1.3.1.1 PROFESSIONAL INFORMATION

SCHEDULING STATUS: **S2**

PROPRIETARY NAME AND DOSAGE FORM

POLLENTYME® ND film coated tablets

COMPOSITION

Active ingredients:

Each film coated tablet contains 5 mg desloratadine.

Inactive ingredients:

Hypromellose, magnesium oxide, microcrystalline cellulose, Opadry blue, pregelatinised starch, zinc stearate.

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

CATEGORY AND CLASS

A.5.7.1 Antihistaminic.

PHARMACOLOGICAL ACTION

Pharmacodynamic properties

Desloratadine is the major, long-acting, active metabolite of loratadine, a non-sedating, second generation H_1-receptor antagonist. It selectively blocks peripheral histamine H_1 receptors since it does not readily penetrate into the central nervous system (CNS). Apart from its anti-histaminic activity, studies also indicated inhibition of events leading to allergic inflammation.

Pharmacokinetic properties

Absorption

Desloratadine plasma concentrations can be detected within 30 minutes of administration. Desloratadine is rapidly absorbed from the gastrointestinal tract and reaches maximum plasma concentrations in 3 hours.

There is no evidence of accumulation and food has no influence on the absorption of desloratadine. The degree of accumulation of desloratadine was consistent with its half-life (approximately 27 hours) at a once daily dosing frequency. The bioavailability of desloratadine was dose proportional over the range of 5 mg to 20 mg.

Distribution

The percentage desloratadine bound to plasma proteins is an average of 85 %.

There is no evidence of clinically relevant medicine accumulation following once daily dosing of desloratadine (5 mg to 20 mg) for 14 days.

Metabolism

The enzyme responsible for the metabolism of desloratadine has as yet not been identified, and as a result some interactions with other medicines cannot be fully excluded.

Desloratadine does not inhibit CYP3A4 *in vivo,* and *in vitro* studies have shown that POLLENTYME ND does not inhibit CYP2D6 and is neither a substrate nor an inhibitor of P-glycoprotein.

Elimination

The mean elimination half-life for desloratadine is 27 hours.

A study using a 7,5 mg dose of desloratadine, indicated no effect of food (high-fat, high caloric breakfast) on the disposition of desloratadine.

INDICATIONS

POLLENTYME ND is indicated in adults and adolescents ≥ 12 years for

- The relief of symptoms associated with seasonal allergic rhinitis.
- The short-term relief of symptoms associated with chronic idiopathic urticaria.

CONTRAINDICATIONS

- Hypersensitivity to desloratadine or to any of the ingredients contained in POLLENTYME ND.
- Cross-sensitivity to other antihistamines.
- Pregnancy and lactation (see **HUMAN REPRODUCTION**).

WARNINGS AND SPECIAL PRECAUTIONS

- Elderly patients are more susceptible to many of the adverse effects of antihistamines.
- Safety of POLLENTYME ND in children under twelve years of age has not been established.
- Safety and efficacy of POLLENTYME ND has not been established for treatment periods in excess of 4 weeks.
- POLLENTYME ND lacks significant sedative effects. However, patients should be warned that a small number of individuals may experience sedation.
- This effect may be compounded by the simultaneous intake of alcohol or other central nervous system depressants.
- POLLENTYME ND should be used with caution in patients with severe liver impairment, as reduced clearance of desloratadine may occur. Dosage adjustment may be needed (see **DOSAGE AND DIRECTIONS FOR USE**).

- Renal impairment - A lower starting dose should be used. In patients with chronic renal impairment (creatinine clearance of 30 ml/min or less), both oral bioavailability and peak plasma concentrations of desloratadine may be increased (see **DOSAGE AND DIRECTIONS FOR USE**).
- POLLENTYME ND should be discontinued prior to allergen extracts skin tests as it may inhibit the cutaneous histamine response, thus producing false-negative results. POLLENTYME ND should be discontinued at least 48 hours before test.
- POLLENTYME ND should be used with caution when one or more of the following medical conditions exist and/or patients using other medicines metabolised by the cytochrome P-450 system: Emphysema; prostatic hypertrophy; narrow angle glaucoma; cardiovascular disorder, epilepsy or during acute attacks of asthma.
- POLLENTYME ND should be administered with caution in patients with medical or familial history of seizures, and mainly young children, being more susceptible to develop new seizures under POLLENTYME ND treatment
- POLLENTYME ND use may cause an increase in weight.

Effects on ability to drive and use machines

POLLENTYME ND can cause side effects such as dizziness or drowsiness and impair the ability to drive and operate machinery. Caution is advised when performing these tasks.

Information on excipients of POLLENTYME ND

POLLENTYME ND contains lactose. Patients with rare hereditary conditions of galactose intolerance e.g. galactosaemia, Lapp lactase deficiency, glucose-galactose malabsorption or fructose intolerance should not take POLLENTYME ND.

POLLENTYME ND contains lactose which may have an effect on the glycaemic control of patients with diabetes mellitus.

INTERACTIONS

POLLENTYME ND lacks significant sedative effects.

- POLLENTYME ND does not appear to potentiate the effects of alcohol, but it should be avoided in excess.
- Concomitant use of POLLENTYME ND with inhibitors of the cytochrome P450 system (e.g. cimetidine, clarithromycin, ketoconazole, erythromycin, fluoxetine) may increase the plasma levels of desloratadine.
- No clinically significant changes in desloratadine plasma concentrations were observed in multi-dose ketoconazole, erythromycin, azithromycin, fluoxetine and cimetidine in interaction studies.
- Concomitant use of POLLENTYME ND with azithromycin or fluoxetine may increase both C_{max} and AUC of these medicines.
- Studies show grapefruit juice has no effect on the disposition of desloratadine.

HUMAN REPRODUCTION

POLLENTYME ND should not be used in pregnancy and lactation.

Safety in pregnancy and lactation has not been established.

Desloratadine has been detected in breastmilk therefore, its administration during lactation is not advised (see **CONTRAINDICATIONS**).

DOSAGE AND DIRECTIONS FOR USE

Adults and children 12 years and over

One tablet orally once daily.

Intermittent allergic rhinitis (presence of symptoms for less than 4 days per week or for less than 4 weeks) should be managed in accordance with the evaluation of patient's disease history and the treatment could be discontinued after symptoms are resolved and reinitiated upon their reappearance.

SIDE EFFECTS

Blood and lymphatic system disorders

Frequency unknown: Leucopenia, agranulocytosis, thrombocytopenia, haemolytic anaemia

Immune system disorders

Less frequent: Allergic reactions, angioedema, dyspnoea

Frequency unknown: Anaphylaxis

Metabolism and nutrition disorders

Frequency unknown: Increased appetite

Psychiatric disorders

Frequency unknown: Confusion, depression, sleep disorders, insomnia, hallucinations, nightmares, abnormal behaviour, aggression

Nervous system disorders

Frequent: Headache

Less frequent: Dizziness, somnolence, sedation, nervousness, psychomotor hyperactivity, seizures, tremor

Eye disorders

Less frequent: Blurred vision

Ear and labyrinth disorders

Less frequent: Tinnitus

Cardiac disorders

Frequency unknown: Palpitations, tachycardia, hypotension, QT prolongation

Respiratory, thoracic and mediastinal disorders

Frequent: Pharyngitis

Gastrointestinal disorders

Frequent: Dry mouth

Frequency unknown: Abdominal pain, nausea, vomiting, dyspepsia, diarrhoea, gastritis

Hepatobiliary disorders

Less frequent: Elevations of liver enzymes, increased bilirubin, hepatitis

Frequency unknown: Jaundice

Skin and subcutaneous tissue disorders

Frequency unknown: Rash, alopecia, pruritus, urticaria, photosensitivity, sweating

Musculoskeletal, connective tissue and bone disorders

Less frequent: Myalgia

Reproductive system and breast disorders

Frequency unknown: Dysmenorrhoea

General disorders and administrative site conditions

Frequent: Fatigue

Frequency unknown: Asthenia, oedema

Investigations

Frequency unknown: Weight gain

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

Symptoms of overdose

Somnolence, tachycardia and headaches have been reported. In children, extrapyramidal manifestations and palpitations have been reported.

Treatment of overdose

Treatment is symptomatic and supportive.

After an overdose of POLLENTYME ND, the stomach should be emptied immediately by inducing emesis or by gastric lavage.

Administration of activated charcoal after emesis may be useful in preventing absorption of POLLENTYME ND.

Saline cathartics may be of value to rapidly dilute bowel contents. POLLENTYME ND is not cleared by haemodialysis. It is not known if it is eliminated by peritoneal dialysis.

IDENTIFICATION

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

PRESENTATION

Blister strips:

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.

HDPE Bottles:

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.

STORAGE INSTRUCTIONS

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.

REGISTRATION NUMBER

42/5.7.1/0849

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

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