PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S2

PROPRIETARY NAME, STRENGTH AND PHAMACEUTICAL FORM

NEOCLARITYNE™, 2.5 MG DESLORATADINE, SYRUP

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

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

- Keep this leaflet. You may need to read it again
- Do not share NEOCLARITYNE™ SYRUP 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.

1. WHAT NEOCLARITYNE™ SYRUP CONTAINS

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

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

Contain sugars: Sorbitol 12 % and Sucrose 40 %.

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2. WHAT NEOCLARITYNE™ SYRUP IS USED FOR

NEOCLARITYNE™ Syrup is an anti-allergy medicine. It helps control your allergic reaction and its symptoms. NEOCLARITYNE™ Syrup relieves symptoms associated with allergic rhinitis (e.g. hay fever), such as sneezing, runny or itchy nose and burning or itchy eyes.

NEOCLARITYNE™ 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 NEOCLARITYNE™ SYRUP

Do not take NEOCLARITYNE™ SYRUP

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

Do not give NEOCLARITYNE™ Syrup to your child if he/she is under two years of age.

Take special care with NEOCLARITYNE™ 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 NEOCLARITYNE™ SYRUP with food and drink

NEOCLARITYNE™ Syrup may be taken with or without food.

Pregnancy and breastfeeding

You should not use NEOCLARITYNE™ 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

NEOCLARITYNE™ 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 NEOCLARITYNE™ SYRUP:

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

Taking other medicines with NEOCLARITYNE™ SYRUP

If you are taking other medicines on a regular basis including complementary or traditional medicines, the use of NEOCLARITYNE™ Syrup with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other health care professional for advice.

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 NEOCLARITYNE™ SYRUP

Always take NEOCLARITYNE™ 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) NEOCLARITYNE™ Syrup once a day, with or without a meal.

Children 6 to 11 years of age:

5 ml (2.5 mg) NEOCLARITYNE™ Syrup once a day, with or without a meal.

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

10 ml (5 mg) NEOCLARITYNE™ Syrup once a day, with or without a meal.

Your doctor will determine the duration of your treatment. NEOCLARITYNE™ 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 NEOCLARITYNE™ Syrup is too strong or too weak, talk to your doctor or pharmacist.

If you take more NEOCLARITYNE™ SYRUP than you should

In the event of an overdose, consult your doctor or pharmacist. If neither is available, the

nearest hospital or poison control centre.

If you forget to take NEOCLARITYNE™ 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 NEOCLARITYNE™ SYRUP is stopped:

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

5. POSSIBLE SIDE-EFFECTS

NEOCLARITYNE™ Syrup can have side-effects.

Not all side effects reported for NEOCLARITYNE™ Syrup 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™ Syrup the following were reported:

Treatment-Related Undesirable Effects Reported by Body System	
Immune system disorders	Hypersensitivity reactions, such as anaphylaxis (severe allergic reactions), angioedema, dyspnoea (difficulty in breathing), pruritis (itching), urticaria (hives), rash have been reported.
Metabolism and nutrition disorders	Increased appetite
Nervous system disorders	Dizziness, somnolence (drowsiness), Insomnia (inability to sleep), headache (head pain) and seizures (convulsions).
Cardiac disorders	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, dry mouth
Hepato-biliary disorders	Abnormal liver function tests, hepatitis (inflammation of the liver), increased bilirubin
Musculoskeletal and connective tissue disorders	Myalgia (muscle pain).
General disorders and administrative site disorders	Fatigue (tiredness)

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

6. STORING AND DISPOSING OF NEOCLARITYNE™ SYRUP

Store 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 NEOCLARITYNE™ SYRUP

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

8. IDENTIFICATION OF NEOCLARITYNE™ SYRUP

Clear orange solution.

9. REGISTRATION NUMBER

37/5.7.1/0226

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

Bayer (Pty) Ltd

27 Wrench Road

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DATE OF PUBLICATION OF THIS PATIENT INFORMATION LEAFLET

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