohydrate

Magnesium stearate

Maize starch

Microcrystalline cellulose.

POLLENTYME S:

Citric acid monohydrate

Glycerol

Peach flavour

Propylene glycol

Sodium benzoate (as preservative)

Sucrose

Purified water.

6.2 Incompatibilities

Not applicable

6.3 Shelf-life

36 months

6.4 Special precautions for storage

Store in the original packaging in a cool, dry place, at or below 25 ºC.

6.5 Nature and contents of container

POLLENTYME TABLETS:

Clear, colourless PVC/aluminium blister strips of 10 tablets. Packs of 10

and 30 tablets are packed in printed outer cartons.

POLLENTYME S:

Type 3, amber glass bottles of 100 ml and 150 ml with white PE closures

packed in printed outer cartons.

Not all pack sizes may necessarily be marketed at one time.

6.6 Special precautions for disposal and other handling

No special requirements.

7. HOLDER OF CERTIFICATES OF REGISTRATION

Astral Pharma (Pty) Ltd

49 Riboville Road

Randjiesfontein

Midrand, 1683

South Africa

8. REGISTRATION NUMBERS

POLLENTYME TABLETS: 34/5.7.1/0507

POLLENTYME S: 37/5.7.1/0547

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

POLLENTYME TABLETS:

Date of registration: 06 June 2003

POLLENTYME S:

Date of registration: 23 July 2004

10. DATE OF REVISION OF THE TEXT

TBA

	POLLENTYME TABLETS	**POLLENTYME S**
	Registration number	**Registration number**
Namibia	NAM NS1 04/5.7.1/1661	NAM NS1 06/5.7.1/0010
Mozambique	2701	2484