Summary of product characteristics

(SMPC)

1. NAME OF THE MEDICINALPRODUCT

Allergin Syrup

2. QUALITATIVE AND QUANTITATIVECOMPOSITION

Each 5ml contains Chlorpheniramine Maleate 2mg

{For a full list of excipients, see section 6.1}

3. PHARMACEUTICAL FORM

Syrup

4. Clinical particulars

4.1 Therapeutic indications

Symptomatic control of all allergic conditions responsive antihistamines including hay fever, vasomotor rhinitis,urticaria,angio neurotic oedema, food allergy, drug and serum reactions,pruritus,and insect bites.

4.2 Posology and method of administration

Posology

Up to 1 year: 1mg (2.5ml) twice daily
1-5year(s) :1-2mg (2.5-5ml) three times daily
6-12years :2-4mg (5-10ml) three to four times daily

Method of administration
Oral administration only.

4.3 Contraindications

Allergin should not be given to premature infants or neonates and also contra indicated in cases of asthma.

4.4 Special warnings and precautions for use

Chlorphenamine, 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 and asthma; hepatic impairment; renal impairment. Children and the elderly are more likely to experience the neurological anticholinergic effects and paradoxical excitation (eg. Increased energy, restlessness, nervousness). Avoid use in elderly patients with confusion.

The anticholinergic properties of chlorphenamine may cause drowsiness, dizziness, blurred vision and psychomotor impairment in some patients which may seriously affect ability to drive and use machinery.

The effects of alcohol may be increased and therefore concurrent use should be avoided.

Should not be used with other antihistamine containing products, including antihistamine containing cough and cold medicines.

Concurrent use with drugs which cause sedation such as anxiolytics and hypnotics may cause an increase in sedative effects, therefore medical advice should be sought before taking chlorphenamine concurrently with these medicines.

Long term use increases the risk of dental caries and it is essential that adequate dental hygiene is maintained.

Methyl, ethyl and propyl hydroxybenzoates (E218, E214 and E216) may cause allergic reactions (possibly delayed).

Keep out of the reach and sight of children.

4.5 Interaction with other medicinal products and other forms of interaction.

Concurrent use of chlorphenamine and hypnotics or anxiolytics may cause an increase in sedative effects, concurrent use of alcohol may have a similar effect therefore medical advice should be sought before taking chlorphenamine concurrently with these medicines.

Chlorphenamine inhibits phenytoin metabolism and can lead to phenytoin toxicity.

The anticholinergic effects of chlorphenamine are intensified by MAOIs (see Contra-indications).

4.6 Pregnancy and Lactation

Pregnancy :

There are no adequate data from the use of chlorphenamine 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:

Chlorphenamine 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.

4.7 Effects on ability to drive and use machines

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

4.8 Undesirable effects

Common side effects are sedation,dizziness,lassitude, and in-coordination.,gastro intestinal disturbances such as nausea,vomiting,diarrhoea, or constipation,anorexia or increased appetite and epigastric pain,muscular weakness,dryness of mouth.

4.9 Overdose

Symptoms

The estimated lethal dose of chlorphenamine is 25 to 50mg/kg body weight. Symptoms and signs include sedation, paradoxical excitation of the CNS, toxic psychosis, convulsions, apnoea, anticholinergic effects, dystonic reactions and cardiovascular collapse including arrhythmias.

Treatment

Management should be as clinically indicated or as recommended by the national poisons centres where available. 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 i.v. diazepam. Haemoperfusion may be used in severe cases.

5 PHARMACOLOGICALPROPERTIES

5.1 Pharmacodynamics properties

Pharmacotherapeutic group: ATC Code R06AB02

Pharmacodynamic effects: Chlorphenamine is a potent antihistamine (H_1antagonist).

Antihistamines diminish or abolish the actions of histamine in the body by competative reversible blockade of histamine H_1-receptor sites on tissues. Chlorphenamine also has anticholinergic activity.

Antihistamines act to prevent the release of histamine, prostaglandins and leukotrines and have been shown to prevent the migration of inflammatory mediators. The actions of chlorphenmine include inhibition of histamine on smooth muscle, cappillary permeability and hence reduction of oedema and wheal in hypersensitivity reactions such as allergy and anaphylaxis

5.2 Pharmacokinetic properties

Chlorphenamine is well absorbed from the gastro-intestinal tract, following oral administration. The effects develop within 30 minutes, are maximal within I to 2 hours and last 4 to 6 hours. The plasma half-life has been estimated to be 12 to 15 hours.

Chlorphenamine is metabolised to the monodesmethyl and didesmethyl derivatives. About 22% of an oral dose is excreted unchanged in the urine.

5.3 Preclinical safety data

No additional data of relevance.

6 PHARMACEUTICALPARTICULARS

6.1 List of excipients

Sugar,Vanilla essence powder, Tartrazine orange colour, Methylparaben, Propyl paraben, Sorbit solution ,Tutti frutti flavor,SodiumCMC ,Sodium saccharine, Bronopol.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years

6.4 Special precautions for storage

Store below 30°

6.5 Nature and contents of container

60 ml transparent PET bottle with child proof cap

6.6 Special precautions for disposal

No special requirements.

Any unused product or waste material should be disposed of in accordance with local requirement.

6.7APPLICANT/MANUFACTURER

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