PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S2

DESLOMED SYRUP (2,5 mg Syrup)

Active 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.
- You must see a doctor if your symptoms worsen or do not improve.

What is in this leaflet

1. What **DESLOMED SYRUP** is and what it is used for.

2. What you need to know before you take **DESLOMED SYRUP**.

3. How to take **DESLOMED SYRUP**.

4. Possible side effects.

5. How to store **DESLOMED SYRUP**.

6. Contents of the pack and other information.

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

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

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

Do not use DESLOMED SYRUP

- If you are hypersensitive (allergic) to Desloratadine or any of the other ingredients of **DESLOMED SYRUP** (listed in section 6).
- If you are pregnant
- If you are breastfeeding
- 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 efficacy 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
- **DESLOMED SYRUP** contains sodium benzoate which may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).

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.**

Other medicines and DESLOMED SYRUP:

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

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.

Do not share medicines prescribed for you with any other person.

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 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

DESLOMED SYRUP can have 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 **DESLOMED SYRUP**, please consult your healthcare 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 get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

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

Store all medicines out of reach 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 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

Adcock Ingram Limited

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Customer care: 0860 ADCOCK/232625

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43/5.7.1/0079

PASIËNT INLIGTINGSBLAD

SKEDULERINGSTATUS S2

DESLOMED SYRUP (2,5 mg Stroop)

Aktiewe bestanddeel per 5 ml is:

Desloratadien	2,5 mg
Preserveermiddels:	
Natriumbensoaat	0,1% m/v
Suikervry	
Bevat versoeters:	
Mengsel ADI 450 (kaliumasesulfaam en sukralose)	1,50 mg

Lees hierdie hele biljet sorgvuldig deur, want dit bevat belangrike inligting vir u.

DESLOMED SYRUP *is beskikbaar sonder 'n doktersvoorskrif, sodat u 'n minder ernstige siekte kan behandel. Nietemin moet u steeds* ***DESLOMED SYRUP*** *versigtig gebruik om die beste resultate daaruit te verkry.*

- Hou hierdie biljet. U mag dit dalk weer moet lees.
- Moenie **DESLOMED SYRUP** met enige ander persoon deel nie.
- Vra u gesondheidsorgverskaffer of apteker indien u meer inligting of advies benodig.
- U moet 'n dokter spreek indien u simptome vererger of nie verbeter nie.

Wat is in hierdie biljet

1. Wat **DESLOMED SYRUP** is en waarvoor dit gebruik word.
2. Wat u moet weet voordat u **DESLOMED SYRUP** neem.
3. Hoe om **DESLOMED SYRUP** te neem.
4. Moontlike newe-effekte.
5. Hoe om **DESLOMED SYRUP** te bêre.
6. Inhoud van die verpakking en ander inligting.

1. WAT DESLOMED SYRUP IS EN WAARVOOR DIT GEBRUIK WORD

DESLOMED SYRUP is 'n antihistamien wat verligting bied vir seisoenale hooikoors.

2. WAT U MOET WEET VOORDAT U DESLOMED SYRUP NEEM

Moet nie DESLOMED SYRUP gebruik nie

- Indien u hipersensitief (allergies) is vir Desloratadien of enige van die ander bestanddele van **DESLOMED SYRUP** (gelys in afdeling 6).
- Indien u swanger is
- Indien u borsvoed
- Indien u porfirie het

Waarskuwings en voorsorgmaatreëls

Wees spesiaal versigtig met DESLOMED SYRUP:

- Lig u dokter in indien u aan lewer- of niersiekte ly.
- Lig u dokter in indien u al ooit 'n ongewone of allergiese reaksie op **DESLOMED SYRUP** gehad het
- Die doeltreffendheid en veiligheid van **DESLOMED SYRUP** by kinders onder 2 jaar is nie vasgestel nie.
- Die veiligheid en doeltreffendheid van **DESLOMED SYRUP** is nie vir behandelingsperiodes van meer as 4 weke vasgestel nie.
- Gewigstoename is aangemeld met die gebruik van desloratadien.
- **DESLOMED SYRUP** moet 48 uur voor velallergeentoetse gestaak word, aangesien dit die resultate kan beïnvloed
- **DESLOMED SYRUP** bevat natriumbensoaat wat geelsug (geelverkleuring van die vel en oë) by pasgebore babas (tot 4 weke oud) kan verhoog.

Swangerskap, borsvoeding en vrugbaarheid:

Indien u swanger is of u baba borsvoed, raadpleeg asseblief u dokter, apteker of ander gesondheidsorg kundige vir advies voordat u **DESLOMED SYRUP** neem.

DESLOMED SYRUP moet nie tydens swangerskap en borsvoeding gebruik word nie.

Bestuur en gebruik van masjinerie

DESLOMED SYRUP het nie beduidende sederende effekte nie. 'n Klein aantal individue kan egter sedasie ervaar. Dit is dus raadsaam om individuele pasiënte se reaksies te bepaal voordat hulle bestuur of ingewikkelde take uitvoer.

Belangrike inligting oor sommige van die bestanddele van DESLOMED SYRUP

DESLOMED SYRUP bevat sorbitol en maltitol. Indien u ingelig is dat u 'n onverdraagsaamheid teenoor sekere suikers het, moet u nie **DESLOMED SYRUP** neem nie.

Ander medisyne en DESLOMED SYRUP:

Lig altyd u gesondheidsorgverskaffer in indien u enige ander medikasie neem. (Dit sluit alle komplementêre of tradisionele medisyne in.)

Lig u dokter in indien u enige ander medisyne neem voordat u met **DESLOMED SYRUP** behandeling begin, veral indien u medisyne neem wat die volgende aktiewe bestanddele bevat:

- Ketokonasool
- Eritromisien

Lig u dokter in indien u behandel word vir enige van die volgende mediese toestande:

- Emfiseem
- Vergrote prostaat
- Nouhoek-gloukoom
- Harttoestande
- Epilepsie
- Akute asma-aanvalle

3. HOE OM DESLOMED SYRUP TE NEEM

Neem **DESLOMED SYRUP** altyd presies soos beskryf in hierdie biljet of soos u dokter of apteker u ingelig het. Raadpleeg u dokter of apteker indien u nie seker is nie. Dit is belangrik om nie meer of minder medikasie as die voorgeskrewe hoeveelheid te neem nie.

Moenie medikasie wat aan u voorgeskryf is, met enige ander persoon deel nie.

Die gewone dosis is soos volg:

Kinders van 2 tot 5 jaar oud: 2,5 ml (1,25 mg) een keer per dag, met of sonder kos.

Kinders van 6 tot 11 jaar oud: 5 ml (2,5 mg) een keer per dag, met of sonder kos.

Volwassenes en adolessente (12 jaar en ouer): 10 ml (5 mg) een keer per dag, met of sonder kos.

Pasiënte met lewer- of nierinperking moet aanvanklik 5 mg **DESLOMED SYRUP** op afwisselende dae ontvang.

Indien u meer DESLOMED SYRUP gebruik as wat u moes

In die geval van oordosering, raadpleeg u dokter of apteker.

Indien nie een van die twee beskikbaar is nie, soek hulp by die naaste hospitaal of gifhulpsentrum.

Behandeling: Behandeling van 'n oordosis met **DESLOMED SYRUP** is simptomaties (verwant aan simptome) en ondersteunend.

Indien u vergeet om DESLOMED SYRUP te neem

Moenie 'n dubbele dosis neem om op te maak vir vergete individuele dosisse nie.

4. MOONTLIKE NEWE-EFFEKTE

DESLOMED SYRUP kan newe-effekte hê.

*Nie alle newe-effekte wat vir **DESLOMED SYRUP** aangemeld is, word in hierdie biljet ingesluit nie. Indien u algemene gesondheid verswak of indien u enige ongewenste gevolge ervaar terwyl u **DESLOMED SYRUP** gebruik, raadpleeg asseblief u gesondheidsorg kundige vir advies.*

Die volgende newe-effekte kan ervaar word tydens die gebruik van **DESLOMED SYRUP:**

Hartafwykings:

Verhoogde hartspoed, hartkloppings.

Gastro-intestinale afwykings:

Droë mond, slegte spysvertering, naarheid.

Algemene afwykings en toedieningsarea toestande:

Moegheid, skielike ernstige allergiese reaksie, swelling.

Ondersoeke:

Toename in lewerensieme en bilirubien is aangemeld.

Metabolisme en voedingsversteurings:

Verhoogde eetlus

Skeletspier- en bindweefselafwykings:

Spierpyn.

Senuweestelselafwykings:

Lomerigheid, hoofpyn, duiseligheid, moegheid, sedasie, senuweeagtigheid, versteurde sig, verwarring en nagmerries.

Voortplantingstelsel- en borsafwykings:

Pynlike menstruasie.

Respiratoriese, torakale en mediastinale afwykings:

Seer keel, asemhalingsprobleme.

Vel- en subkutane weefselafwykings:

Jeukerigheid, veluitslag, jeukerige uitslag, bles word.

Aanmelding van newe-effekte

Indien u newe-effekte ervaar, raadpleeg u dokter of apteker. U kan ook newe-effekte by SAHPRA aanmeld via die Med Safety Toep (Medsafety X SAHPRA) en die eAanmeldingsplatform (who-umc.org) wat op die SAHPRA se webwerf gevind kan word.

Deur newe-effekte aan te meld, kan u help om meer inligting te verskaf oor die veiligheid van **DESLOMED SYRUP.**

U kan dit ook aan Adcock Ingram Limited aanmeld by die volgende e-pos: Adcock.AEReports@adcock.com

5. HOE OM DESLOMED SYRUP TE BÊRE

Bêre alle medisyne buite bereik van kinders.

Bêre teen of benede 25 ºC in 'n diggeslote houer.

Moenie gebruik ná die vervaldatum wat op die etiket/kartonboksie aangedui is nie.

Neem alle ongebruikte medisyne terug aan u apteker.

Moenie ongebruikte medisyne in afvoerpype of rioolstelsels (bv. toilette) weggooi nie.

6. INHOUD VAN DIE VERPAKKING EN ANDER INLIGTING

Wat DESLOMED SYRUP bevat:

***Elke 5 ml bevat**:*

Die aktiewe bestanddeel is: Desloratadien

Ander bestanddele is: Watervrye sitroensuur, kleursel FD&C geel No. 6, dinatriumedetaat, vloeibare maltitol, lemoengeursel tipe soet 96472-33, propileenglikol, natriumsitraat, sorbitoloplossing.

Hoe DESLOMED SYRUP lyk en inhoud van die verpakking:

DESLOMED SYRUP is 'n deurskynende, oranje gekleurde waterige oplossing met 'n soet oranje reuk. Dit word verpak in 50 ml, 100 ml of 150 ml in 'n ronde, amber poliëtileentereftalaatbottel (PET) met 'n opskroef, wit hoëdigtheid poliëtileen (HDPE) prop met 'n wit laedigtheid poliëtileen (LDPE) peuter-duidelike ring en deursigtige LDPE-seël.

50 ml, 100 ml of 150 ml in 'n ronde, amber glasbottel met 'n opskroef, wit polipropileen prop met EXPE-voering.

50 ml, 100 ml of 150 ml bottels word in kartonboksies verpak met 'n biljet.

Houer van Sertifikaat van Registrasie

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