

### 1.3.1.1 PROFESSIONAL INFORMATION

SCHEDULING STATUS: S2

#### 1. NAME OF MEDICINE:

**DESLOMED SYRUP (2,5 mg Syrup)**

#### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION:

Each 5 ml of **DESLOMED SYRUP** contains:

Desloratadine 2,5 mg

Preservative:

Sodium benzoate 0,1% *m/v*

Sugar free

Contains sweeteners:

Blend ADI 450 (acesulfame potassium and sucralose) 1,50 mg

For a full list of excipients see section 6.1

#### 3. PHARMACEUTICAL FORM

Syrup

A clear, orange coloured aqueous solution with a sweet orange odour.

#### 4. CLINICAL PARTICULARS

##### 4.1 Therapeutic indications

**DESLOMED SYRUP** is indicated for symptomatic relief of seasonal types of allergy that present with symptoms such as rhinitis.

## **4.2 Posology and method of administration**

*Children 2 to 5 years of age:*

2,5 ml (1,25 mg) once a day, with or without food.

*Children 6 to 11 years of age:*

5 ml (2,5 mg) once a day, with or without food.

*Adults and adolescents (12 years of age and over):*

10 ml (5 mg) once a day, with or without food.

Patients with hepatic or renal impairment should be given 10 ml (5 mg) **DESLOMED SYRUP** on alternate days initially.

## **4.3 Contraindications:**

Hypersensitivity to active substance or to any of the excipients.

Pregnancy and lactation (see section 4.6).

Cross sensitivity to other antihistamines.

Porphyria.

## **4.4 Special warnings and precautions for use**

Patients with the rare hereditary condition of sorbitol or maltitol intolerance should not take **DESLOMED SYRUP**.

Patients with hepatic or renal impairment should be given 5 mg **DESLOMED SYRUP** on alternate days initially.

**DESLOMED SYRUP** lacks significant sedative effects.

Efficacy and safety of **DESLOMED SYRUP** in children under 2 years of age has not been established.

Safety and efficacy of **DESLOMED SYRUP** has not been established for treatment periods in excess of 4 weeks.

**DESLOMED SYRUP** should be discontinued prior to skin tests allergen extracts as it may inhibit the cutaneous histamine response, thus producing false-negative results.

**DESLOMED SYRUP** should be discontinued at least 48 hours before test. **DESLOMED SYRUP** should be used with caution when one or more of the following medical conditions exist and/or patient is using other medication metabolised by the cytochrome P450 system: -emphysema, prostatic hypertrophy, narrow angle glaucoma, cardiovascular disorder, epilepsy or during acute attack of asthma.

H1 receptor antihistamines such as **DESLOMED SYRUP** have been shown to cause weight gain.

#### **4.5 Interaction with other medicines and other forms of interactions**

Concomitant use of **DESLOMED SYRUP** with alcohol did not potentiate the performance impairing effects of alcohol.

Co-administration of desloratadine with ketoconazole increases the maximum desloratadine concentration ( $C_{max}$ ) by 45 % and the area under the time concentration curve (AUC) by 37 %. Co-administration of desloratadine with erythromycin increased the  $C_{max}$  of desloratadine by 24 % and the AUC by 14%.

The increase in  $C_{max}$  and AUC of desloratadine when co-administered with either ketoconazole or erythromycin did not cause any clinically relevant adverse events in the population studied.

#### **4.6 Fertility, pregnancy and lactation**

**DESLOMED SYRUP** should not be used during pregnancy (see '**CONTRAINDICATIONS**').

**DESLOMED SYRUP** is distributed into breast milk therefore is not recommended for use during lactation (see '**CONTRAINDICATIONS**').

#### 4.7 Effects on ability to drive and use machines

**DESLOMED SYRUP** lacks significant sedative effects. Patients should be warned, however, that a small number of individuals may experience sedation. It is therefore advisable to determine response before driving or performing complicated tasks.

#### 4.8 Undesirable effects

At the recommended dose of 5 mg daily, undesirable effects with **DESLOMED SYRUP** were reported in 4 % of patients in excess of those treated with placebo.

System organ class	Frequent	Less Frequent	Frequency Unknown
<i>Metabolism and nutritional disorder</i>			Increased appetite.
<i>Nervous system disorders</i>		No excess incidence of somnolence was reported.  Headache was reported in 2% of patients receiving <b>DESLOMED SYRUP</b> .  Dizziness, fatigue, sedation, nervousness, blurred vision, confusion and nightmares.	
<i>Cardiac disorders</i>			Tachycardia, palpitations
<i>Respiratory, thoracic and mediastinal disorders:</i>	Pharyngitis.		Dyspnoea

<i>Gastrointestinal disorders</i>		Dyspepsia, nausea, dry mouth.	
<i>Skin and subcutaneous tissue disorders</i>			Pruritis, rash, urticaria, alopecia.
<i>Musculoskeletal and connective tissue disorders</i>		Myalgia	
<i>Reproductive system and breast disorders:</i>		Dysmenorrhoea.	
<i>General disorders and administrative site conditions</i>		Fatigue	Anaphylaxis, oedema
<i>Investigations:</i>		Elevations of liver enzymes and bilirubin have been reported.	

### **Reporting of suspected adverse reactions**

Reporting suspected adverse reactions after authorization of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the “**6.04 Adverse Drug Reaction**

**Reporting Form**”, found online under SAHPRA’s publications:

<https://www.sahpra.org.za/publications/Index/8>

May also report to Adcock Ingram Limited using the following email:

Adcock.AEReports@adcock.com

#### **4.9 Overdose**

In the event of overdosage, symptomatic and supportive treatment is recommended. Desloratadine is not eliminated by haemodialysis and it is not known if it is eliminated by peritoneal dialysis.

### **5. PHARMACOLOGICAL PROPERTIES**

#### **5.1 Pharmacodynamic properties**

##### A 5.7.1 Antihistaminics

##### **5.1.1. Mechanism of action**

Desloratadine is a long-acting, non-sedating antihistamine with selective peripheral H<sub>1</sub>-receptor histamine antagonist activity.

##### **5.1.2 Pharmacodynamic properties:**

Desloratadine is described as non-sedating as it does not cross the blood brain barrier and lacks anti-cholinergic side effects. In addition to antihistaminic activity, desloratadine has demonstrated anti-allergic and anti-inflammatory activity from numerous *in vitro* as well as *in vivo* studies. Desloratadine inhibits the broad cascade of events that initiate and propagate allergic inflammation.

##### **5.2 Pharmacokinetic properties:**

After oral administration, desloratadine is well absorbed from the gastrointestinal tract with peak plasma concentrations achieved after approximately 3 hours. Plasma concentrations of desloratadine can be detected within 30 minutes of administration. The duration of action is 24 hours and the elimination half-life is 27 hours in healthy subjects. The degree of accumulation of desloratadine was consistent with its half-life and a once daily dosing frequency. In adults and adolescents, the bioavailability of desloratadine dose was proportional over the range 5 mg to 20 mg.

Plasma protein binding of desloratadine is 82 to 87 % and desloratadine is extensively metabolised to the active metabolite, 3-hydroxydesloratadine. Once-daily dosing of desloratadine ( 5 mg to 20 mg) for 14 days did not reveal any evidence of clinically relevant substance accumulation.

The bioequivalence of desloratadine was not affected by the presence of food (high fat, high caloric breakfast) in a single dose crossover trial using a 7,5 mg dose of desloratadine. In another study, grapefruit juice had no effect on the pharmacokinetics 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.

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Citric acid anhydrous, colour FD&C yellow No. 6, disodium edetate, liquid maltitol, orange flavour type sweet 96472-33, propylene glycol, sodium citrate, sorbitol solution

### **6.2 Incompatibilities**

Not applicable

### **6.3 Shelf life**

Two years

### **6.4 Special precautions for storage**

Store at or below 25 °C in a tightly closed container.

KEEP OUT OF REACH OF CHILDREN.

### **6.5 Nature and contents of container**

50 ml, 100 ml or 150 ml in a round, amber polyethylene terephthalate (PET) bottle with screw-on, white high density polyethylene (HDPE) closure with a white low density polyethylene (LDPE) tamper evident ring and clear fitted LDPE plug.

50 ml, 100 ml or 150 ml in a round, amber glass bottle with a screw-on, white polypropylene closure with EXPE liner.

50 ml, 100 ml or 150 ml bottles are packed into cartons with a leaflet.

## **7. HOLDER OF CERTIFICATE OF REGISTRATION**

Adcock Ingram Limited

1 New Road

Erand Gardens

Midrand, 1685

Customer Care: 0860 ADCOCK / 232625

## **8. REGISTRATION NUMBER**

43/ 5.7.1/ 0079

## **9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of Registration: 27 July 2012

## **10. DATE OF REVISION OF THE TEXT**

Date of revision: 22 April 2022

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