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**PATIENT INFORMATION LEAFLET FOR POLLENTYME S AND TABS**

**PROPOSED FINAL PATIENT INFORMATION LEAFLET FOR POLLENTYME TABLETS &**

**POLLENTYME S**

**PATIENT INFORMATION LEAFLET**

**SCHEDULING STATUS:**

S1

**PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:**

**POLLENTYME TABLETS** (tablets)

**POLLENTYME S** (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 pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve.

**1. WHAT POLLENTYME CONTAINS:**

**POLLENTYME TABLETS**

*The active substance is:*

Each **POLLENTYME TABLET** contains 10 mg loratadine (micronized).

*The other Ingredients are:*

Lactose monohydrate, magnesium stearate, maize starch and microcrystalline cellulose.

**POLLENTYME TABLETS** contain sugar in the form of lactose monohydrate.

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**POLLENTYME S:**

*The active substance is:*

Each 5 ml of **POLLENTYME S** contains 5 mg loratadine (micronized).

*The other Ingredients are:*

Citric acid monohydrate, glycerol, peach flavour, propylene glycol,

0,1 % m/v sodium benzoate (as preservative), purified water.

**POLLENTYME S** contains sugar (sucrose).

**2. WHAT POLLENTYME 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).

**3. BEFORE YOU TAKE POLLENTYME:**

**Do not take POLLENTYME:**

- If you are hypersensitive (allergic) to loratadine or any other ingredients of **POLLENTYME** (see **WHAT POLLENTYME CONTAINS**).
- 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.

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### **Take special care with POLLENTYME**

- **POLLENTYME** may cause some drowsiness.
- 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** should not be given to babies and children younger than 2 years of age.
- If you have liver disease.
- 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 **Taking other medicines**).

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

### **Taking POLLENTYME with food and drink:**

**POLLENTYME** can be taken with or without food.

### **Pregnancy and Breastfeeding:**

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before using **POLLENTYME**.

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**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.

**Important information about some of the ingredients of POLLENTYME:**

**POLLENTYME TABLETS** contain lactose. Patients with the rare hereditary conditions of lactose or galactose intolerance should not take **POLLENTYME TABLETS**.

**POLLENTYME TABLETS** contains lactose which may have an effect on the control of your blood sugar if you have diabetes mellitus.

**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**.

**POLLENTYME S** contains sucrose which may have an effect on the control of your blood sugar if you have diabetes mellitus.

**Taking other medicines with POLLENTYME:**

Always tell your healthcare professional 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.
- Do not consume alcohol when you are on **POLLENTYME** treatment.

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- 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**).
- 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.

**4. HOW TO TAKE POLLENTYME:**

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

Always take **POLLENTYME** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

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.

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*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 control 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 your medicine, take your recommended dose as soon as you remember.

Do not take a double dose to make up for forgotten individual doses.

**5. 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 doctor, pharmacist or other healthcare professional 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.

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

- Increased, irregular or fast heart beat (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:

- abnormal blood test results including anaemia
- tremors, sweating
- abnormal coordination (jerky and unsteady movements)
- dizziness, drowsiness
- feeling depressed, sleep disorders, confusion
- increased appetite or loss of appetite
- 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”)
- nausea, vomiting
- stomach pain or discomfort, inflammation of the stomach
- diarrhoea
- dry mouth, nose or throat
- muscle pain

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- skin rash, sensitivity to light, dry skin, hair loss
- blurred vision, worsening eyesight
- ringing or buzzing in the ears
- extreme tiredness.

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

**6. STORING AND DISPOSING OF POLLENTYME:**

Store all medicines out of reach of children.

Store in a cool (at or below 25 °C), dry place.

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 all unused medicine to your pharmacist.

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).

**7. PRESENTATION OF POLLENTYME:**

**POLLENTYME TABLETS:** Clear, colourless PVC/aluminium blister strips of 10 tablets.

Packs of 10 and 30 tablets contained in printed outer cartons.

**POLLENTYME S:** Brown (amber) glass bottles of 100 ml and 150 ml, white polypropylene screw cap and measuring cup. Bottles are packed into printed outer cartons.



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**8. IDENTIFICATION OF POLLENTYME:**

**POLLENTYME TABLETS:** White or almost white, round, flat tablet scored on one side.

**POLLENTYME S:** Clear to yellowish syrup, free from any visible particulate matter, with a characteristic peach flavour and odour.