SCHEDULING STATUS: S2

PROPRIETARY NAME (AND DOSAGE FORM):

ALLERGEX® ELIXIR (ELIXIR)

COMPOSITION:

Each 5 ml contains:

Chlorpheniramine maleate	2 mg
Preservatives:	
Methylparaben	0,12 % *m/v*
Propylparaben	0,016 % *m/v*
Contains sugar: sucrose	4,2 g/5ml

List of Excipients :Chloroform; Chloroform spirit; Colour Red F1127 C.I 14720/42090 ;Oil of aniseed 339601; Oil of cassia100091; Oil of cloves 400606; Oil of coriander 420913; Oil of orange Valenica LR 12772; purified water and Sodium cyclamate

PHARMACOLOGICAL CLASSIFICATION:

A 5.7.1 Medicines affecting autonomic functions - Antihistamines.

PHARMACOLOGICAL ACTION:

Chlorpheniramine maleate is an antihistamine.

INDICATIONS:

Treatment of all conditions responsive to antihistaminic therapy. It may also be used as an antitussive.

CONTRAINDICATIONS:

Epilepsy. Premature infants or neonates. Acute attacks of asthma.

Do not use in children under 2 years of age

WARNINGS AND SPECIAL PRECAUTIONS:

The use of this medicine leads to drowsiness which is aggravated by the simultaneous intake of alcohol. Patients should be warned not to drive a motor vehicle, operate dangerous machinery or climb dangerous heights, as impaired decision making could lead to accidents.

Because of its antimuscarinic properties chlorpheniramine maleate should be used with care in conditions such as narrow angle glaucoma, urinary retention and prostatic hypertrophy.

Antihistamines may suppress positive skin test results and should be stopped several days before the test.

INTERACTIONS:

Monoamine oxidase inhibitors may enhance the antimuscarinic effects of antihistamines and antihistamines have an additive antimuscarinic action with other antimuscarinic drugs such as atropine and tricyclic antidepressants.

Antihistamines may suppress positive skin test results and should be stopped several days before the test

PREGNANCY AND LACTATION:

Safety in pregnancy and lactation has not been established.

DOSAGE AND DIRECTIONS FOR USE:

Adults : 2 to 8 medicine measures daily in divided doses.

Children: 2 - 5 years: ½ - 1 medicine measure 3 times daily.

6 - 12 years: 2 medicine measures 3 or 4 times daily.

Not recommended for children under 2 years of age.

SIDE EFFECTS:

Sedation varying from slight drowsiness to deep sleep, and including lassitude, dizziness and inco-ordination. Gastrointestinal disturbances such as nausea, vomiting, diarrhoea or constipation, anorexia or increased appetite and epigastric pain. Antimuscarinic effects including blurred vision, difficulty in micturition, dysuria, dryness of the mouth and tightness of the chest may be produced. Other central effects include hypotension, muscular weakness, tinnitus, euphoria and headache. Paradoxical CNS stimulation may occur, especially in children, with insomnia, nervousness, tachycardia, tremors and convulsions.

Chlorpheniramine maleate may produce epileptiform seizures in patients with focal lesions of the cerebral cortex. Allergic reactions and cross-sensitivity to related drugs may be produced.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

Overdosage may be fatal especially in infants and children in whom the main symptoms are CNS stimulation and antimuscarinic effects, including ataxia, excitement, hallucinations, muscle tremor, convulsions, dilated pupils, dry mouth, flushed face and hyperpyrexia. Deepening coma, cardiorespiratory collapse and death may occur.

In adults, the usual symptoms are of CNS depression with drowsiness, coma and convulsions. Hypotension may occur. Elderly patients are more susceptible to the CNS depressant and hypotensive effects even at therapeutic levels.

Treatment: Symptomatic and supportive.

IDENTIFICATION:

Raspberry red syrup. Odour of fruit and of cloves. Taste of cloves.

PRESENTATION:

50 ml in amber PVC bottles and 100 ml in amber glass bottles and 200ml amber PVC bottles and 200 ml in an amber glass bottles.

STORAGE INSTRUCTIONS:

Store at or below 25 ºC, in a cool place. Protect from light.

KEEP OUT OF THE REACH OF CHILDREN.

REGISTRATION NUMBER:

C807 (Act 101/1965)

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