LORATADINE

ALLERTA®

10 mg Tablet

Antihistamine

FORMULATION

Each tablet contains:

Loratadine .....10 mg

PRODUCT DESCRIPTION

Loratadine (Allerta®) Tablet is a white, round, biconvex tablet, bisected on one side and plain on the other side.

WHAT IS IN THE MEDICINE?

This medicine contains Loratadine, an anti-allergy. Loratadine blocks the action of naturally occurring histamine, a substance that causes allergic symptoms. Loratadine is less likely to cause drowsiness and dizziness than the older class of anti-allergy medicines.

STRENGTH OF THE MEDICINE

See Formulation

WHAT IS THE MEDICINE USED FOR?

These medicines are used for the relief of symptoms associated with:

- Allergic rhinitis such as sneezing; runny, itchy nose; and itchy, watery eyes
- Skin symptoms of allergy such as itch and rash

HOW MUCH AND HOW OFTEN SHOULD YOU USE THIS MEDICINE?

This medicine should be taken orally (by mouth) once a day.

Age Group	Once a Day Dose of Loratadine (Allerta®)
Adults and children over 12 years	1 tablet
Children 2 to 12 years	
Body weight more than 30 kg	1 tablet
Body weight 30 kg or less	1/2 tablet
Children 1 to 2 years	—
	Or, as recommended by a doctor

WHEN SHOULD YOU NOT TAKE THIS MEDICINE?

- If you are allergic to any ingredient in the product
- If you are pregnant or breastfeeding

UNDESIRABLE EFFECTS

Undesirable effects with Loratadine are rare, dose-related, and are usually temporary and mild in severity.

The most common undesirable effects include headache, drowsiness, fatigue (excessive tiredness), insomnia (sleeplessness), nervousness, hyperkinesia (hyperactivity), malaise (feeling of bodily discomfort), wheezing, upper respiratory tract infection, dry mouth, epistaxis (nose bleed), sore throat, abdominal pain, diarrhea, stomatitis (inflammation in the mouth or tongue), tooth disorder, conjunctivitis (irritation and redness of the thin membrane covering the eye), and rash.

The following undesirable effects have been reported rarely in postmarketing studies: abnormal liver function including jaundice, hepatitis, and hepatic necrosis (death of liver cells), alopecia (hair loss), anaphylaxis (rare, life-threatening allergic reaction), breast enlargement, erythema multiforme (a skin condition characterized by symmetrical, red, raised skin areas all over the body), peripheral edema, seizure, and thrombocytopenia (decreased number of platelets).

The following undesirable effects have been reported in at least 1 child or adult patient receiving Loratadine in clinical studies:

Nervous System: Agitation, amnesia, anxiety, asthenia (weakness), confusion, decreased libido, depression, dizziness, dysphonia (difficulty in speaking), gloomy dreams, hypertonia (muscle stiffness), hypoesthesia (abnormally decreased sensitivity), impaired concentration, irritability, migraine, paresthesia (sensation of tingling, pricking or numbness of the skin), tremor, vertigo

Respiratory: Bronchitis, bronchospasm, cough, dyspnea (shortness of breath), hemoptysis (expectoration of blood), hiccup, laryngitis, nasal dryness, sinusitis, sneezing

Cardiovascular: Hypertension, hypotension, irregular heartbeat, palpitations, syncope (fainting/temporary loss of consciousness), tachycardia (rapid heart rate)

Gastrointestinal: Altered salivation, altered taste, anorexia (loss of appetite), constipation, dyspepsia, flatulence (gassiness), gastritis, increased appetite, loose stools, nausea, vomiting

Ocular (Eye) and Otic (Ear): Altered lacrimation, blepharospasm (eyelid spasm, continuous blinking), blurred vision, earache, eye pain, tinnitus (ringing in the ears)

Sensitivity Reactions: Angioedema (characterized by deep swelling around the eyes and lips and sometimes of the hands and feet), light sensitivity, pruritus (itching), purpura (small purple-red marks in skin or other tissue caused by bleeding), urticaria/rash

Other undesirable effects: Arthralgia (joint pain), back pain, breast pain, chest pain, dermatitis, dry hair, dry skin, dysmenorrhea, fever, flushing, impotence, increased sweating, influenza-like symptoms, leg cramps, menorrhagia (heavy menstrual bleeding), myalgia (muscle aches), rigors (shaking), thirst, urinary retention (difficulty urinating), urine discoloration, vaginitis (inflammation of the vagina), viral infections, weight gain.

WHAT OTHER MEDICINE OR FOOD SHOULD BE AVOIDED WHILE TAKING THIS MEDICINE?

Tell your doctor about other medicines you or the child is taking, especially other medicines for cough, cold and allergy.

WHAT SHOULD YOU DO IF YOU MISS A DOSE?

Take the missed dose as soon as you remember then the subsequent dose as recommended (i.e., after 24 hours).

HOW SHOULD YOU KEEP THIS MEDICINE?

Keep the product out of reach and sight of children.
Store at temperatures not exceeding 30°C.

SIGNS AND SYMPTOMS OF OVERDOSAGE

Signs and symptoms of Loratadine overdose include sleepiness, drowsiness, headache, nausea, vomiting, decreased blood pressure, tachycardia, and extrapyramidal manifestations or movement disorders such as involuntary movements, tremors and rigidity, body restlessness, muscle contractions, and changes in breathing and heart rate.

WHAT TO DO IF YOU HAVE TAKEN MORE THAN THE RECOMMENDED DOSAGE

If you have taken more than the recommended dosage, consult a doctor.

CARE THAT SHOULD BE TAKEN WHEN TAKING THIS MEDICINE

This medicine should be given with care to patients with kidney or liver disease including patients taking other drugs that affect the liver.
Do not use after the expiry date on the label.

WHEN SHOULD YOU CONSULT YOUR DOCTOR?

Before taking this medication, tell your doctor if you have kidney or liver disease. You may need a dosage adjustment or special monitoring during treatment.

For suspected adverse drug reaction, seek medical attention immediately and report to the FDA at www.fda.gov.ph AND Unilab at (+632) 858-1000 or productsafety@unilab.com.ph. By reporting undesirable effects, you can help provide more information on the safety of this medicine.

AVAILABILITY: Allerta 10 mg Tablet - Box of 50 tablets (in blister pack X 10s)
Envelope of 5 tablets (in blister pack X 5s)

DATE OF REVISION OF PATIENT INFORMATION LEAFLET (PIL): **Oct 2018**

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Manufactured for **UNILAB, Inc.**
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