SCHEDULING STATUS: **S2**

PROPRIETARY NAME AND DOSAGE FORM:

ADCO-DESLORATADINE SYRUP (SYRUP)

Read all of this leaflet carefully because it contains important information for you

ADCO-DESLORATADINE SYRUP is available without a doctor's prescription, for you to treat a mild illness. Nevertheless you still need to use **ADCO-DESLORATADINE SYRUP** carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share **ADCO-DESLORATADINE SYRUP** with any other person.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve.

WHAT ADCO-DESLORATADINE SYRUP CONTAINS:

Active ingredient:

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.

WHAT ADCO-DESLORATADINE SYRUP IS USED FOR:

ADCO-DESLORATADINE SYRUP is an antihistamine that provides relief of seasonal hay fever.

BEFORE USING ADCO-DESLORATADINE SYRUP:

Do not use ADCO-DESLORATADINE SYRUP:

- if you are pregnant.
- if you are breast feeding.

- if you are allergic to any of the syrup ingredients.
- if you are allergic to any other antihistamines.
- if you have porphyria.

Take special care with ADCO-DESLORATADINE SYRUP:

- Tell your doctor if you suffer from liver or kidney disease.
- Tell your doctor if you have ever had any unusual or allergic reaction to **ADCO-DESLORATADINE SYRUP.**
- 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 48 hours before skin allergen tests are performed as it may affect the results

Pregnancy and breast feeding:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advise before taking

ADCO-DESLORATADINE SYRUP.

ADCO-DESLORATADINE SYRUP should not be used during pregnancy and breast feeding.

Driving and using machinery:

ADCO-DESLORATADINE SYRUP lacks significant sedative effects. However, a small number of individuals may experience sedation. It is therefore advisable to determine individual patients' response before driving or performing complicated tasks.

Taking other medicines with ADCO-DESLORATADINE SYRUP:

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of ADCO-DESLORATADINE SYRUP with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.

Tell your doctor if you are taking any other medicines before you start treatment with **ADCO-DESLORATADINE SYRUP**, especially if you are taking medicines containing the following active substances:

- *Ketoconazole*
- *Erythromycin*

Tell your doctor if you are being treated for any of the following medical conditions:

- Emphysema
- Enlarged prostate
- Narrow angle glaucoma
- Heart conditions
- Epilepsy
- Acute attacks of asthma

HOW TO TAKE ADCO-DESLORATADINE SYRUP:

Always take **ADCO-DESLORATADINE SYRUP** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. It is important not to take more or less medication than the amount prescribed.

The usual dose is as follows:

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.

If you use more ADCO-DESLORATADINE SYRUP than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison centre.

Treatment of an overdose with **ADCO-DESLORATADINE SYRUP** is symptomatic (relating to the symptoms) and supportive.

If you forget to take ADCO-DESLORATADINE SYRUP:

Do not take a double dose to make up for forgotten individual doses.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, rush the patient to the nearest hospital or poison centre.

POSSIBLE SIDE EFFECTS:

ADCO-DESLORATADINE SYRUP can sometimes cause unwanted effects.

Note: Not all side effects reported are included in this leaflet. Should your general health worsen while taking ADCO-DESLORATADINE SYRUP, please consult your doctor, pharmacist or other health care professional for advice.

The following side effects may be experienced while using **ADCO-DESLORATADINE SYRUP:**

Cardiac disorders:

Increased heart rate, palpitations.

Gastrointestinal disorders:

Dry mouth, indigestion, nausea.

General disorders and administration site conditions:

Fatigue, sudden severe allergic response, swelling.

Investigations:

Increase in liver enzymes and bilirubin have been reported.

Musculoskeletal and connective tissue disorders:

Muscle pain.

Nervous system disorders:

Drowsiness, headache, dizziness, fatigue, sedation, nervousness, blurred vision, confusion and nightmares.

Reproductive system and breast disorders:

Painful menstruation.

Respiratory, thoracic and mediastinal disorders:

Sore throat, difficulty in breathing.

Skin and subcutaneous tissue disorders:

Itching, rash, itchy rash, baldness.

STORAGE AND DISPOSAL INFORMATION:

KEEP ALL MEDICINES OUT OF REACH AND SIGHT OF CHILDREN.

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

Do not use after the expiry date stated on the label or carton.

Return all unused medicine to your pharmacy. Do not dispose of unused medicine in drains or sewerage systems e.g. toilets.

PRESENTATION OF ADCO-DESLORATADINE SYRUP:

50ml,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.

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

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

IDENTIFICATION:

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

REGISTRATION NUMBER:

43/5.7.1/0079

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE REGISTRATION CERTIFICATE:

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