# **CLARITYNE® TABLET**

Loratadine (10mg)

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## What CLARITYNE TABLET is used for

CLARITYNE TABLET relieves symptoms associated with allergic rhinitis (for example, hay fever), such as sneezing, runny or itchy nose, and burning or itchy eyes.

CLARITYNE TABLET may also be used to help relieve symptoms of urticaria (itching, redness and number and size of hives).

Relief of these symptoms lasts a full day and helps you to resume your normal daily activities and sleep.

## **How CLARITYNE TABLET** works

CLARITYNE TABLET belongs to a class of medicines known as antihistamines. Antihistamines help to reduce allergic symptoms by preventing the effects of a substance called histamine, which is produced in the body.

# Before you take CLARITYNE TABLET

### When you must not take it Do not take CLARITYNE TABLET:

If you are allergic (hypersensitive) to lorated ine or any of the other ingredients of CLARITYNE TABLET.

### Before you start to take it

Before taking CLARITYNE TABLET, tell your doctor or pharmacist:

if you have liver disease.

#### Pregnancy and breast-feeding

If you are pregnant, taking CLARITYNE TABLET is not recommended.

If you are nursing, taking CLARITYNE TABLET is not recommended. Loratadine is excreted in breast milk.

Ask your doctor or pharmacist for advice before taking any medicine.

### Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

### Taking CLARITYNE TABLET with food and drink

CLARITYNE TABLET can be taken with or without a meal.
CLARITYNE TABLET has not been shown to add to the effects of an alcoholic drink.

## **How to take CLARITYNE TABLET**

Always take CLARITYNE TABLET exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

### How much to take and When to take

# Adults and children over 12 years of age:

Take one tablet once daily with a glass of water, with or without food.

# Children 2 to 12 years of age are dosed by weight:

Body weight more than 30 kg:

Take one tablet once daily with a glass of water, with or without food.

## Patients with severe liver problems:

Adults and children with body weight more than 30 kg:

Take one tablet once every other day with a glass of water, with or without food.

CLARITYNE TABLET is not recommended for infants younger than 2 years old.

### How long to take it

Take CLARITYNE TABLET as prescribed by your doctor

### If you forget to take it

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 a forgotten dose.

### If you take too much (overdose)

Take CLARITYNE TABLET only as it is prescribed for you. No serious problems are expected with accidental overdose. However, if you take more CLARITYNE TABLET than you were told to, contact your doctor or pharmacist immediately. Sleepiness, rapid heartbeat and headache have been reported with overdoses of CLARITYNE TABLET.

## If you stop taking CLARITYNE TABLET

If you have any further questions on the use of this product, ask your doctor or pharmacist.

## While you are taking CLARITYNE TABLET

### Things you must do

Important information about some of the ingredients of CLARITYNE TABLET

CLARITYNE TABLET tablets contains lactose; thus if you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

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## Things you must not do Laboratory tests

If you are scheduled to have any skin tests for allergies you should not take CLARITYNE TABLET for two days before having these tests, because this medicine may affect test results.

## Things to be careful of Driving and using machines

At the recommended dose, CLARITYNE TABLET is not expected to cause you to be drowsy or less alert. However, very rarely some people experience drowsiness, which may affect their ability to drive or use machines.

### **Side effects**

Like all medicines, CLARITYNE TABLET can cause side effects, although not everybody gets them.

The most commonly reported side effects in children aged 2 through 12 years include headache, nervousness and tiredness. The most commonly reported side effects in adults and adolescents include drowsiness, headache, increased appetite, and difficulty sleeping.

During the marketing of CLARITYNE TABLET, cases of severe allergic reaction, dizziness, irregular or rapid heartbeat, nausea (feeling sick), dry mouth, upset stomach, liver problems, hair loss, rash, and tiredness have been reported very rarely. It is not possible to determine how frequently these reactions may occur.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers → Reporting)

## Storage and disposal of CLARITYNE TABLET

### Storage

- Store below 30°C. Blister pack tablet should be protected from excessive moisture.
- Keep out of reach of children.
- Do not use CLARITYNE
   TABLET after the expiry date
   which is stated on the blister
   after EX (or EXP). The expiry
   date refers to the last day of that
   month.
- Do not use CLARITYNE TABLET if you notice any change in the appearance of the tablet.

#### **Disposal**

 Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

### **Product description**

#### What it looks like

CLARITYNE TABLET: White to off-white oval tablet with Schering Trademark, score, and "10" on one side, plain on the other. Available in blister packs of 10's, 10 X 10's and 50 x 10's

Not all pack sizes may be marketed.

### Ingredients

Active ingredient: Loratadine 10 mg.

Inactive ingredients: Corn starch, lactose and magnesium stearate.

### MAL number:

MAL19890576A (Belgium Source)

MAL10070583AS (Indonesia Source)

### **Product Manufacturer:**

Belgium Source Schering-Plough Labo NV, Industriepark, 30 B-2220 Heist-op-den-Berg, Belgium Indonesia Source
PT. MERCK SHARP DOHME
PHARMA Tbk
Jl. Raya Pandaan Km. 48,

Ji. Raya Pandaan Km. 48, Pandaan, Pasuruan, Jawa Timur, Indonesia

### **Product Registration Holder**

Merck Sharp & Dohme (Malaysia) Sdn. Bhd. T2-9, Jaya 33, No. 3 (Lot 33), Jalan Semangat, Seksyen 13, 46100 Petaling Jaya, Selangor, Malaysia.

### **Date of revision**

27/11/2013 (version 092012)