Applicant/ PHCR: Bayer (Pty) Ltd
Product Name: Deselex Syrup
Dosage Form and Strength: Syrup, each 5 ml syrup contains desloratadine 2,5 mg

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S2

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

DESELEX®, 2.5 MG DESLORATADINE, SYRUP

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

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

- Keep this leaflet. You may need to read it again
- Ask your pharmacist if you need more information or advice
- You must see a doctor if your symptoms worsen or do not improve after 14 days.

1. WHAT DESELEX SYRUP CONTAINS

The active substance is Desloratadine 2,5 mg per 5 ml syrup.

The other ingredients are: disodium edetate, citric acid, propylene glycol, sorbitol, sodium citrate, sucrose, bubble gum flavour, FD & C dye no. 6, purified water and 0,1 % *m/v* sodium benzoate as preservative.

Contains sugar(s): Sorbitol 12 % and sucrose 40 %.

2. WHAT DESELEX SYRUP IS USED FOR

DESELEX SYRUP is an anti-allergy medicine. It helps control your allergic reaction and its symptoms.

DESELEX SYRUP relieves symptoms associated with allergic rhinitis (e.g. hay fever), such as sneezing, runny or itchy nose and burning or itchy eyes.

DESELEX SYRUP may also be used to relieve the symptoms associated with chronic idiopathic urticaria (itching, redness and number and size of hives).

3. BEFORE YOU TAKE DESELEX SYRUP

Do not take DESELEX SYRUP

If you are hypersensitive (allergic) to desloratadine or to any of the other ingredients of DESELEX SYRUP.

Do not give DESELEX SYRUP to your child if he/she is under two years of age.

Take special care with DESELEX SYRUP

Tell your doctor if you:

- have liver or kidney problems.
- have a medical or family history of seizures
- have any other medical conditions.

Taking DESELEX SYRUP with food and drink

DESELEX SYRUP may be taken with or without food.

Pregnancy and breastfeeding

You should not use DESELEX SYRUP if you are pregnant or breastfeeding your baby.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other health care professional for advice before taking this medicine

Driving and using machinery

DESELEX SYRUP lack significant sedative effects. Some people may experience sedation and

if you do, you should not drive or perform complicated tasks.

Important information about some of the ingredients of DESELEX SYRUP:

DESELEX SYRUP contains sucrose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking DESELEX SYRUP.

Taking other medicines with DESELEX SYRUP

Always tell your healthcare professional if you are taking any other medicine.

(This Includes complementary or traditional medicine).

Especially tell your doctor if you take:

- ketoconazole: an antifungal medicine used to treat certain kinds of fungal or yeast infections.
- erythromycin: an antibiotic medicine used to treat certain kinds of bacterial infections and often used for people who have an allergy to penicillins.
- azithromycin: an antibiotic medicine to treat certain kinds of bacterial infections (such as pneumonia and ear infections).
- antihistamines: a medicine commonly used to treat allergies.
- fluoxetine: a medicine used to treat depression.
- cimetidine: a medicine used treat stomach ulcers, acid reflux, or to prevent and treat symptoms of heartburn associated with acid, indigestion and sour stomach.

4. HOW TO TAKE DESELEX SYRUP

Always take DESELEX SYRUP exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The usual dose is:

Children 2 to 5 years of age:

2.5 ml (1.25 mg) DESELEX SYRUP once a day, with or without a meal.

Children 6 to 11 years of age:

5 ml (2.5 mg) DESELEX SYRUP once a day, with or without a meal.

Adults and adolescents (12 years of age and over):

10 ml (5 mg) DESELEX SYRUP once a day, with or without a meal.

Your doctor will determine the duration of your treatment. DESELEX SYRUP should not be taken for longer than 4 weeks for allergic rhinitis and 6 weeks for chronic idiopathic urticaria.

If you have the feeling that DESELEX SYRUP is too strong or too weak, talk to your doctor or pharmacist.

If you take more DESELEX SYRUP than you should

In the event of an overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take DESELEX SYRUP:

If you forget to take your dose on time, take it as soon as possible, then go back to your regular dosing schedule. Do not take a double dose to make up for forgotten individual doses.

Effects when treatment with DESELEX SYRUP is stopped:

There should be no symptoms from stopping taking DESELEX SYRUP, but if you experience any effects, consult your doctor or pharmacist.

5. POSSIBLE SIDE-EFFECTS

DESELEX SYRUP can have side-effects.

Contact a doctor or pharmacist if you have any reaction to DESELEX SYRUP that continues, is bothersome or that you think is serious.

During the marketing of DESELEX SYRUP the following were reported:

Treatment-Related Undesirable Effects Reported by Body System	
Immune system disorder	Severe allergic reactions (difficulty in breathing, wheezing, itching, hives and swelling) and rash have been reported.
Metabolism and nutrition disorders	Increased appetite.
Nervous system disorders	Dizziness, drowsiness, inability to sleep, headache (head pain), seizures (convulsions).
Cardiac disorders	Rapid heartbeat, palpitations (unpleasant sensation of irregular and/or forceful beating of the heart).
Gastro-intestinal disorders	Stomach pain, nausea (feeling sick), vomiting, upset stomach, diarrhoea, dry mouth.
Hepato-biliary disorders	Abnormal liver function tests, hepatitis (liver inflammation), elevated bilirubin.
Musculoskeletal and connective tissue disorders	Muscle pain.
General disorders and administrative site conditions	Fatigue (tiredness).

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

6. STORING AND DISPOSING OF DESELEX SYRUP

Keep all medicines out of the reach and sight of children.

Store at or below 30 °C in the original container. Do not store in a bathroom or a refrigerator.

Do not use this product after the expiry date that appears on the package.

Return all unused medicine to your pharmacist.

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

7. PRESENTATION OF DESELEX SYRUP

Amber glass bottles of 50, 60 ml, 100, 150 and 200 ml.

8. IDENTIFICATION OF DESELEX SYRUP

Clear orange solution.

9. REGISTRATION NUMBER

37/5.7.1/0227

10. NAME AND ADDRESS OF THE HOLDER OF REGISTRATION CERTIFICATE

Bayer (Pty) Ltd

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11. DATE OF PUBLICATION

Date on the registration certificate: 11 December 2003

Date of the most recently revised patient information leaflet: 21 June 2013