PROFESSIONAL INFORMATION

SCHEDULING STATUS: S2

1. NAME OF THE MEDICINE

NEOLORIDIN 2,5 tablet

NEOLORIDIN 5 tablet

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each NEOLORIDIN 2,5 tablet contains 2,5 mg desloratadine.

Each NEOLORIDIN 5 tablet contains 5 mg desloratadine.

Contains sweetener:

NEOLORIDIN 2,5: 10 mg aspartame per tablet.

NEOLORIDIN 5: 10 mg aspartame per tablet.

Contains sugar alcohol:

NEOLORIDIN 2,5: 55,5 mg mannitol per tablet.

NEOLORIDIN 5: 52,5 mg mannitol per tablet.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

NEOLORIDIN 2,5 tablets are white to light pink coloured, mottled, round, flat, uncoated with a break line on one side and plain on the other side. The tablets should be free of all physical defects.

NEOLORIDIN 5 tablets are orange coloured, round, flat, uncoated with a break line on one side and plain on the other side. The tablets should be free of all physical defects.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

NEOLORIDIN is indicated for the relief of symptoms associated with:

- Seasonal allergic rhinitis.
- Short-term relief of chronic idiopathic urticaria.

4.2 Posology and method of administration

NEOLORIDIN 2,5

Children 2 to 5 years of age:

Half a tablet once a day, with or without a meal.

Children 6 to 11 years of age:

One tablet (2,5 mg) once a day, with or without a meal.

Adults and adolescents (≥ 12 years):

Two tablets (2,5 mg) once a day, with or without a meal.

NEOLORIDIN 5

Adults and adolescents (≥ 12 years):

One tablet (5 mg) orally once daily, with or without a meal, for the relief of symptoms associated with allergic rhinitis (including intermittent and persistent allergic rhinitis) and chronic idiopathic urticaria.

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 the patient's disease history and the treatment can be discontinued after symptoms have resolved and reinitiated upon their reappearance.

In persistent allergic rhinitis (presence of symptoms for more than 4 days per week and for more than 4 weeks) continued treatment may be proposed to the patients during allergen exposure periods.

Improvement of symptoms associated with seasonal allergic rhinitis usually becomes noticeable within 1 – 2 hours after administration of desloratadine.

4.3 Contraindications

- Hypersensitivity to desloratadine or to any of the inactive ingredients of NEOLORIDIN (see sections 2 and 6.1).
- Cross-sensitivity to other antihistamines, e.g. loratadine.
- Safety during pregnancy and lactation has not been established (see section 4.6).
- Porphyria.

4.4 Special warnings and precautions for use

Safety of NEOLORIDIN in elderly patients has not been established.

NEOLORIDIN should be used with caution in patients with:

- Severe liver impairment, as reduced clearance of desloratadine may occur.
- Renal impairment – a lower starting dose should be used. In patients with chronic renal impairment (creatinine clearance of 30 mL/minute or less), both oral bioavailability and peak plasma concentrations of desloratadine may be increased.

NEOLORIDIN lacks significant sedative effects, although some patients may still experience drowsiness.

NEOLORIDIN should be discontinued prior to skin tests with allergen extracts as it may inhibit the cutaneous histamine response, thus producing false-negative results. NEOLORIDIN should be discontinued at least 48 hours before the test.

NEOLORIDIN should be used with caution when the following medical conditions exist and/or by patients using other medicine metabolised by the cytochrome P450 system (see section 4.5): emphysema, prostatic hypertrophy, narrow angle glaucoma, cardiovascular disorder, epilepsy or during acute attacks of asthma.

NEOLORIDIN should be administered with caution in patients with medical or familial history of seizures, and mainly in young children, who are more susceptible to develop new seizures while

receiving NEOLORIDIN treatment. Healthcare providers may consider discontinuing NEOLORIDIN in patients who experience a seizure while on treatment.

Efficacy and safety of NEOLORIDIN 2,5 in children under 2 years of age have not been established.

Safety and efficacy of desloratadine have not been established for treatment periods in excess of 4 weeks for allergic rhinitis and 6 weeks for chronic idiopathic urticaria.

NEOLORIDIN contains aspartame (which is a source of phenylalanine); caution is advised in patients with phenylketonuria.

4.5 Interaction with other medicines and other forms of interaction

Concomitant use of NEOLORIDIN with inhibitors of the cytochrome P450 enzyme system, such as cimetidine, ketoconazole, clarithromycin and erythromycin, may increase the plasma concentration of desloratadine (an increase in the C_{max} and in the AUC). Dosage adjustments should be considered.

Co-administration of fluoxetine with desloratadine, as contained in NEOLORIDIN, caused an increase in the C_{max} of desloratadine by 15 % and an increase of 13 % in AUC and 17 % in C_{max} of 3-OH desloratadine, respectively.

The C_{max} and AUC of fluoxetine were reduced by 9 % and 11 %, respectively. The corresponding mean parameters of norfluoxetine increased by 23 % and 18 %, respectively, with co-administration of desloratadine, as contained in NEOLORIDIN, and fluoxetine.

Concomitant use with alcohol may cause alcohol intolerance and intoxication. Caution should be taken if alcohol is taken concomitantly.

4.6 Fertility, pregnancy and lactation

Safety and efficacy in pregnancy and breastfeeding have not been established. Desloratadine, as in NEOLORIDIN, has been detected in breast milk. Small amounts of desloratadine entering breast milk may cause drowsiness or excitability in the infant.

NEOLORIDIN should not be used during pregnancy and breastfeeding (see section 4.3).

4.7 Effects on ability to drive and use machines

NEOLORIDIN lacks significant sedative effects. Nevertheless, some patients may experience sedation and it can affect the ability to drive a vehicle and use machines (see section 4.8). Caution is advised before driving a vehicle or operating machinery until the effects of NEOLORIDIN are known.

4.8 Undesirable effects

Metabolism and nutrition disorders

Frequency unknown: Increased appetite.

Psychiatric disorders

Less frequent: Hallucinations.

Frequency unknown: Abnormal behaviour, aggression.

Nervous system disorders

Frequent: Headache.

Less frequent: Dizziness, somnolence, insomnia, seizures, psychomotor hyperactivity.

Cardiac disorders

Less frequent: Tachycardia, palpitations.

Frequency unknown: QT prolongation.

Gastrointestinal disorders

Frequent: Dry mouth.

Less frequent: Abdominal pain, nausea, vomiting, dyspepsia, diarrhoea.

Hepato-biliary disorders

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

Frequency unknown: Jaundice.

Skin and subcutaneous tissue disorders

Frequency unknown: Photosensitivity.

Musculoskeletal and connective tissue disorders

Less frequent: Myalgia.

General disorders and administration site conditions

Frequent: Fatigue.

Less frequent: Hypersensitivity reactions (such as anaphylaxis, angioedema, dyspnoea, pruritus, rash and urticaria).

Frequency unknown: Asthenia.

Investigations

Frequency unknown: Increased body mass.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of NEOLORIDIN is important. It allows continued monitoring of the benefit/risk balance of NEOLORIDIN. Healthcare providers are requested to report any suspected adverse reactions to SAHPRA via the Med Safety App (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA's website.

4.9 Overdose

Symptoms of overdose:

Somnolence, tachycardia and headaches have been reported. In children, extrapyramidal manifestations and palpitations have been reported (see section 4.8).

Treatment of overdose:

Treatment is symptomatic and supportive. Administration of activated charcoal may be useful in preventing absorption of NEOLORIDIN. NEOLORIDIN is not cleared by haemodialysis; it is not known if it is eliminated by peritoneal dialysis.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category and class

A 5.7.1 Antihistaminics.

Pharmacotherapeutic group: Antihistamines – H_1 antagonist.

ATC code: R06A X27.

Pharmacodynamic effects

Desloratadine is the major, long acting, active metabolite of loratadine, a non-sedating second generation H_1 antagonist. It blocks peripheral histamine H_1 receptors since it crosses the blood-brain barrier to a limited extent. Except for its antihistaminic activity, studies also indicated inhibition of events leading to allergic inflammation.

5.2 Pharmacokinetic properties

Absorption

Desloratadine plasma concentrations can be detected within 30 minutes of desloratadine administration. Desloratadine is well absorbed with maximum concentration achieved after approximately 3 hours.

Elimination

The terminal phase half-life is approximately 27 hours. The degree of accumulation of desloratadine was consistent with its half-life (approximately 27 hours) and a once daily dosing frequency. In adults and adolescents, the bioavailability of desloratadine was dose proportional over the range of 5 mg to 20 mg.

Distribution

Desloratadine is moderately bound (83 – 87 %) to plasma proteins. There is no evidence of clinically relevant medicine accumulation following once daily dosing of desloratadine (5 mg to 20 mg) for 14 days.

Biotransformation

The enzyme responsible for the metabolism of desloratadine has not been identified yet, and therefore some interactions with other medicines cannot be excluded. *In vivo* studies with specific inhibitors of CYP3A4 and CYP2D6 have shown that these enzymes are not important in the metabolism of desloratadine. Desloratadine does not inhibit CYP3A4 or CYP2D6 and is neither a substrate nor an inhibitor of P-glycoprotein.

In a single dose crossover trial using a 7,5 mg dose of desloratadine, the tablet and syrup formulations were bioequivalent and not affected by the presence of food (high-fat, high caloric breakfast). In another study, grapefruit juice had no effect on the disposition of desloratadine.

In separate single dose studies, at the recommended doses, paediatric patients had comparable AUC and C_{max} values of desloratadine to those in adults who received a 5 mg dose of desloratadine syrup.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Aspartame

Colloidal anhydrous silica

Croscarmellose sodium

Indion 204 (containing methacrylic acid polymer with divinyl benzene and acrylic acid)

Mannitol

Sodium stearyl fumarate

Trusil Mango Special powder (flavourant).

NEOLORIDIN 5 also contain Sunset Yellow Lake I.H. (Cl 15985) (colourant).

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

NEOLORIDIN 2,5: 24 months.

NEOLORIDIN 5: 36 months.

6.4 Special precautions for storage

Store at or below 25 °C.

Protect from light.

Keep blister strips in the outer carton until required for use.

6.5 Nature and contents of container

NEOLORIDIN tablets are packed in an aluminium/aluminium foil blister strip containing ten tablets.

One or three blister strips are packed in an outer carton.

Pack sizes: 10 and 30.

6.6 Special precautions for disposal

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Zydus Healthcare SA (Pty) Ltd

Southdowns Office Park, Building B, Ground Floor

22 Karee Street

Centurion 0157

8. REGISTRATION NUMBERS

NEOLORIDIN 2,5: 55/5.7.1/0305

NEOLORIDIN 5: 41/5.7.1/0214

9. DATE OF FIRST AUTHORISATION

NEOLORIDIN 2,5: 10 December 2024

NEOLORIDIN 5: 05 October 2007

10. DATE OF REVISION OF THE TEXT

Not revised yet.