

# Clarityn® Clarityne®



Brand of loratadine, a potent, long-acting & non-sedating antihistamine

Read this leaflet carefully because it contains important information for you.

This medicine is available without a prescription. However, you will still need to take Clarityn® /Clarityne® 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 contact a doctor if your symptoms worsen or do not improve.

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

In this leaflet:

1. What Clarityn®/Clarityne® is and what it is used for
2. Before you take Clarityn®/Clarityne®
3. How to take Clarityn®/Clarityne®
4. Possible side effects
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6. Further information

## 1. What Clarityn®/Clarityne® are and what they are used for

Clarityn®/Clarityne® 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.

Clarityn®/Clarityne® relieves symptoms associated with allergic rhinitis, such as sneezing, runny or itchy nose and burning or itchy eyes.

Clarityn®/Clarityne® 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.

## 2. Before you take Clarityn®/Clarityne®

*Do not take Clarityn®/Clarityne®*

If you are allergic (hypersensitive) to loratadine or any of its other ingredients.

*Take special care with Clarityn®/Clarityne®*

Before taking Clarityn®/Clarityne®, tell your pharmacist or doctor if you have liver disease.

*Taking other medicines*

If you are taking any other medicines, including medicine taken without a prescription, please consult your pharmacist or doctor before use.

*Laboratory tests:*

If you are scheduled to have any skin tests for allergies, you should not take Clarityn®/Clarityne® for two days before.

*Taking Clarityn®/Clarityne® with food and drink*

Clarityn®/Clarityne® can be taken with or without a meal. It has not been shown to add to the effects of an alcoholic drink.

*Pregnancy and breast-feeding*

If you are pregnant, taking Clarityn®/Clarityne® is not recommended.

If you are nursing, taking Clarityn®/Clarityne® is not recommended. Loratadine is excreted in breast milk.

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

*Driving and using machinery*

At the recommended dose, Clarityn®/Clarityne® 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 machinery.

*Important information about the ingredients of Clarityn®/Clarityne®*

Clarityn®/Clarityne® tablets contain lactose while Clarityn® syrup contains sucrose. If you have an intolerance to some sugars, please speak to your pharmacist or doctor before taking this medicine.

## 3. How to take Clarityn®/Clarityne®

### Clarityn®/Clarityne® Tablet

Age	How much to take	How often to take
Adults and children 6 years and over > 30kg	1 tablet	Once daily

### Clarityn® Syrup

Age	How much to take	How often to take
Adults and children 12 years and over	Two 5ml spoonfuls	Once daily
Children 2 to 12 years >30kg <30kg	Two 5ml spoonfuls One 5ml spoonful	Once daily Once daily

Do not give this medicine to children under 2 years of age.

If you have severe liver problems, your pharmacist or doctor may advise you to take one tablet once every other day with a glass of water, with or without food.

*If you take more than you should*

Take Clarityn®/Clarityne® only as it is described in the directions. No serious problems are expected with accidental overdose. However, if you take more than you were told to, contact your pharmacist or doctor immediately.

Sleepiness, rapid heartbeat and headache have been reported with overdoses of Clarityn®/Clarityne®.

*If you forget to take a dose*

If you forget to take your dose on time, take it as soon as possible and then go back to your regular dosing schedule. Do not take a double dose to make up for a forgotten dose.

*If you stop taking your Clarityn®/Clarityne®*

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

#### **4. Possible side effects**

Like all medicines, Clarityn®/Clarityne® can cause side effects, although not everybody gets them.

The most commonly reported side effects in children aged 2 years 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 Clarityn®/Clarityne®, cases of severe allergic reaction (including swelling), dizziness, irregular or rapid heartbeat, nausea (feeling sick), dry mouth, upset stomach, liver problems, hair loss, rash, convulsion and tiredness have been reported very rarely. It is not possible to determine how frequently these reactions may occur.

If you experience any of these side effects or you notice any not listed in this leaflet, stop taking Clarityn®/Clarityne® and contact your pharmacist or doctor at once.

#### **5. How to store Clarityn®/Clarityne®**

Storage temperature: Please refer to outer carton for more information.

*Clarityn®/Clarityne® Tablet:* Blister pack tablet should be protected from excessive moisture.

*Clarityn® Syrup:* Do not freeze. Keep the bottle in the outer carton in order to protect from light.

Keep out of reach and sight of children.

For the shelf-life, please refer to labels.

Do not use Clarityn®/Clarityne® after the expiry date which is stated on the pack after "Exp.".

The expiry date refers to the last day of the month.

Do not use this medicine if you notice any change in the appearance of the tablet or syrup.

Further information can be obtained from the pharmacist or the doctor.

#### **6. Further information**

*What Clarityn®/Clarityne® Tablets contain*

The active substance is loratadine 10mg.

The other ingredients of the tablet are lactose monohydrate, maize starch, magnesium stearate.

*What Clarityn®/Clarityne® Tablets look like and the contents of the pack*

Clarityn®/Clarityne® Tablets are white to off-white oval tablets with flask and dish logo, score and '10' on one side, plain on the other side.

Clarityn® Tablet is supplied in packs of 10's.

Clarityne® Tablet is supplied in packs of 100's.

*What Clarityn® Syrup contains*

Each 5ml of Clarityn® Syrup contains 5mg of micronized loratadine.

The other ingredients include propylene glycol, glycerin, citric acid monohydrate, sodium benzoate, sugar, peach flavour and purified water. It contains preservative of sodium benzoate 0.1%w/v.

Clarityn® Syrup is supplied in bottles of 60ml and 100ml.

Manufacturers:

*Clarityn®/Clarityne® Tablet*

PT. Merck Sharp Dohme Pharma Tbk

Jl. Raya Pandaan Km. 48, Pandaan,

Pasuruan, Jawa Timur, Indonesia Schering-Plough Labo N.V.

Heist-op-den-Berg

Belgium

*Clarityn® Syrup*

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**This Patient Information Leaflet was last revised in Feb 2017.**