Applicant/ PHCR: **Bayer (Pty) Ltd**

Product Name: **Deselex Tablets**

Dosage Form and Strength: **Tablet, each tablet contains desloratadine 5 mg**

PROPOSED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S2

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

DESELEX™, 5 MG DESLORATADINE, TABLETS

READ ALL OF THIS LEAFLET CAREFULLY BECAUSE IT CONTAINS IMPORTANT INFORMATION FOR YOU

DESELEX TABLETS is available with or without a doctor's prescription, for you to treat a mild illness. Nevertheless you still need to use DESELEX TABLETS 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.

WHAT DESELEX TABLETS CONTAIN

The active substance is Desloratadine 5 mg per tablet.

The other ingredients are: Calcium phosphate, maize starch, microcrystalline cellulose, talc and purified water.

Contains sugar: lactose monohydrate.

WHAT DESELEX TABLETS ARE USED FOR

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

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

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

BEFORE YOU TAKE DESELEX TABLETS

DESELEX TABLETS should not be used:

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

TAKE SPECIAL CARE WITH DESELEX TABLETS

DESELEX can have side effects which may include sedation. It is therefore advisable that you determine your response regarding sedation before you continue with your treatment.

Do not take for longer than 4 weeks.

Tell your doctor if you:

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

Taking DESELEX TABLETS with food and drink

DESELEX TABLETS may be taken with or without a meal.

Pregnancy and breast-feeding

If you are pregnant, taking DESELEX TABLETS is not recommended. Ask your doctor or pharmacist for advice before taking any medicine during pregnancy.

If you are breastfeeding, DESELEX TABLETS is not recommended. Ask your doctor or pharmacist for advice.

Driving and using machinery

DESELEX TABLETS lack significant sedative effects. However some people may suffer sedation. Test your response before driving or performing complicated tasks.

Important information about some of the ingredients of Deselex Tablets:

Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucosegalactose malabsorption should not take DESELEX TABLETS.

TAKING OTHER MEDICINES WITH DESELEX TABLETS

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines).

Ketoconazole, erythromycin, azithromycin, or fluoxetine can enhance the plasma concentrations of desloratadine.

HOW TO TAKE DESELEX TABLETS

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

The usual dose is one DESELEX TABLETS a day for adults and adolescents over 12 years of age, regardless of mealtimes.

Regarding the duration of treatment, your physician will determine the type of allergic rhinitis you are suffering from and will determine for how long you should take DESELEX.

If your allergic rhinitis is intermittent (presence of symptoms for less than 4 days per week or for less than 4 weeks) your physician will recommend you for a treatment schedule that will depend on the evaluation of the history of your disease.

If your allergic rhinitis is persistent (presence of symptoms for 4 days or more per week and for more than 4 weeks), your physician may recommend you a longer term treatment.

For chronic idiopathic urticaria, the duration of treatment may be variable from patient to patient and therefore you should follow the instructions of your physician.

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

If you take more DESELEX TABLETS than you should

If you take more DESELEX TABLETS than you were told to, consult immediately with your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take DESELEX TABLETS:

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 TABLETS are stopped:

There should be no symptoms from stopping taking DESELEX TABLETS, if you experience some consult your doctor or pharmacist.

POSSIBLE SIDE-EFFECTS

DESELEX TABLETS can have side-effects. Contact a doctor or pharmacist if you have any reaction to DESELEX TABLETS that continues, is bothersome or that you think is serious.

During the marketing of DESELEX TABLETS the following were reported:

Treatment-Related Undesirable Effects Reported by Body System	
Immune system disorders	Hypersensitivity reactions (such as anaphylaxis, angioedema, dyspnoea, pruritus, rash, and urticaria)
Metabolism and nutrition disorders	Increased appetite
Nervous system disorders	Dizziness, drowsiness, inability to sleep, seizures (convulsions), restlessness with increased body movement, headache (head pain).
Cardiac disorders	Rapid heart beat, 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).
Musculoskeletal and connective tissue disorders	Myalgia (muscle pain).
General disorders and administrative site conditions	Fatigue (tiredness).

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

STORING AND DISPOSING OF DESELEX TABLETS

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

Store below 25 °C in a dry place away from moisture. Do not freeze. (Do not store in a bathroom or a refrigerator).

Keep the blister card in the carton until you need to take the tablets.

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).

PRESENTATION OF DESELEX TABLETS:

DESELEX are packed in blister packs. Blisters are packed in cartons 10 or 30 tablets.

IDENTIFICATION OF DESELEX TABLETS

Light blue round embossed tablets (embossed with the Schering-Plough logo).

REGISTRATION NUMBER

35/5.7.1/0207

NAME, TELEPHONE NUMBER AND ADDRESS OF HOLDER OF REGISTRATION CETIFICATE

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DATE OF PUBLICATION OF THIS PATIENT INFORMATION LEAFLET

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Date of the most recently revised patient information: 09 March 2018