SCHEDULING STATUS: **S2**

PROPRIETARY NAME AND DOSAGE FORM:

ADCO-DESLORATADINE SYRUP

COMPOSITION:

Each 5 ml contains 2,5 mg desloratadine

Preservative: Sodium benzoate 0,1 % m/v

Sugar free

Contains sweeteners: Blend ADI 450 (acesulfame potassium and sucralose) 1.50 mg,

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.

CATEGORY AND CLASS:

A 5.7.1 Antihistaminics

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

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 was 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 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.

INDICATIONS:

ADCO-DESLORATADINE SYRUP is indicated for symptomatic relief of seasonal types of allergy that present with symptoms such as rhinitis.

CONTRAINDICATIONS:

Hypersensitivity to any of the ingredients.

Pregnancy and lactation (see **'HUMAN REPRODUCTION'**).

Cross sensitivity to other antihistamines.

Porphyria.

WARNINGS AND SPECIAL PRECAUTIONS:

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

ADCO-DESLORATADINE SYRUP lacks significant sedative effects.

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

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

ADCO-DESLORATADINE SYRUP should be discontinued prior to skin tests allergen extracts as it may inhibit the cutaneous histamine response, thus producing false-negative results. **ADCO-DESLORATADINE SYRUP** should be discontinued at least 48 hours before test. **ADCO-DESLORATADINE 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 attacks of asthma.

Effects on ability to drive and use machines:

ADCO-DESLORATADINE 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 individual response before driving or performing complicated tasks.

INTERACTIONS:

Concomitant use of **ADCO-DESLORATADINE 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.

HUMAN REPRODUCTION:

Safety and/or efficacy has not been established.

ADCO-DESLORATADINE SYRUP should not be used during pregnancy (see '**CONTRAINDICATIONS'**).

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

DOSAGE AND DIRECTIONS FOR USE:

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 **ADCO-DESLORATADINE SYRUP** on alternate days initially.

SIDE EFFECTS:

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

Cardiac disorders:

Frequency unknown: Tachycardia, palpitations.

Gastrointestinal disorders:

Less frequent: Dyspepsia, nausea, dry mouth.

General disorders and administration site conditions:

Less frequent: Fatigue.

Frequency unknown: Anaphylaxis, oedema.

Investigations:

Less frequent: Elevations of liver enzymes and bilirubin have been reported.

Musculoskeletal and connective tissue disorders:

Less frequent: Myalgia.

Nervous system disorders:

No excess incidence of somnolence was reported.

Headache was reported in 2 % of patients receiving **ADCO-DESLORATADINE SYRUP.**

Less frequent: Dizziness, fatigue, sedation, nervousness, blurred vision, confusion and nightmares.

Reproductive system and breast disorders:

Less frequent: Dysmenorrhoea.

Respiratory, thoracic and mediastinal disorders:

Frequent: Pharyngitis.

Frequency unknown: Dyspnoea.

Skin and subcutaneous tissue disorders:

Frequency unknown: Pruritus, rash, urticaria, alopecia.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

In the event of overdose, symptomatic and supportive treatment is recommended.

Desloratadine is not eliminated by haemodialysis and it is not known if it is eliminated by peritoneal dialysis.

IDENTIFICATION:

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

PRESENTATION:

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.

STORAGE INSTRUCTIONS:

Store at or below 25 ºC in tightly closed container.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

43/5.7.1/0079

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