SCHEDULING STATUS: **S2**

1.NAME OF MEDICINE:

DESLOMED SYRUP

Strength

Desloratadine 2,5 mg

Pharmaceutical form

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

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

4. CLINICAL PARTICULARS

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 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

Safety and/or efficacy has not been established.

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	**Undesirable effects**
Metabolism and nutritional disorder	Increased appetite
Nervous system disorders *Less frequent*	No excess incidence of somnolence was reported. Headache was reported in 2% of patients receiving **DESLOMED SYRUP.** Dizziness, fatigue, sedation, nervousness, blurred vision, confusion and nightmares.
Cardiac disorders	

Frequency unknown	Tachycardia, palpitations
Respiratory, thoracic and mediastinal disorders: *Frequent:* *Frequency unknown:*	 Pharyngitis. Dyspnoea
Gastrointestinal disorders *Less frequent*	 Dyspepsia, nausea, dry mouth.
Skin and subcutaneous tissue disorders *Frequency unknown*	 Pruritis, rash, urticaria, alopecia.
Musculoskeletal and connective tissue disorders *Less frequent*	 Myalgia
Reproductive system and breast disorders: *Less frequent*	 Dysmenorrhoea.
General disorders and administrative site conditions *Less frequent* *Frequency unknown*	 Fatigue Anaphylaxis, oedema
Investigations: *Less frequent:*	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. Healthcare 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 haemodialysis and it is known if it is eliminated by peritoneal dialysis.

5. PHARMACEUTICAL PROPERTIES

5.1 Pharmacodynamics properties

A 5.7.1 Antihistaminics

Mechanism of action

Desloratadine is a long-acting, non-sedating antihistamine with selective peripheral H_1-receptor histamine antagonist activity.

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 in the broad cascade of events that initiate and propagate allergic inflammation.

5.2 Pharmacokinetics

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 proportional over the range 5 mg to 20 mg.

Plasma protein binding of desloratadine is 82 to 87 % and desloratadine is extensively metabolised to 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 single dose crossover trail 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 dosed, 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 ºC in 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 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

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8. REGISTRATION NUMBER

43/ 5.7.1/ 0079

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of Registration: 12 July 2012

10.DATE OF REVISION OF TEXT

Date of revision: 22 April 2022

Namibia: NS1 14/5.7.1/0631