1.3.2 PROPOSED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S2**

PROPRIETARY NAME DOSAGE FORM

POLLENTYME® ND film coated tablets

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

POLLENTYME ND is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless, you still need to use POLLENTYME ND carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share POLLENTYME ND 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 after 10 days.

WHAT POLLENTYME ND CONTAINS

The active substance is desloratadine.

Each POLLENTYME ND contains 5 mg desloratadine.

The other ingredients are hypromellose, magnesium oxide, microcrystalline cellulose, Opadry blue, pregelatinised starch, zinc stearate.

POLLENTYME ND contains sugar (lactose anhydrous 4,5 mg per tablet).

WHAT POLLENTYME ND IS USED FOR

POLLENTYME ND tablets are used for the relief of seasonal hay fever with symptoms such as sneezing, runny nose and itchy, burning eyes.

POLLENTYME ND tablets may also be taken for allergic skin conditions such as rash, itching or urticaria (hives).

BEFORE YOU TAKE POLLENTYME ND

Do not take POLLENTYME ND:

- If you are hypersensitive (allergic) to desloratadine or any of the ingredients of POLLENTYME ND (see **WHAT POLLENTYME ND CONTAINS**).
- If you are pregnant or breastfeeding your baby (see **Pregnancy and breastfeeding**).

Take special care with POLLENTYME ND:

- If you are an elderly patient (as there is a higher risk of unwanted side effects).
- Safety has not been established in children under the age of 12 years.
- Do not use POLLENTYME ND for more than 4 weeks without consulting your doctor, pharmacist or healthcare provider as the safety and effectiveness of POLLENTYME ND has not been established if treatment continues for more than 4 weeks.
- POLLENTYME ND may lead to drowsiness and impaired concentration.
- If you drink alcohol or take other central nervous system depressants (sedatives or tranquilisers) whilst taking POLLENTYME ND you may experience unwanted side effects.
- If you suffer from a liver or kidney disorder, the dosage you should take may need to be adjusted.
- You should stop taking POLLENTYME ND at least 48 hours before having skin allergen testing, as POLLENTYME ND may interfere with the results of such testing.
- If you have one of the following medical conditions: Emphysema (a condition of the lungs), prostatic hypertrophy (enlarged prostate), narrow angle glaucoma (a condition of the eyes), cardiovascular disorder (a heart condition), epilepsy, asthma.
- If you have medical or familial history of seizures.
- POLLENTYME ND use may cause an increase in weight.

Taking POLLENTYME ND with food and drink

POLLENTYME ND can be taken with or without food. Grapefruit juice has no effect on how POLLENTYME ND works.

Excessive use of alcohol may cause unwanted side effects such as drowsiness and should be avoided.

Pregnancy and breastfeeding

POLLENTYME ND should not be used if you are pregnant or breastfeeding your baby (see **Do not take POLLENTYME ND**).

If you are pregnant or breastfeeding your baby, please consult your healthcare provider for advice before taking POLLENTYME ND.

Driving and using machinery

POLLENTYME ND may make you dizzy or drowsy or impair your ability to drive and use machinery. Do not drive or operate machinery until you know how POLLENTYME ND affects you.

Important information about some of the ingredients of POLLENTYME ND

POLLENTYME ND contains lactose. Patients with rare hereditary conditions of lactose or galactose intolerance should not take POLLENTYME ND.

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

Taking other medicines with POLLENTYME ND

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

The following medicines when taken in combination with POLLENTYME ND may affect the way POLLENTYME ND works:

- Medicines used to treat fungal infections such as ketoconazole,

- Antibiotics, such as erythromycin, clarithromycin or azithromycin,
- Cimetidine, used to treat indigestion and stomach ulcers,
- Fluoxetine used to treat depression.

HOW TO TAKE POLLENTYME ND

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

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

The usual dose for adults and children (over 12 years of age) is one tablet, once daily.

Swallow the tablet whole with a glass of water.

Improvement of your symptoms should be noticeable 1 to 2 hours after taking POLLENTYME ND.

If you take more POLLENTYME ND than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

Symptoms of overdose may include fast or irregular heartbeat, drowsiness in adults and, palpitations and movement disorders in children. Take this leaflet and any remaining tablets with you, so that the doctor knows what you have taken.

If you forget to take POLLENTYME ND

If you forget to take a dose of POLLENTYME ND, continue to take the next POLLENTYME ND tablet at the usual time.

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

Continue to take the next tablet at the usual time.

POSSIBLE SIDE EFFECTS

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

If any of the following happens, stop taking POLLENTYME ND 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 ND. 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:

- you bruise more easily than usual. This could be because of a blood disorder (thrombocytopenia)
- convulsions (fits)
- increased, irregular or fast heart beat (tachycardia)
- jaundice (yellow discolouration of the skin and eyes), hepatitis (inflammation of the liver with symptoms such as nausea, mild fever, abdominal pain), abnormal liver function (you may experience the following: clay coloured stool, dark urine, itching, loss of appetite).

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
- pharyngitis (body aches or pain, congestion, cough, hoarseness, runny nose)
- dry mouth.

Less frequent side effects

- dizziness, drowsiness, restlessness with increased body movement, feeling sleepy, nervousness, tremor
- blurred vision
- ringing in ears (tinnitus)
- abnormal blood test results.

Side effects with unknown frequency

- increased appetite
- hallucinations (seeing things)
- confusion, feeling depressed, sleep disorders, problems sleeping, nightmares, abnormal behaviour, aggression
- low blood pressure (hypotension)
- stomach pain or discomfort, nausea, vomiting, diarrhoea, indigestion
- redness of the skin, hives or welts, skin rash, hair loss, severe itching, sensitivity to light, sweating
- muscle pain or muscle cramps
- difficult or painful menstruation
- extreme tiredness, weakness
- weight gain.

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

STORING AND DISPOSING OF POLLENTYME ND

Store at or below 25 ºC in original packaging.

Keep the container or blisters in the carton until required for use.

Keep the container tightly closed. Protect from light.

KEEP OUT OF REACH OF CHILDREN.

Do not use the tablets after the expiry date printed on the blisters or container.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

PRESENTATION OF POLLENTYME ND

POLLENTYME ND is packed into hard, silver-coloured aluminium foil/clear transparent film blister strips of 1 x 7 tablets, 1 x 10 tablets or 3 x 10 tablets each inside a printed outer cardboard box.

POLLENTYME ND is also packed into white, HDPE bottles with a desiccant and a white PP screw cap. Each bottle contains 10 or 30 tablets.

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

IDENTIFICATION OF POLLENTYME ND

POLLENTYME ND is a blue, round, film coated tablet debossed with a “D” on one side of the tablet and plain on the other.

REGISTRATION NUMBER

42/5.7.1/0849

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