

CLARITYNE[®] SYRUP

Loratadine (1mg/1mL)

What is in this leaflet:

1. What CLARITYNE SYRUP is used for
2. How CLARITYNE SYRUP works
3. Before you take CLARITYNE SYRUP
4. How to take CLARITYNE SYRUP
5. While you are taking CLARITYNE SYRUP
6. Side effects
7. Storage and disposal of CLARITYNE SYRUP
8. Product Description
9. Product Manufacturer and Product Registration Holder
10. Date of revision

What CLARITYNE SYRUP is used for

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

CLARITYNE SYRUP 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 SYRUP works

CLARITYNE SYRUP 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 SYRUP

When you must not take it
Do not take CLARITYNE SYRUP:

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

Before you start to take it

Before taking CLARITYNE SYRUP, tell your doctor or pharmacist:

- if you have liver disease.

Pregnancy and breast-feeding

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

If you are nursing, taking CLARITYNE SYRUP 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 SYRUP with food and drink

CLARITYNE SYRUP can be taken with or without a meal.

CLARITYNE SYRUP has not been shown to add to the effects of an alcoholic drink.

How to take CLARITYNE SYRUP

Always take CLARITYNE SYRUP 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 it

Adults and children over 12 years of age:

Take two teaspoonfuls (10 ml) once daily, with or without food; water or other liquid is not needed to swallow the CLARITYNE SYRUP.

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

Body weight more than 30 kg:

Take two teaspoonfuls (10 ml) once daily, with or without food; water or other liquid is not needed to swallow the CLARITYNE SYRUP.

Body weight 30 kg or less:

Give one teaspoonful (5 ml) once daily, with or without food; water or other liquid is not needed to swallow the CLARITYNE SYRUP.

Patients with severe liver problems:

Adults and children with body weight more than 30 kg:

Take two teaspoonfuls (10 ml) once every other day, with or without food; water or other liquid is not needed to swallow the CLARITYNE SYRUP.

Children with body weight 30 kg or less:

Give one teaspoonful (5 ml) once every other day, with or without food; water or other liquid is not needed to swallow the CLARITYNE SYRUP.

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

How long to take it

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

If you stop taking CLARITYNE SYRUP

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

CLARITYNE[®] SYRUP

Loratadine (1mg/1mL)

While you are taking CLARITYNE SYRUP

Things you must do

Important information about some of the ingredients of CLARITYNE SYRUP

CLARITYNE SYRUP contains sucrose; 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.

Things you must not do

Laboratory tests:

If you are scheduled to have any skin tests for allergies you should not take CLARITYNE SYRUP 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 SYRUP 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 SYRUP 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 SYRUP, 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 SYRUP

Storage

- Keep out of the reach and sight of children.
- Store below 30°C.

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

Clear, colourless to light yellow syrup. Available in bottles of 60 ml and 100 ml.

Not all pack sizes may be marketed.

Ingredients

Active ingredient: Loratadine 1 mg/ml.

Inactive ingredients: Propylene glycol, glycerin, citric acid monohydrate, sodium benzoate, sugar, peach flavour and purified water.
Preservative: Sodium Benzoate 0.1% w/v.

MAL number:

MAL19950088A (Belgium Source)

MAL10080045AS (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,
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)