PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S2

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

NEOCLARITYNE™, 5 MG DESLORATADINE, TABLETS.

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

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

- Keep this leaflet. You may need to read it again.
- Do not share NEOCLARITYNE TABLETS 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 after 14 days.

WHAT NEOCLARITYNE TABLETS CONTAINS

The active substance is: Desloratadine 5 mg per tablet.

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

Contains sugar: lactose monohydrate.

WHAT NEOCLARITYNE TABLETS ARE USED FOR

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

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

NEOCLARITYNE 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 NEOCLARITYNE TABLETS

Do not take NEOCLARITYNE TABLETS:

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

TAKE SPECIAL CARE WITH NEOCLARITYNE TABLETS

- NEOCLARITYNE 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.

Taking NEOCLARITYNE TABLETS with food and drink

NEOCLARITYNE TABLETS may be taken with or without a meal.

Pregnancy and Breast-feeding

If you are pregnant or breast feeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicine.

Driving and using machinery

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

TAKING OTHER MEDICINES WITH NEOCLARITYNE 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 NEOCLARITYNE TABLETS

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

Always take NEOCLARITYNE 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 NEOCLARITYNE TABLETS a day for adults and adolescents over 12 years of age, regardless of mealtimes.
If you have the feeling that NEOCLARITYNE TABLETS are too strong or too weak, talk to your doctor or pharmacist.

If you take more NEOCLARITYNE TABLETS than you should

If you take more NEOCLARITYNE 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 NEOCLARITYNE TABLETS

If you forget to take NEOCLARITYNE TABLETS 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 NEOCLARITYNE TABLETS is stopped:

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

POSSIBLE SIDE-EFFECTS

NEOCLARITYNE TABLETS can have side-effects.

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

During the marketing of NEOCLARITYNE TABLETS the following were reported.

Treatment-Related Undesirable Effects Reported by Body System	
Immune system disorders	Hypersensitivity reactions (such as anaphylaxis (severe allergic reactions), angioedema, dyspnea (difficulty in breathing), pruritus (itching), rash and urticaria (hives).
Metabolism and nutrition disorders	Increased appetite.
Nervous system disorders	Dizziness, somnolence (drowsiness), insomnia (inability to sleep), seizures (convulsions), psychomotor hyperactivity (restlessness with increased body movement) and headache (head pain).
Cardiac disorders	Tachycardia (rapid heartbeat), palpitations (unpleasant sensation of irregular and /or forceful beating of the heart).
Gastro-intestinal disorders	Abdominal pain (stomach pain), nausea (the urge to vomit), vomiting, dyspepsia (heartburn), diarrhoea and dry mouth.
Hepato-biliary disorders	Elevations of liver enzymes, increased bilirubin, hepatitis (inflammation of the liver).
Musculoskeletal and connective tissue disorders	Myalgia (muscle pain).
General disorders and administrative site conditions	Fatigue (tiredness).

RESTRICTED

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

STORING AND DISPOSING OF NEOCLARITYNE TABLETS

Store all medicines out of reach of children.

- Store at or 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 NEOCLARITYNE TABLETS

Blister packs containing 10 or 30 tablets.

IDENTIFICATION OF NEOCLARITYNE TABLETS

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

REGISTRATION NUMBER

35/5.7.1/0208

NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

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