UNILAB

Cetirizine Dihydrochloride

Alnix®

10 mg Film-Coated Tablet

ANTIHISTAMINE (Piperazine Derivative)

FORMULATIONS
Each film-coated tablet contains:
Cetirizine dihydrochloride ……..……..…….. 10 mg

PRODUCT DESCRIPTIONS
Cetirizine Dihydrochloride (Alnix®) 10 mg tablet: white, round, biconvex, film-coated tablet, bisected on one side and plain on the other side.

WHAT IS IN THE MEDICINE?
This medicine contains cetirizine, an anti-allergy, which blocks the action of histamine, a substance that causes allergic symptoms. Cetirizine is less likely to cause drowsiness and dizziness than the older class of anti-allergy medicines.

STRENGTH OF THE MEDICINE
See formulation.

WHAT IS THIS MEDICINE USED FOR?
This medicine is used for the relief of symptoms associated with:
• allergic rhinitis such as sneezing; runny, itchy nose; and itchy, watery eyes
• allergic conjunctivitis
• 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).

Age Group	Oral Dose of Cetirizine Dihydrochloride 10 mg Tablet
6 to 12 years	1 tablet once a day or 1/2 tablet twice a day
Adults and children over 12 years	1 tablet once daily
	Or, as recommended by a doctor.

Note: Dose adjustment is needed in elderly patients and those with kidney and liver disease.

WHEN SHOULD YOU NOT TAKE THIS MEDICINE?
• If you are allergic to cetirizine or other ingredients in the product
• If you have serious kidney problems

UNDESIRABLE EFFECTS
The most common undesirable effects of cetirizine include:

For adults and children over 12 years: abdominal pain, dizziness, dry mouth, excessive tiredness, headache, nausea, pharyngitis (sore throat), somnolence (drowsiness/sleepiness).

For children ages 6 months to 12 years: abdominal pain, bronchospasm (sudden, uncontrolled narrowing of airways in lungs), cough, diarrhea, epistaxis (nose bleeding), excessive tiredness, headache, nausea, pharyngitis (sore throat), rhinitis, somnolence (drowsiness/sleepiness), vomiting.

The following undesirable effects have also been reported with cetirizine use:

Infections and infestations: Bronchitis (inflammation of the bronchi), conjunctivitis (irritation and redness of the thin membrane covering the eye), pneumonia (inflammation of the lungs)
Neoplasms benign, malignant and unspecified (incl cysts and polyps): Nasal polyp Blood and lymphatic system disorders: Hemolytic anemia (anemia resulting from destruction of red blood cells), lymphadenopathy (swelling of the lymph nodes), thrombocytopenia (decreased number of platelets)
Immune system disorders: Anaphylaxis (rare, life-threatening allergic reactions), angioedema (rapid swelling of the skin), facial edema, glomerulonephritis (inflammation of the kidney), hypersensitivity, periorbital edema (accumulation of fluid surrounding the eye socket), urticaria (hives)
Metabolism and nutrition disorders: Anorexia (decreased appetite), edema (swelling), increased appetite, generalized edema, leg edema, peripheral edema
Psychiatric disorders: Aggression, anxiety, confusion, depersonalization, depression, dysphonia (disorder of the voice), emotional lability, enuresis (involuntary urination), euphoria (exaggerated feeling of well-being), hallucination, hyperventilation (rapid or deep breathing), insomnia, nervousness, suicidal ideation
Nervous system disorders: Abnormal coordination, abnormal thinking, agitation, amnesia, blurred vision, convulsions, dysgeusia (changed taste), hyperesthesia (increased sensitivity to any stimulation), hyperkinesia (hyperactivity), hypoesthesia (abnormally decreased sensitivity), impaired concentration, involuntary movements (dyskinesia, dystonia, tics), memory impairment, migraine, myelitis (inflammation of the spinal cord), oculogyration (uncontrolled circular movement of the eyeballs), orofacial dyskinesia (involuntary movement of the mouth and face), paradoxical central nervous system stimulation, paralysis, paresthesia (abnormal sensation such as burning, prickling or tingling), paroniria (nightmare), ptosis (drooping of eyelids), seizures, sleep disorders, tremor, vertigo, visual field defect
Eye disorders: Blindness, eye accommodation (focusing) disorders, eye bleeding, eye pain, glaucoma, xerophthalmia (dry eye)
Ear and labyrinth disorders: Deafness, otalgia (ear pain), tinnitus (ringing in the ears)
Cardiac disorders: Cardiac failure, chest pain, dyspnea (shortness of breath), heart failure, palpitation, tachycardia (rapid heart rate)
Vascular disorders: Anaphylactic shock (severe allergic reaction), hemorrhoids, hot flushes, hypertension (increased blood pressure), pallor (pale skin), rectal bleeding, syncope (fainting/temporary loss of consciousness)
Respiratory, thoracic and mediastinal disorders: Increased sputum, parosmia (distorted sense of smell), respiratory disorder, rhinitis (inflammation of the nose), sinusitis, upper respiratory tract infection
Gastrointestinal disorders: Changed taste, constipation, diarrhea, dry mouth, dyspepsia (indigestion, feeling of fullness), enlarged abdomen, eructation (burping), flatulence (gassiness), gastritis (inflammation of the stomach), increased salivation, melena (black stools), stomatitis/ulcerative stomatitis (mouth sores), swelling of the tongue, taste loss, tongue discoloration, tooth caries
Hepatobiliary disorders: Abnormal liver function (elevated liver enzymes and bilirubin), cholestasis (inflammation of the gall bladder), hepatitis
Skin and subcutaneous tissue disorders: Acne, alopecia (baldness), bullous eruption (large blisters), dermatitis (skin inflammation), dry skin, eczema, fixed drug eruption, furunculosis (boils), hyperkeratosis (thickened skin), hypertrichosis (excessive hair growth), photosensitivity, pruritus (itchiness), purpura (small purple-red skin marks), rash, seborrhea (oily skin), skin disorder, skin nodule
Musculoskeletal and connective tissue disorders: Back pain, hypertonia (muscle stiffness), rigors (shaking), twitching
Renal and urinary disorders: Cystitis (inflammation of the urinary bladder), difficulty in urinating, dysuria (painful urination), hematuria (blood in the urine), polyuria (excessive urination), urinary incontinence, urinary retention, urinary tract infection, urination frequency
Reproductive system and breast disorders: Breast pain in women, decreased libido, dysmenorrhea, intermenstrual bleeding, leukorrhea (whitish vaginal discharge), menorrhagia (heavy menstrual bleeding), vaginitis (inflammation of the vagina)
General disorders and administration site conditions: Asthenia (weakness), ataxia (incoordination), fever, malaise (feeling of bodily discomfort), pain
Investigations: Increased weight
Injury, poisoning and procedural complications: Accidental injury, ototoxicity (ear poisoning)

WHAT OTHER MEDICINE OR FOOD SHOULD BE AVOIDED WHILE TAKING THIS MEDICINE?
Do not use this product together with alcohol, medicines for anxiety or sleep disorder (e.g., Alprazolam, Diazepam, Chlordiazepoxide, Temazepam, Triazolam, etc.), medicines for depression (e.g., Amitriptyline, Doxepin, Nortriptyline, Fluoxetine, Sertraline, Paroxetine, etc.), other cold or allergy medicines, or any other medicines that cause drowsiness, sleepiness and relaxation because of the possibility for increased toxicity.

The extent of absorption of cetirizine is not reduced with food, although the rate of absorption is decreased by 1 hour.

Tell your doctor if you are taking other medicines, including vitamins, supplements, and herbal medicines.

WHAT SHOULD YOU DO IF YOU MISS A DOSE?
If you miss a dose, just take the next dose if still needed for the condition being treated and the subsequent doses at the recommended time or schedule.

Do not double the dose.

HOW SHOULD YOU KEEP THIS MEDICINE?
• Store at temperatures not exceeding 25°C
• Keep the product out of sight and reach of children

SIGNS AND SYMPTOMS OF OVERDOSE
Adverse events reported after intake of at least 5 times the recommended daily dose are: confusion, diarrhea, dizziness, excessive tiredness, headache, feeling of bodily discomfort, mydriasis (pupil dilatation), itchiness, restlessness, sedation, somnolence (drowsiness/sleepiness), stupor (decreased mental alertness), tachycardia (rapid heart rate), tremor, and urinary retention.

WHAT TO DO WHEN 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
• May cause drowsiness. Exercise caution when engaging in activities requiring mental alertness.
• Avoid excessive alcohol consumption when taking this medicine.
• Do not take more than the recommended dose.
• Do not use after the expiry date on the label.

WHEN SHOULD YOU CONSULT YOUR DOCTOR?
• Ask a doctor before use if:
  o You have kidney or liver disease
  o You are epileptic or at risk of convulsions
  o You have difficulty passing urine
  o You are pregnant or breastfeeding
  o Are due for an allergy testing

• Stop use and ask a doctor if:
  o Symptoms worsen or do not improve
  o New symptoms occur
  o Any undesirable effect occurs

ADVERSE DRUG REACTION REPORTING STATEMENT
For suspected adverse drug reaction, seek medical attention immediately and report to the FDA at www.fda.gov.ph AND Unilab at +632-8-**UNILAB**-1 (+632-8-**864522**-1) for Metro Manila or toll-free +1-800-10-UNILAB-1 for provinces, or e-mail productsafety@unilab.com.ph. By reporting undesirable effects, you can help provide more information on the safety of this medicine.

AVAILABILITY
Cetirizine Dihydrochloride (Alnix®)10 mg Tablet - Box of 100s (in blister foil)
DRP-2677
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