



**1. Name of the Product**

Clarityne® Syrup 5 mg/5mL (Grape Flavour)

**2. Description of the Product**

Clarityne® syrup contains loratadine. 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. It also contains disodium edetate, Artificial flavor 936.1368U, glycerol, maltitol, sodium dihydrogen phosphate dihydrate, phosphoric acid, propylene glycol, purified water, sodium benzoate, sorbitol, sucralose as excipients. It appears as clear and colorless to light yellow solution, free from foreign matter.

**3. What is in the Medicine?**

Each 5 mL of syrup contains 5 mg Loratadine

**4. Strength of the Medicine?**

Syrup: 5 mg/5 mL

**5. What is this Medicine used for?**

Clarityne® is indicated for the fast, non-drowsy, 24 hours relief of symptoms associated with allergic rhinitis, such as sneezing, runny or itchy nose and burning or itchy eyes. Clarityne® may also be used to help relieve symptoms of urticaria (itching, redness and number and size of hives).

**6. How much and how often should you use this Medicine?**

Method of Administration: Oral use.

Dosage Regimen:

Adults and Children 12 years of age and over: Two teaspoonfuls (10 mL) once daily.

Children 2 to 12 years of age:

Body weight >30 kg: 10 mL (10 mg), (two teaspoonfuls), once daily.

Body weight ≤30 kg: 5 mL (5 mg), (one teaspoonful), once daily.

Additional information on special populations

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 10mg every other day with a glass of water, with or without food.

**7. When should you not take this Medicine?**

Do not take Clarityne® if you are allergic (hypersensitive) to loratadine or any of its ingredients.

**8. Care that should be taken when taking this Medicine?**

Warnings/Precautions

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

Effects on ability to drive or use machines

At the recommended dose, 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.

Fertility, Pregnancy and Breast-feeding

Pregnancy

If you are pregnant, ask your doctor or pharmacist for advice before taking any medicine. As a precautionary measure, it is preferable to avoid the use of Clarityne® during pregnancy.

Breast-feeding

Loratadine is excreted in breast milk. The product is not recommended for use in breast-feeding women. Ask your pharmacist or doctor for advice before taking any medicine.

Fertility

There are no data available on male and female fertility.

**9. Undesirable Effects of this Medicine**

Like all medicines, 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 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 Clarityne® and contact your pharmacist or doctor at once.

**RESTRICTED**

**10. What other medicine or food should be avoided while taking this Medicine?**

Taking other medicines

If you are taking any other medicines, including medicine taken without a prescription, please consult your pharmacist or doctor before use. Examples include medicine to treat fungus e.g. ketoconazole, antibiotics e.g. erythromycin, medicine to treat stomach acidity e.g. cimetidine, medicines that can affect the liver.

Laboratory tests

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

Pediatric population

Interaction studies have only been performed in adults.

**11. What should you do if you miss a dose?**

Take the missed dose as soon as remembered but once daily only. Do not take a double dose to make up for a forgotten dose.

**12. Signs and Symptoms of Overdose?**

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

**13. What to do when you have taken more than the recommended dosage?**

Take 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.

**14. How should you keep this Medicine?**

Store below 30°C and protect from excessive moisture.

**15. When should you consult your doctor?**

If undesirable effects listed in Section 9 are experienced.

**Manufactured by:**

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**Imported by**

Bayer (South East Asia) Pte Ltd

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