

Alanil

Tablet/ Suspension

Fexofenadine Hydrochloride USP

COMPOSITION

Alanil 120 Tablet: Each film-coated tablet contains Fexofenadine Hydrochloride USP 120 mg.
Alanil 180 Tablet: Each film-coated tablet contains Fexofenadine Hydrochloride USP 180 mg.
Alanil 50 ml Suspension: Each 5 ml suspension contains Fexofenadine Hydrochloride USP 30 mg.

PHARMACOLOGY

Fexofenadine hydrochloride is an antihistamine with selective peripheral H1-receptor antagonist activity, which does not cross the blood-brain barrier. In laboratory animals, no anticholinergic, alpha1-adrenergic or beta-adrenergic-receptor blocking effects were observed. Sedation or other central nervous system effects were not observed. It is rapidly absorbed following oral administration and 60% to 70% bound to plasma proteins. Approximately 5% of the total oral dose is metabolized. The mean elimination half-life of Fexofenadine is 14.4 hours.

INDICATIONS

Seasonal Allergic Rhinitis

Alanil is indicated for the relief of symptoms associated with seasonal allergic rhinitis in adults and children.
Symptoms to treat effectively: sneezing, rhinorrhea, itchy nose/palate/throat, itchy/watery/red eyes.

Chronic Idiopathic Urticaria

Alanil is indicated for treatment of uncomplicated skin manifestations of chronic idiopathic urticaria in adults and children.
Alanil significantly reduces pruritus and the number of wheals.

DOSAGE AND ADMINISTRATION

Route of administration : Oral.

Tablets

Seasonal Allergic Rhinitis and Chronic Idiopathic Urticaria:

Adults and Children 12 Years and Older: 120 mg or 180 mg tablet once daily.
Children 6 to 11 Years: 30 mg twice daily.

Suspension

Seasonal Allergic Rhinitis:

Children 2 to 11 Years: 30 mg (5ml) twice daily.

Chronic Idiopathic Urticaria:

Children 2 to 11 Years: 30 mg (5 ml) twice daily.
Children 6 Months to less than 2 Years: 15 mg (2.5 ml) twice daily.

USE IN RENAL IMPAIREMENT

In adult patients with decreased renal function a dose of 60 mg once daily is recommended as the starting dose. For pediatric patients with decreased renal function, the recommended starting dose of Fexofenadine is 30 mg once daily for patients 2 to 11 years of age and 15 mg once daily for patients 6 months to less than 2 years of age.

OR AS DIRECTED BY THE PHYSICIAN.

CONTRAINDICATIONS

Fexofenadine is contraindicated in patients with known hypersensitivity to any of its ingredients.

WARNING & PRECAUTION

Do not take this medicine if you are allergic to Fexofenadine or any ingredients contained in this drug.

SIDE EFFECTS

Common side effects : Common side effects include headache, upper respiratory tract infection, back pain. Other rare side effects are hypotension, palpitation, arrhythmias, sleep disturbances, tremor, convulsions and hypersensitivity reactions.

Rare side effects : Rare side effects of Fexofenadine include allergic reactions, fever, chills, body aches, cough and other flu symptoms.

USE IN PREGNANCY AND LACTATION

Pregnancy category: C. There are no adequate and well-controlled studies in pregnant women. Fexofenadine should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Lactation : It is not known if Fexofenadine is excreted in human milk. Caution should be exercised when Fexofenadine is administered to a nursing mother.

USE IN CHILDREN & ADOLESCENTS

Can be used from 6 months of age or above.

DRUG INTERACTIONS

With medicine : Co-administration of Fexofenadine with Ketoconazole and Erythromycin led to increased plasma levels of Fexofenadine. Fexofenadine should not be taken closely in time with Aluminum and Magnesium containing antacids.

With food & others : Severe Interactions of Fexofenadine include: grapefruit.

OVERDOSE

Overdose symptoms may include dry mouth, dizziness, or drowsiness. If someone has overdosed and has serious symptoms such as passing out or trouble breathing, call your doctor or seek emergency medical attention right away.

STORAGE

Keep all medicines out of reach of children.
Protect from light, Store below 30° C and dry place.

PACKING

Alanil 120 Tablet: Each box contains 3X10 tablets in blister strips.
Alanil 180 Tablet: Each box contains 3X10 tablets in blister strips.
Alanil 50 ml Suspension: Each carton contains 50 ml suspension in glass bottle with a 5 ml calibrated dropper and a measuring cup.

* Further information is available on request.

Manufactured by:



The ACME Laboratories Ltd.
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For Health, Vigour and Happiness

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