DESLAMED®

COMPOSITION

Active ingredient:

Desloratadine……0.5mg/ml

Excipients:

Sorbitol, propylene glycol, sucralose, hypromellose 2910, sodium citrate dihydrate, tutti frutti flavour, citric acid monohydrate, disodium edetate, purified water.

PHARMACEUTICAL FORM

Oral solution, 150 ml bottle

PHARMACOTHERAPEUTIC GROUP

Anti-histamines – H1 receptor antagonist

PHARMACOLOGICAL ACTION

Desloratadine is a non-sedating, long-acting histamine antagonist with potent, selective peripheral H1- receptor antagonist activity. Desloratadine has demonstrated antiallergic, antihistaminic and anti-inflammatory activity.

After oral administration, desloratadine selectively blocks peripheral histamine H1-receptors because the substance is excluded from entry to the central nervous system.

INDICATIONS

DESLAMED is indicated for the relief of symptoms associated with:

- Allergic rhinitis (inflammation of the nasal passages caused by an allergy, for example, hay fever or allergy to dust mites). These symptoms include sneezing, runny or itchy nose, itchy palate, and itchy, red or watery eyes.
- Urticaria (a skin condition caused by an allergy). DESLAMED is effective in relieving itching and reducing the size and number of hives.

Relief of these symptoms lasts a full day and helps you to resume your normal daily activities and sleep.

DOSAGE AND ADMINISTRATION

DESLAMED can be taken regardless of mealtime.

Children 1 to 5 years of age: 2.5 ml (2/1 teaspoonful) DESLAMED oral solution once a day.

Children 6 to 11 years of age: 5 ml (1 teaspoonful) DESLAMED oral solution once a day.

Adults and adolescents (12 years of age and over): 10 ml (2 teaspoonfuls) DESLAMED oral solution once a day.

Use the measuring cup provided in the pack to take the appropriate amount of oral solution.

If you forget to take your dose on time, take it as soon as possible, then go back to your regular dosing schedule. Do not take a double dose to make up for a forgotten dose.

PRECAUTIONS

In the case of severe renal insufficiency, DESLAMED should be used with caution.

DESLAMED contains sorbitol; thus patients with rare hereditary problems of fructose intolerance, glucose -galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

CONTRAINDICATIONS

Do not take DESLAMED if you are allergic to desloratadine, or to any of the excipients or to loratadine.

INTERACTIONS

There are no known interactions of desloratadine with other medicines. Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

In a clinical pharmacology trial, desloratadine taken concomitantly with alcohol did not potentiate the performance impairing effects of alcohol. Use caution when taking DESLAMED Chapha with alcohol

PREGNANCY AND LACTATION

The safe use of desloratadine during pregnancy has not been established. The use of DESLAMED during pregnancy is therefore not recommended.

Desloratadine is excreted into breast milk, therefore the use of DESLAMED is not recommended in breastfeeding women.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

At the recommended dose, DESLAMED is not expected to cause you to be drowsy or less alert. However, very rarely some people experience drowsiness, which may affect their ability to drive or use machines. Do not engage in activities requiring mental alertness, such as driving a car or operating machinery until you have established your own response to the medicinal product.

SIDE EFFECTS

Like all medicines, DESLAMED can cause side effects, although not everybody gets them.

In clinical studies in most children and adults, the overall incidence of side effects was similar for the desloratadine and the placebo groups. However common side effects in children less than 2 years of age were diarrhea, fever and insomnia, while in adults and adolescents, fatigue, dry mouth and headache were reported in excess of placebo.

The following side effects were reported very rarely during the post-marketing period:

Hallucinations, dizziness, drowsiness, insomnia, psychomotor hyperactivity, seizures, fast heartbeat, palpitations, abdominal pain, nausea, vomiting, upset stomach, diarrhea, elevations of liver enzymes, increased bilirubin, liver inflammation, muscle pain, allergic reactions (difficulty in breathing, wheezing, itching, hives and swelling).

OVERDOSAGE

No serious problems are expected with accidental overdose. However if you take more DESLAMED oral solution than you were told, tell your doctor or pharmacist immediately.

In the event of overdose, consider standard measures to remove unabsorbed active substance. Symptomatic and supportive treatment is recommended. Based on a multiple dose clinical trial in adults and adolescents, in which up to 45 mg of desloratadine was administered (9 times the clinical dose), no clinically relevant effects were observed.

PHARMACOKINETICS

Desloratadine plasma concentrations can be detected within 30 minutes of desloratadine administration in adults and adolescents.

Desloratadine is well absorbed with maximum concentration achieved after approximately 3 hours; the terminal phase half-life is approximately 27 hours.

Desloratadine is moderately bound (83-87)% to plasma proteins.

The enzyme responsible for the metabolism of desloratadine has not been identified yet, and therefore, some interactions with other medicinal products cannot be fully excluded.

Desloratadine does not inhibit CYP3A4 or CYP2D6 and is neither a substrate nor an inhibitor of P-glycoprotein.

Grapefruit juice has no effect on the disposition of desloratadine.

CONSERVATION

Store in a cool dry place below 30°C. Protect from light.

Keep out of the reach of children.

Do not use after the expiry date which is stated on the bottle.

CHAPHA
PATIENT-CENTRIC SOLUTIONS

Manufactured by **Chaoul Pharmaceuticals (CHA-PHA) S.A.L.**, Lebanon