Cetirizine Dihydrochloride

Alnix®

2.5 mg per mL Syrup (Oral Drops)
5 mg per 5 mL Syrup
10 mg Tablet

ANTIHISTAMINE

FORMULATIONS
Each mL syrup (oral drops) contains: Cetirizine dihydrochloride..... 2.5 mg
Each 5 mL (1 teaspoonful) syrup contains: Cetirizine dihydrochloride ..... 5 mg
Each film-coated tablet contains: Cetirizine dihydrochloride ..... 10 mg

PRODUCT DESCRIPTIONS

- Cetirizine (Alnix) 2.5 mg per mL Syrup (Oral Drops)
  A colorless to slightly yellow-colored, clear syrup with fruity grape odor, and sweet grape taste using the Taste*Rite*® Technology. Taste*Rite*® Technology is a unique tastemasking system developed specifically for liquid dosage forms. This technology significantly reduces the bitterness of medicine so that children taste the flavor and not the medicine.

- Cetirizine (Alnix) 5 mg per 5 mL Syrup
  A colorless to slightly yellow-colored, clear syrup with fruity grape odor, and sweet grape taste using the Taste*Rite*® Technology.

- Cetirizine (Alnix) Tablet
  A white, round, biconvex, film-coated tablet, bisected on one side and plain on the other side.

WHAT IS IN THE MEDICINE?
These medicines contain cetirizine, an anti-allergy. Cetirizine 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 Formulations

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
- allergic conjunctivitis
- skin symptoms of allergy such as itch and rash

HOW MUCH AND HOW OFTEN SHOULD YOU USE THIS MEDICINE?
The medicine should be taken orally (by mouth).

Age Group	Cetirizine (Alnix) Dose		
	2.5 mg per mL Syrup (Oral Drops)	**5 mg per 5 mL Syrup**	**10 mg Tablet**
Infants 6 months to less than 12 months	2.5 mg (1 mL) once daily	–	–
Children: 12 months to less than 2 years	2.5 mg (1 mL) once or twice daily (every 12 hours)	–	–
2 to 5 years	5 mg (2 mL) once daily or 2.5 mg (1 mL) twice daily (every 12 hours)	5 mL (1 teaspoonful) once daily or 2.5 mL (1/2 teaspoonful) twice daily (every 12 hours)	–
6 to 12 years	–	10 mL (2 teaspoonsful) once daily or 5 mL (1 teaspoonful) twice daily (every 12 hours)	1/2 tablet twice daily or 1 tablet once daily
Adults and children over 12 years	–	–	1 tablet once daily
	Or, as recommended by a doctor.		

WHEN SHOULD YOU NOT TAKE THIS MEDICINE?
- If you are allergic to cetirizine or other ingredients in the product.

UNDESIRABLE EFFECTS
The following undesirable effects have been reported:

In adults and children 12 years and older:
- Drowsiness/sleepiness
- Excessive tiredness
- Dry mouth
- Sore throat
- Dizziness
- Headache
- Nausea

In children 6 to 11 years old:
- Headache
- Sore throat
- Stomach pain
- Coughing
- Drowsiness/Sleepiness
- Diarrhea
- Bronchospasm (sudden, uncontrolled narrowing of airways in lungs)
- Epistaxis (nose bleeding)
- Nausea
- Vomiting

The following rare events have been reported but it is not known whether they are directly related to cetirizine use.

Nervous System: Ataxia (uncontrolled muscle movement, incoordination), confusion, abnormal thinking, agitation, amnesia, anxiety, convulsions, depersonalization (alteration in the perception of the self so that the usual sense of one's own reality is lost), depression, dysphonia (difficulty in speaking), emotional lability (emotional instability), euphoria (an exaggerated unrealistic sense of well-being), impaired concentration, insomnia/sleep disorders, nervousness, hyperesthesia (increased sensitivity to any stimulation), hypoesthesia (abnormally decreased sensitivity), hyperkinesia (hyperactivity), hypertonia (muscle stiffness), migraine, myelitis (inflammation of the spinal cord), paralysis, paresthesia (abnormal sensation, such as burning, prickling, or tingling), ptosis (drooping of eyelids), syncope (fainting/temporary loss of consciousness), tremor, twitching, vertigo

Cardiovascular: Palpitation, tachycardia (rapid heart rate), increased blood pressure, chest pain, heart failure, rarely decreased blood pressure

Respiratory: Bronchitis, dyspnea (shortness of breath), hyperventilation (rapid breathing), increased sputum, pneumonia, respiratory disorder, rhinitis, sinusitis, upper respiratory tract infection

Gastrointestinal: Anorexia (loss of appetite), increased appetite, increased salivation, tongue discoloration, swelling of tongue, tooth caries, taste loss, taste perversion, dyspepsia, gastritis, stomatitis/ulcerative stomatitis (sores in the mouth), enlarged abdomen, eructation (burping), flatulence (gassiness), constipation, melena (black stools caused by bleeding in the stomach or small intestine), rectal bleeding, hemorrhoids

Genitourinary and Renal: Cystitis (inflammation of the urinary bladder), dysuria (painful urination), hematuria (blood in the urine), polyuria (excessive urination/frequent urination), urinary incontinence (inability to control urination), urinary retention (difficulty urinating), urinary tract infection, glomerulonephritis (inflammation of the kidney)

Reproductive: Dysmenorrhea, intermenstrual bleeding (bleeding between two menstrual periods), female breast pain, leucorrhea (whitish vaginal discharge), menorrhagia (heavy menstrual bleeding), decreased libido, vaginitis (inflammation of the vagina)

Hepatic: Hepatitis and increased liver enzymes (e.g, aminotransferases, bilirubin)

Ocular (Eye) and Otic (Ear): Visual problems, blindness, conjunctivitis (irritation and redness of the thin membrane covering the eye), eye pain, glaucoma, loss of eye accommodation, eye bleeding, periorbital edema (accumulation of fluid surrounding the socket of the eye), xerophthalmia (dry eye), deafness, otalgia (earache), ototoxicity (toxicity to the ears), tinnitus (ringing in the ears)

Skin: Acne, alopecia (baldness), angioedema (rapid swelling of the skin), bullous eruption (large blisters), dermatitis (skin inflammation), dry skin, eczema, furunculosis (boils), hyperkeratosis (thickened skin), hypertrichosis (excessive hair growth), increased sweating, light sensitivity, pruritus (itchiness), purpura (small purple-red marks in skin), urticaria/rash, seborrhea, skin disorder, skin nodule

Musculoskeletal: Arthralgia (joint pain), arthritis, arthrosis/osteoporosis, muscle weakness, myalgia (muscle aches), asthenia (weakness), malaise (feeling of bodily discomfort), leg cramps

Other undesirable effects: Anaphylaxis (rare, life-threatening allergic reaction), back pain, cholestasis (inflammation of the gall bladder), dehydration, diabetes mellitus, swelling (generalized, facial, leg, or peripheral), fever, increased weight, lymphadenopathy (swelling of the lymph nodes), pallor, rigors (shaking), hemolytic anemia (anemia resulting from destruction of red blood cells), thrombocytopenia (decreased number of platelets), parosmia (distorted sense of smell), thirst

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.

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 (if once daily) or after 12 hours (if twice daily).
Do not double the dose.

HOW SHOULD YOU KEEP THIS MEDICINE?
Keep the product out of reach and sight of children.
Store at temperatures not exceeding 30^0C.

SIGNS AND SYMPTOMS OF OVERDOSAGE
Signs and symptoms of cetirizine overdose include sleepiness, drowsiness, restlessness, and irritability.

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?
- May cause drowsiness. Exercise caution when engaging in activities requiring mental alertness.
- 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 dosage adjustment or special monitoring during treatment.

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) 858-1000 or productsafety@unilab.com.ph. By reporting undesirable effects, you can help provide more information on the safety of this medicine.

AVAILABILITY: Cetirizine Dihydrochloride (Alnix®) 5 mg/mL Syrup - Bottles of 30 mL and 60 mL
Cetirizine Dihydrochloride (Alnix®) 2.5 mg/mL (Oral Drops) - Bottle of 10 mL
Cetirizine Dihydrochloride (Alnix®) 10 mg Tablet - Box of 100s (in blister foil)

Cetirizine Dihydrochloride (Alnix®) Date of First Authorization:
- 10 mg Tablet: March 2011 - DRP-2677
- 2.5 mg/mL Syrup (Oral Drops): April 2010 - DR-XY31328
- 5 mg/mL Syrup: July 2010 - DR-XY31329

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