PROFESSIONAL INFORMATION

SCHEDULING STATUS: **S2**

1. NAME OF MEDICINE:

DEMILTIX (2,5 mg Syrup)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION:

Each 5 ml of **DEMILTIX** 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

DEMILTIX 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) **DEMILTIX** 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 **DEMILTIX.**

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

DEMILTIX lacks significant sedative effects.

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

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

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

DEMILTIX should be discontinued at least 48 hours before test. **DEMILTIX** 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 **DEMILTIX** have been shown to cause weight gain.

DEMILTIX contains sodium benzoate which may increase jaundice in newborn babies (up to 4 weeks old).

4.5 Interaction with other medicines and other forms of interactions

Concomitant use of **DEMILTIX** 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

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

DEMILTIX 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

DEMILTIX 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 **DEMILTIX** were reported in 4 % of patients in excess of those treated with placebo.

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

Gastrointestinal disorders		Dyspepsia, nausea, dry mouth.	
Skin and subcutaneous tissue disorders			Pruritis, rash, urticaria, alopecia.
Musculoskeletal and connective tissue disorders		Myalgia	
Reproductive system and breast disorders:		Dysmenorrhoea	
General disorders and administrative site conditions		Fatigue	Anaphylaxis, oedema
Investigations		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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

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_1-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 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 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 ºC in a tightly closed container.

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.

PROFESSIONAL INFORMATION

7. HOLDER OF CERTIFICATE OF REGISTRATION

Adcock Ingram Limited

1 New Road

Erand Gardens

Midrand,1685

Customer Care: 0860 ADCOCK / 232625

8. REGISTRATION NUMBER

59/5.7.1/0453

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of Registration: 16 April 2024

10.DATE OF REVISION OF THE TEXT

12 September 2025