ALLERFIN®

Chlorpheniramine Maleate

ACTION

Chlorpheniramine is a potent antihistamine (H1-antagonist).
Antihistamines diminish or abolish the actions of histamine in the body by competitive reversible blockade of histamine H1-receptor sites on tissues. Chlorpheniramine also has anticholinergic activity.
Antihistamines act to prevent the release of histamine, prostaglandins and leukotrienes and have been shown to prevent the migration of inflammatory mediators. The actions of chlorpheniramine include inhibition of histamine on smooth muscle, capillary permeability and hence reduction of oedma and wheal in hypersensitivity reactions such as allergy and anaphylaxis.

INDICATIONS

Allerfin is indicated for symptomatic control of all allergic conditions responsive to antihistamines, including hay fever, vasomotor rhinitis, urticaria, angioneurotic oedema, food allergy, drug and serum reactions, insect bites. Also indicated for the symptomatic relief of itch associated with chickenpox.

DOSAGE AND ADMINISTRATION

Oral administration only

Do not exceed the stated dose or frequency of dosing
Cough and cold medicines should not be used in children under 6 years.
Cough and cold medicines for children of 6-12 years should be indicated for use as a second line treatment on the doctor advice, and with duration of use restricted to no more than 5 days. Cough and cold medicines should not be used as a sedative.
For the indications above (symptomatic control of all allergic conditions responsive to antihistamines, including hay fever, vasomotor rhinitis, urticaria, angioneurotic oedema, food allergy, drug and serum reactions, insect bites) Allerfin Syrup and Tablets should be used as follows:

Allerfin Syrup

Adults and children 12 years and over: 8 ml (4 mg) every 4 - 6 hourly.
Maximum daily dose: 48 ml (24 mg) in any 24 hours.
Elderly: The elderly are more likely to experience neurological anticholinergic effects. Consideration should be given to using a lower daily dose (e.g. a maximum of 12 mg in any 24 hours).
Children aged 6 - 12 years: 4 ml (2 mg) every 4 - 6 hourly.
Maximum daily dose: 24 ml (12 mg) in any 24 hours.
Children aged 2 - 6 years: 2 ml (1 mg) every 4 to 6 hourly.
Maximum daily dose: 12 ml (6 mg) in any 24 hours.
Children aged 1 - 2 years: 2 ml (1 mg) twice daily.
The minimum interval between the doses should be 4 hours.
Maximum daily dose: 4 ml (2 mg) in any 24 hours.
Allerfin syrup is not recommended for children below 1 year

Allerfin Tablets

Adults and children 12 years and over: 1 tablet 4 to 6 hourly.
Maximum daily dose: 6 tablets (24 mg) in any 24 hours.
Elderly: The elderly are more likely to experience neurological anticholinergic effects. Consideration should be given to using a lower daily dose (e.g. a maximum of 12 mg in any 24 hours).
Children aged 6 - 12 years: half a tablet 4 to 6 hourly.
Maximum daily dose: 3 tablets (12 mg) in any 24 hours.
Allerfin tablets is not recommended for children under 6 years.

CONTRAINDICATIONS

Allerfin is contraindicated in patients who are hypersensitive to antihistamines or to any of the its ingredients.The anticholinergic properties of Chlorpheniramine are intensified by monoamine oxidase inhibitors (MAOIs). Allerfin is therefore contra-indicated in patients who have been treated with MAOIs within the last fourteen days.

WARNINGS AND PRECAUTIONS

Cough and cold medicines should not be used in children under 6 years.
Cough and cold medicines for children of 6-12 years should be indicated for use as a second line treatment on the doctor advice, and with duration of use restricted to no more than 5 days.
Allerfin should not be used as a sedative.
Should not be used with other antihistamine containing products, including antihistamine containing cough and cold medicines.
Chlorpheniramine, in common with other drugs having anticholinergic effects, should be used with caution in epilepsy; raised intra-ocular pressure including glaucoma; prostatic hypertrophy; severe hypertension or cardiovascular disease; bronchitis, bronchiectasis or asthma; hepatic impairment. Children and the elderly are more likely to experience the neurological anticholinergic effects and paradoxical excitation (eg. Increased energy, restlessness, nervousness).
The effects of alcohol may be increased and therefore concurrent use should be avoided.
Allerfin syrup contains ethanol. Harmful for those suffering from alcoholism.
To be taken into account in pregnant and breast feeding women, children and high risk groups such as patients with liver disease or epilepsy.
Allerfin Syrup contains sucrose. This should be taken into account in patients with diabetes mellitus.
Long term use of Allerfin syrup increases the risk of dental caries and it is essential that adequate dental hygiene is maintained.
Patients with rare hereditary problems of galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.
Allerfin should be kept out of sight and reach of children.

Drug Interactions

Concurrent use of Chlorpheniramine and hypnotics or anxiolytics may cause an increase in sedative effects, therefore medical advice should be sought before taking Chlorpheniramine concurrently with these medicines.
Chlorpheniramine inhibits phenytoin metabolism and can lead to phenytoin toxicity.
The anticholinergic effects of Chlorpheniramine are intensified by MAOIs

Fertility, Pregnancy and Lactation:

Pregnancy

There are no adequate data from the use of Chlorpheniramine in pregnant women. The potential risk for humans is unknown, Use during the third trimester may result in reactions in the newborn or premature neonates. Not to be used during pregnancy unless considered essential by a physician.

Lactation

Chlorpheniramine maleate and other antihistamines may inhibit lactation and may be secreted in breast milk. Not to be used during lactation unless considered essential by a physician.

Effects on Ability to Drive and Use Machines

The anticholinergic properties of Chlorpheniramine may cause drowsiness, dizziness, blurred vision and psychomotor impairment, which can seriously hamper the patients' ability to drive and use machinery.

SIDE EFFECTS

The following categories were used for the classification of undesirable effects: very common (≥1/10), common (≥1/100, <1/10), uncommon (≥1/1000, ≤1/100), rare (≥1/10,000, ≤1/1000), very rare (≤1/10,000). Adverse event frequencies have been estimated from spontaneous reports from post-marketing data.

Blood and lymphatic system disorders:
Frequency unknown: haemolytic anaemia and other blood dyscrasias
Immune system disorders:
Frequency unknown: allergic reaction, angioedema, anaphylactic reactions
Metabolism and nutritional disorders:
Frequency unknown: anorexia
Psychiatric disorders:
Frequency unknown: confusion*, excitation*, irritability*, nightmares* and depression
Nervous System disorders:
Very Common: sedation, somnolence
Common: disturbance in attention, abnormal coordination, dizziness headache
Eye disorders:
Frequency unknown: blurred vision
Ear and labyrinth disorders:
Frequency unknown: tinnitus
Cardiac disorders:
Frequency unknown: palpitations, tachycardia, arrhythmias
Vascular disorders:
Frequency unknown: hypotension
Respiratory, thoracic and mediastinal disorders:
Frequency unknown: thickening of bronchial secretions
Gastrointestinal disorders:
Common: nausea, dry mouth
Frequency unknown: vomiting, diarrhea, abdominal pain, dyspepsia
Hepatobiliary disorders:
Frequency unknown: hepatitis, including jaundice
Skin and subcutaneous tissue disorders:
Frequency unknown: exfoliative dermatitis, rash, urticarial, photosensitivity
Musculoskeletal and connective tissue disorders:
Frequency unknown: muscle twitching and muscle weakness
Renal and urinary disorders:
Frequency unknown: urinary retention
General disorders and administration site conditions
Common: fatigue
Frequency unknown: chest tightness
* Children and the elderly are more susceptible to the neurological anticholinergic effects and paradoxical excitation (e.g. increased energy, restlessness, nervousness).

OVERDOSAGE

The estimated lethal dose of chlorpheniramine is 25-50 mg/kg body weight. Symptoms and signs include sedation, paradoxical CNS stimulation, toxic psychosis, apnea, convulsions, anticholinergic effects, dystonic reactions and cardiovascular collapse including arrhythmias.
Symptomatic and supportive measures should be provided with special attention to cardiac, respiratory, renal and hepatic functions and fluid and electrolyte balance. If overdosage is by the oral route, treatment with activated charcoal should be considered provided there are no contraindications for use and the overdose has been taken recently (treatment is most effective if given within an hour of ingestion.) Treat hypotension and arrhythmias vigorously. CNS convulsions may be treated with IV. diazepam. Haemoperfusion may be used in severe cases.

STORAGE:

Allerfin Syrup: Keep tightly closed below 30°C, away from light.
Allerfin Tablets: Store below 30°C, away from light.

PRESENTATIONS:

Tablets:

ALLERFIN 4 mg Chlorpheniramine maleate 4 mg/tablets
Excipients: Lactose monohydrate, maize starch and magnesium stearate.

Syrup:

ALLERFIN 2.5 mg/5 ml Chlorpheniramine maleate 2.5 mg/5 ml
Excipients: Anhydrous citric acid, sodium benzoate, sucrose, lemon oil, ethanol 96%, glycerin and purified water.

30/9/2017

Council of Arab Health Ministers, Union of Arab Pharmacists

THIS IS A MEDICAMENT

- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous.
- Follow the doctor's prescription strictly, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

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The Arab Pharmaceutical Manufacturing PSC,
Sult-Jordan

Keep medicament out of reach of children
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