

TRADE NAME: ALLERBAN SYRUP®
REGISTRATION NUMBER: TBA
NON-PROPRIETARY NAME: CHLORPHENIRAMINE MALEATE 2 mg/5 ml SYRUP
DISTRIBUTION CATEGORY: PHARMACY ONLY
PHARMACOLOGICAL CLASSIFICATION: R06A – Antihistamines for systemic use

COMPOSITION:

Each 5 ml contains:
CHLORPHENIRAMINE MALEATE.....2 mg
Preservatives:
Methyparaben..... 0.1 % m/v
Propylparaben.....0.01 % m/v

IDENTIFICATION: Clear Pink Solution

PRESENTATION: 50 and 100 ml in amber glass bottles

PHARMACOLOGICAL ACTION: Chlorpheniramine is an antihistamine.

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

CONTRA-INDICATIONS: Epilepsy. Premature infants or neonates. Acute attacks of asthma.

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

DOSAGE AND DIRECTIONS FOR USE

Adults: 2 to 8 medicine measures daily in divided doses
Children: 6 months to 1 year - 2.5 ml twice daily
1 year to 5 years - 2.5 ml-5ml three times daily
6 years to 12 years - 10 ml three to four times daily

SIDE EFFECTS AND SPECIAL PRECAUTIONS:

Sedation varying from slight drowsiness to deep sleep, lassitude, dizziness and inco-ordination. Gastro-intestinal 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 mouth and tightness of chest may be produced. Other central effects may 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 cross-sensitivity to related drugs may be produced.

Because of its antimuscarinic properties Chlorpheniramine maleate should be used with care in conditions such as narrow angle glaucoma, urinary retention and prostatic hypertrophy. 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. The sedative effects of central nervous system depressants including alcohol, barbiturates, hypnotics, narcotic analgesics, sedatives and tranquilisers may be enhanced.

OVERDOSAGE: 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 the 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.

STORAGE CONDITIONS:

Do not store above 30 °C. Keep out of reach of children.

NAME OF APPLICANT

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