Clarityne®

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

PACKAGE INSERT FOR MALAYSIA MARKET

1. NAME OF THE MEDICINAL PRODUCT

Clarityne® Tablet 10mg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each **CLARITYNE®** Tablet contains 10 mg micronized loratadine. For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

CLARITYNE® Tablet: White to off-white oval tablet with score on one side, and plain on the other.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

CLARITYNE® Products are indicated for the relief of symptoms associated with allergic rhinitis, such as sneezing, nasal discharge (rhinorrhea) and itching, as well as ocular itching and burning. Nasal and ocular signs and symptoms are relieved rapidly after oral administration. **CLARITYNE®** Products are also indicated for relief of symptoms and signs of chronic urticaria and other allergic dermatologic disorders.

4.2 Posology and method of administration

Adults and Children 12 years of age and over:

CLARITYNE® Tablet: One tablet (10 mg) once daily;

Children 6 to 12 years of age:

CLARITYNE® Tablet:

Body Weight >30 kg -- One tablet (10 mg) once daily

Safety and efficacy of CLARITYNE® has not been established in children younger than 2 years of age.

Patients with severe liver impairment should be administered a lower initial dose because they may have reduced clearance of loratadine; an initial dose of 5 mg once daily, or 10 mg every other day is recommended.

4.3 Contraindications

CLARITYNE® Products are contraindicated in patients who are hypersensitivity to the active substance or to any of the excipients in these formulations.

4.4 Special warnings and precautions for use

CLARITYNE® Products should be administered with caution in patients with severe liver impairment (see section 4.2).

CLARITYNE® Tablet: This medicinal product contains lactose; thus patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

The administration of **CLARITYNE®** Products should be discontinued at least 48 hours before skin tests since antihistamines may prevent or reduce otherwise positive reactions to dermal reactivity index.

4.5 Interaction with other medicinal products and other forms of interaction

When administered concomitantly with alcohol, loratadine has no potentiating effects as measured by psychomotor performance studies. Potential interaction may occur with all known inhibitors of CYP3A4 or CYP2D6 resulting in elevated levels of loratadine (see Section 5.2), which may cause an increase in adverse events.

4.6 Pregnancy and lactation

Safe use of **CLARITYNE®** Products during pregnancy has not been established; therefore, use only if the potential benefit justifies the potential risk to fetus. Since loratadine is excreted in breast milk, a decision should be made whether to discontinue nursing or discontinue the drug.

4.7 Effects on ability to drive and use machines

In clinical trials that assessed driving ability, no impairment occurred in patients receiving loratadine. However, patients should be informed that very rarely some people experience drowsiness, which may affect their ability to drive or use machines.

4.8 Undesirable effects

In clinical trials in a paediatric population, children aged 2 through 12 years, common adverse reactions reported in excess of placebo were headache (2.7%), nervousness (2.3%), and fatigue (1%).

In clinical trials involving adults and adolescents in a range of indications including AR and CIU, at the recommended dose of 10 mg daily, adverse reactions with loratadine were reported in 2% of patients in excess of those treated with placebo.

The most frequent adverse reactions reported in excess of placebo were somnolence (1.2%), headache (0.6%), increased appetite (0.5%) and insomnia (0.1%). Other adverse reactions reported very rarely during the post-marketing period are listed in the following table.

Immune system disorders	Anaphylaxis including angioedema
Nervous system disorders	Dizziness & convulsion
Cardiac disorders	Tachycardia, palpitation
Gastrointestinal disorders	Nausea, dry mouth, gastritis
Hepatobiliary disorders	Abnormal hepatic function
Skin and subcutaneous tissue disorders	Rash, alopecia
General disorders and administration site conditions	Fatigue

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: antihistamines – H1 antagonist, ATC code: R06A X13.
Loratadine, the active ingredient in **CLARITYNE®** products, is a tricyclic antihistamine with selective, peripheral H1-receptor activity.
Loratadine has no clinically significant sedative or anticholinergic properties in the majority of the population and when used at the recommended dosage.
During long-term treatment there were no clinically significant changes in vital signs, laboratory test values, physical examinations or electrocardiograms.
Loratadine has no significant H2-receptor activity. It does not inhibit norepinephrine uptake and has practically no influence on cardiovascular function or on intrinsic cardiac pacemaker activity.

5.2 Pharmacokinetic properties

After oral administration, loratadine is rapidly and well absorbed and undergoes an extensive first pass metabolism, mainly by CYP3A4 and CYP2D6. The major metabolite-desloratadine (DL)- is pharmacologically active and responsible for a large part of the clinical effect. Loratadine and DL achieve maximum plasma concentrations (Tmax) between 1–1.5 hours and 1.5–3.7 hours after administration, respectively.
Increase in plasma concentrations of loratadine has been reported after concomitant use with ketoconazole, erythromycin, and cimetidine in controlled trials, but without clinically significant changes (including electrocardiographic).
Loratadine is highly bound (97 % to 99 %) and its active metabolite moderately bound (73 % to 76 %) to plasma proteins.
In healthy subjects, plasma distribution half-lives of loratadine and its active metabolite are approximately 1 and 2 hours, respectively. The mean elimination half-lives in healthy adult subjects were 8.4 hours (range = 3 to 20 hours) for loratadine and 28 hours (range = 8.8 to 92 hours) for the major active metabolite.
Approximately 40 % of the dose is excreted in the urine and 42 % in the faeces over a 10 day period and mainly in the form of conjugated metabolites. Approximately 27 % of the dose is eliminated in the urine during the first 24 hours. Less than 1 % of the active substance is excreted unchanged in active form, as loratadine or DL. The bioavailability parameters of loratadine and of the active metabolite are dose proportional. The pharmacokinetic profile of loratadine and its metabolites is comparable in healthy adult volunteers and in healthy geriatric volunteers. Concomitant ingestion of food can delay slightly the absorption of loratadine but without influencing the clinical effect. In patients with chronic renal impairment, both the AUC and peak plasma levels (Cmax) increased for loratadine and its metabolite as compared to the AUCs and peak plasma levels (Cmax) of patients with normal renal function. The mean elimination half-lives of loratadine and its metabolite were not significantly different from that observed in normal subjects. Haemodialysis does not have an effect on the pharmacokinetics of loratadine or its active metabolite in subjects with chronic renal impairment. In patients with chronic alcoholic liver disease, the AUC and peak plasma levels (Cmax) of loratadine were double while the pharmacokinetic profile of the active metabolite was not significantly changed from that in patients with normal liver function. The elimination half-lives for loratadine and its metabolite were 24 hours and 37 hours, respectively, and increased with increasing severity of liver disease. Loratadine and its active metabolite are excreted in the breast milk of lactating women.

5.3 Preclinical safety data

Preclinical data reveal no special hazard based on conventional studies of safety, pharmacology, repeated dose toxicity, genotoxicity and carcinogenic potential. In reproductive toxicity studies, no teratogenic effects were observed. However, prolonged parturition and reduced viability of offspring were observed in rats at plasma levels (AUC) 10 times higher than those achieved with clinical doses. No evidence of mucous membrane irritation was observed after daily administration of up to 12 tablets (120 mg) of oral lyophilisates into the hamster cheek pouch for five days.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

CLARITYNE® Tablet: corn starch, lactose and magnesium stearate.

6.2 Incompatibilities

No incompatibilities identified.

6.3 Special precautions for storage

Store below 30°C. Blister pack tablet should be protected from excessive moisture.
Keep out of reach of children.

6.5 Nature and contents of container

CLARITYNE® Tablet: In blister packs of 10 x 10's.

7. PRODUCT REGISTRATION HOLDER

Bayer Co. (Malaysia) Sdn Bhd
25-03 & 25-04, Level 25, Imazium, No. 8, Jalan SS21/37,
Damansara Uptown, 47400 Petaling Jaya, Selangor

8. MANUFACTURER

PT. BAYER, INDONESIA
Jalan Raya Jakarta Bogor KM 32 Cisalak, Kec. Sukmajaya, Kota Depok, Jawa Barat.

9. DATE OF REVISION OF THE TEXT

June 2022

PATIENT INFORMATION LEAFLET FOR SINGAPORE MARKET

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 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 Clarityne® are and what they are used for
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.
Clarityne® relieves 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).
Relief of these symptoms lasts a full day and helps you to resume your normal daily activities and sleep.

2. Before you take Clarityne®
Do not take Clarityne®
If you are allergic (hypersensitive) to loratadine or any of its other ingredients.
Take special care with Clarityne®
Before taking 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 Clarityne® for two days before.
Taking Clarityne® with food and drink
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, 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.
If you are nursing, ask your doctor or pharmacist for advice before taking any medicine.
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, 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 Clarityne®
Clarityne® tablets contain lactose. If you have an intolerance to some sugars, please speak to your pharmacist or doctor before taking this medicine.

3. How to take Clarityne®
Clarityne® Tablet

Age	How much to take	How often to take
Adults and children 6 years and over > 30 kg	1 Tablet	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 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 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 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, 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.

5. How to store Clarityne®
Storage temperature: Please refer to outer carton for more information.
Blister pack tablet should be protected from excessive moisture.
Keep out of reach and sight of children.
Do not use 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.
Further information can be obtained from the pharmacist or the doctor.

6. Further information
What Clarityne® Tablets contain
The active substance is loratadine 10mg.
The other ingredients of the tablet are lactose monohydrate, maize starch, magnesium stearate.

What Clarityne® Tablets look like and the contents of the pack
Clarityne® Tablets are white to off white oval tablets, score on one side, plain on the other side.

Manufacturer:
PT Bayer Indonesia
Jalan Raya Jakarta Bogor KM 32 Cisalak,
Kec. Sukmajaya, Kota Depok Jawa Barat

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