1.3.2 PATIENT INFORMATION LEAFLET FOR

POLLENTYME TABLETS AND POLLENTYME S

SCHEDULING STATUS: S1

POLLENTYME® TABLETS, 10 mg tablets

POLLENTYME® S, 5 mg/ml syrup

Loratadine (micronised)

POLLENTYME TABLETS:

Contains sugar (lactose monohydrate, 75 mg per tablet)

POLLENTYME S:

Contains sugar (sucrose, 3 g per 5 ml syrup)

Read all of this leaflet carefully because it contains important information for you

POLLENTYME is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use POLLENTYME carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share POLLENTYME with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve.

What is in this leaflet

1. What POLLENTYME is and what it is used for

2. What you need to know before you take POLLENTYME

3. How to take POLLENTYME

4. Possible side effects

5. How to store POLLENTYME

6. Contents of the pack and other information

1. What POLLENTYME is and what it is used for

POLLENTYME tablets or syrup are used to relieve allergy symptoms such as sneezing, runny nose and itchy, burning eyes whether these are due to hay fever or whether they occur all year round. POLLENTYME tablets or syrup may also be taken for allergic skin conditions such as rash, itching or urticaria (hives).

2. What you need to know before you take POLLENTYME

Do not take POLLENTYME:

- If you are hypersensitive (allergic) to loratadine or any other ingredients of POLLENTYME (listed in section 6).
- If you are hypersensitive (allergic) to antihistamines (medicines used in the treatment of allergy).
- If you have a liver disease.
- Safety of POLLENTYME in the elderly has not been established.

Warnings and precautions

Take special care with POLLENTYME:

- POLLENTYME may cause some drowsiness.
- If you have a medical or family history of seizures.
- If you drink alcohol or take other central nervous system depressants (sedatives or tranquilisers) whilst taking POLLENTYME you may experience unwanted side effects.

- If you are an elderly person, you may experience dizziness, sleepiness, dry mouth, or difficulty with urination. Take caution when using POLLENTYME tablets or syrup.
- When POLLENTYME is taken for extended periods, side effects including dry mouth, tooth decay, tooth crumbling, swelling and redness of the gums, yeast infection in the mouth (oral thrush) and general mouth discomfort, may be experienced.
- POLLENTYME use may cause an increase in weight.
- If you are scheduled to undergo any tests for skin allergies, you should not take POLLENTYME for 2 days before the tests as it may affect the test results (see **Other medicines and POLLENTYME**).

Your doctor may request tests to monitor your condition before or during treatment.

Children and adolescents

POLLENTYME should not be given to babies and children younger than 2 years of age.

Other medicines and POLLENTYME

Always tell your healthcare provider if you are taking any other medicine. This includes complementary or traditional medicines.

Do not use the following medicines in combination with POLLENTYME:

- Sleeping tablets, used in the treatment of sleeping disturbances.
- Tricyclic antidepressants or an antidepressant containing maprotiline, used in the treatment of depression.
- If you have to go for an allergy skin test, stop using POLLENTYME several days before, as it may influence the results of the test (see **Take special care with POLLENTYME**).

- Erythromycin, used to treat bacterial infections.
- Fluconazole, itraconazole, ketoconazole, metronidazole or miconazole, used to treat fungal infections.
- Quinidine, used to treat heart rhythm conditions.
- Cimetidine, used to treat indigestion and stomach ulcers.
- Medicines that can cause temporary hearing loss may mask side effects such as dizziness or ringing in the ears.
- Medicines that cause sensitivity of the skin may mask the side effects of light sensitivity.

POLLENTYME with food, drink and alcohol

POLLENTYME can be taken with or without food.

Do not consume alcohol when you are on POLLENTYME treatment.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking POLLENTYME.

Driving and using machinery

POLLENTYME may impair your ability to drive and use machinery. Do not drive, operate machinery, or do anything else that could be dangerous until you know how POLLENTYME affects you.

POLLENTYME TABLETS contain lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking POLLENTYME TABLETS.

POLLENTYME S contains sucrose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking POLLENTYME S.

3. How to take POLLENTYME

Do not share medicines prescribed for you with any other person.

Always take POLLENTYME exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dosages are as follows:

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.

If you take more POLLENTYME than you should

In the event of overdosage, consult your doctor or pharmacist immediately.

If neither is available, contact the nearest hospital or poison centre.

Take this leaflet and any remaining tablets or syrup with you, so that the doctor knows what you have taken.

If you forget to take POLLENTYME

If you forget to take POLLENTYME, take your recommended dose as soon as you remember. Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

POLLENTYME can have side effects.

Not all side effects reported for POLLENTYME are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while taking POLLENTYME please consult your healthcare provider for advice.

If any of the following happens, stop taking POLLENTYME and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, lips, mouth or throat which may cause difficulty in breathing
- rash or itching.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to POLLENTYME. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- increased, irregular or fast heartbeat (tachycardia)
- low blood pressure
- hepatitis (inflammation of the liver with symptoms such as nausea, mild fever, abdominal pain)
- convulsions (fits).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- headache

Less frequent side effects:

- dizziness
- nausea
- dry mouth
- stomach pain or discomfort, inflammation of the stomach
- skin rash
- hair loss
- muscle pain
- extreme tiredness.

Side effects of unknown frequency:

- abnormal blood test results including anaemia
- tremors, sweating
- abnormal coordination (jerky and unsteady movements)
- drowsiness
- increased appetite or loss of appetite
- feeling depressed, sleep disorders, confusion
- abnormal liver function (clay coloured stool, dark urine, itching, loss of appetite, yellow eyes or skin)
- difficulty in passing urine, pain when passing urine
- tingling sensation in hands, feet or lips (feeling of “pins and needles”)
- vomiting

- diarrhoea
- dry nose or throat
- sensitivity to light, dry skin
- blurred vision, worsening eyesight
- ringing or buzzing in the ears
- weight increase.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8**.**

By reporting side effects, you can help provide more information on the safety of POLLENTYME.

5. How to store POLLENTYME

Store all medicines out of reach of children.

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

Do not remove from the outer carton until required for use.

Do not use after the expiry date printed on the label or carton.

Return any expired or unused medicine to your pharmacist for safe disposal. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What POLLENTYME contains

The active substance is loratadine (micronised).

POLLENTYME TABLETS:

Each tablet contains 10 mg loratadine (micronised).

The other ingredients are lactose monohydrate, magnesium stearate, maize starch and microcrystalline cellulose.

POLLENTYME S:

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

The other ingredients are citric acid monohydrate, glycerol, peach flavour, propylene glycol, sodium benzoate 0,1 % *m/v* (as preservative), sucrose, purified water.

What POLLENTYME looks like and contents of the pack

POLLENTYME TABLETS:

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

Packed in clear, colourless PVC/aluminium blister strips of 10 tablets. Packs of 10 and 30 tablets packed in printed outer cartons.
Not all pack sizes may necessarily be marketed at one time.

POLLENTYME S:

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

Packed in 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.

Holder of Certificates of Registration

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TBA

Registration numbers

POLLENTYME TABLETS**:** 34/5.7.1/0507

POLLENTYME S: 37/5.7.1/0547

Access to the corresponding Professional Information

For professional information please contact

regulatory@astralpharma.co.za.

	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