SCHEDULING STATUS S2

PROPRIETARY NAME AND PHARMACEUTICAL DOSAGE FORM

DESLOMED SYRUP

Actives substance per 5 ml is:

Desloratadine 2,5 mg

Preservatives:

Sodium benzoate 0,1% m/v

Sugar free

Contains sweeteners:

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

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

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

- Keep this leaflet. You may need to read it again.
- Do not share DESLOMED SYRUP with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.

1. WHAT DESLOMED SYRUP IS AND WHAT IT IS USED FOR

DESLOMED SYRUP is an antihistamine that provides relief of seasonal hay fever.

The active substance is: Desloratadine 2,5 mg

The other ingredients are:

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

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE DESLOMED SYRUP

Do not use DESLOMED SYRUP

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

Warnings and precautions

Take special care with DESLOMED 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 **DESLOMED SYRUP**
- Efficacy and safety of **DESLOMED SYRUP** in children under 2 years of age has not been established.
- Safety and effiacy of **DESLOMED SYRUP** has not been established for both treatment periods in excess of 4 weeks.
- Weight gain has been reported with the use of desloratadine.
- **DESLOMED SYRUP** should be discontinued 48 hours before skin allergen tests are performed as it may affect the results

Pregnancy, breastfeeding and fertility:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking **DESLOMED SYRUP**

DESLOMED SYRUP should not be used during pregnancy and breastfeeding.

Driving and using machinery

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

Important information about some of the ingredients of DESLOMED SYRUP

DESLOMED SYRUP contains sorbitol and maltitol. If you have been told that you have an intolerance to some sugars, you should not take **DESLOMED SYRUP.**

Taking other medicines with DESLOMED SYRUP:

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of ~~**ADCO-DESLORATATINE**~~ **DESLOMED 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 **DESLOMED 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 asthma attacks

3. HOW TO TAKE DESLOMED SYRUP

Always take **DESLOMED SYRUP** exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. 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 **DESLOMED SYRUP** on alternate days initially.

If you use more DESLOMED SYRUP than you should

In the event of overdosage, consult your doctor or pharmacist.

If neither is available, seek, seek help at the nearest hospital or poison control centre.

Treatment: Treatment of an overdose with **DESLOMED SYRUP** is symptomatic (relating to symptoms) and supportive.

If you forget to take DESLOMED SYRUP

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

4. POSSIBLE SIDE EFFECTS

Not all side effects reported for DESLOMED SYRUP are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this DESLOMED SYRUP, please consult your doctor, pharmacist or other healthcare professional for advice.

DESLOMED SYRUP can sometimes cause unwanted effects.

Note: Not all side effects reported are included in this leaflet. Should your general health worsen while taking **DESLOMED SYRUP**, please consult your doctor, pharmacist or other health care professional for advice. The following side effects may be experienced while taking **DESLOMED**

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.

Metabolism and nutritional disorders:

Increased appetite

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.

Reporting of side effects

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist. You can also report side effects 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. By reporting side effects, you can help provide more information on the safety of **DESLOMED SYRUP**.

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

Adcock.AEReports@adcock.com

5. HOW TO STORE DESLOMED SYRUP

KEEP OUT OF REACH AND SIGHT OF CHILDREN

Store at or below 25 ºC in a tightly closed container.

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

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What DESLOMED SYRUP contains:

Each 5 ml contains*:*

The active substance is: Desloratadine

Other Ingredients are: 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 DESLOMED SYRUP looks like and contents of the pack:

DESLOMED SYRUP is a clear, orange coloured aqueous solution with a sweet orange odour.

It is packaged in 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.

Holder of Certificate of Registration

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Access to the corresponding professional information

It is contained in the packaging of the medicine

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