Cetirizine + Phenylephrine HCl

Alnix® Plus

5 mg/10 mg TABLET

ANTIHISTAMINE / NASAL DECONGESTANT

FORMULATION
Each film-coated tablet contains:
Cetirizine dihydrochloride, BP..... 5 mg
Phenylephrine HCl, USP..... 10 mg

PHARMACOLOGIC CATEGORY
Antihistamine / Nasal Decongestant

PRODUCT DESCRIPTION
A white, round, biconvex, film-coated tablet, plain on both sides.

WHAT IS IN THE MEDICINE?
This medicine contains cetirizine and phenylephrine HCl.

Cetirizine, an antiallergy, 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.

Phenylephrine HCl, a nasal decongestant, clears obstructed air passages and nasal sinuses due to congestion making breathing easier. It also reduces postnasal drip.

STRENGTH OF THE MEDICINE
See Formulation

WHAT IS THIS MEDICINE USED FOR?
This medicine is used for the relief of clogged nose; sneezing; runny, itchy nose; and itchy, watery eyes associated with allergic rhinitis.

HOW MUCH AND HOW OFTEN SHOULD YOU USE THIS MEDICINE?

Adults and children over 12 years: Orally, 1 tablet every 12 hours, or as directed by a doctor.

WHEN SHOULD YOU NOT TAKE THIS MEDICINE?

- If you are allergic to any ingredient in the product
- If you are taking medicines for depression
- If you have high blood pressure or severe heart disease

UNDESIRABLE EFFECTS

Cetirizine: The most common undesirable effects of Cetirizine include headache, drowsiness/sleepiness, dry mouth, sore throat, coughing, bronchospasm (sudden, uncontrolled narrowing of airways in lungs), epistaxis (nose bleeding), stomach pain, diarrhea, nausea, and 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

Phenylephrine HCl:

The most common undesirable effects of Phenylephrine are tremor (muscle shaking), restlessness, anxiety (feeling of uneasiness), nervousness, dizziness, high blood pressure, rapid and irregular pulse, weakness, nausea, vomiting, and sweating.

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

Do not use this product together with sympathomimetic agents (e.g., Epinephrine, etc.) and general anesthetics (e.g., Halothane, etc.) because of the possibility for increased toxicity.

Concurrent administration with medicines for depression (e.g., Amitriptyline, Imipramine, Sertraline, Moclobemide, etc.) may result in hypertensive crisis (sudden, severe increase in blood pressure that can lead to stroke).

Taking an adrenergic-blocking agent (e.g., Phenothiazine drugs, Phentolamine, Propranolol, etc.) before the administration of this product may decrease the effect of Phenylephrine.

Tell your doctor about other medicines you are taking, especially other medicines for cough, cold or allergy.

WHAT SHOULD YOU DO WHEN 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 (i.e., every 12 hours).

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. Protect from light.

SIGNS AND SYMPTOMS OF OVERDOSAGE
Symptoms of Cetirizine overdose include sleepiness, drowsiness, restlessness, and irritability.

Phenylephrine HCl overdose is usually associated with tiredness, sweating, dizziness, slow heart beat, and coma.

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
- 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 A DOCTOR?
- Before giving this medicine, tell your doctor if you have:
  - High blood pressure or any type of heart problems
  - Glaucoma
  - Thyroid problems
  - Diabetes
  - Liver or kidney disease
  - An enlarged prostate, bladder problems or difficulty urinating
- If symptoms do not improve or new symptoms occur.

AVAILABILITY
Cetirizine + Phenylephrine HCl (Alnix®Plus) 5 mg/10 mg Tablet
in Box of 100s (in blister foil).

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.

Manufactured by AMHERST LABORATORIES, INC.
UNILAB Pharma Campus, Barangay Mamplasan, Biñan, Laguna
Philippines for **UNILAB, Inc.**
No. 66 United Street, Mandaluyong City, Metro Manila, Philippines

Date of Revision: August 2017

Reg. IPOPHIL

Trusted Quality Healthcare