

CHLORPHENAMINE MALEATE

FAHRENAL
2 mg per 5mL SYRUP

ANTHISTAMINE

DESCRIPTION:

Chlorphenamine maleate, an alkylamine derivative, is a sedating antihistamine that causes a moderate degree of sedation; it also has antimuscarinic activity. Chlorphenamine is a racemic mixture of dextrorotatory isomer, dexchlorpheniramine has about twice the activity of chlorphenamine by weight. Fahrenal (Chlorphenamine) is a clear syrupy liquid in menthol flavor. Available in Amber Glass Bottle of 60 mL (Box of 1's)

WHAT IS IN THE MEDICINE?

FAHRENAL contains: Chlorphenamine Maleate, is antihistamine medicine that relieves the symptoms of allergies. It's known as a drowsy (sedating) antihistamine. This means that it is likely to make you feel more sleepy than some other antihistamines

STRENGTH OF THE MEDICINE : See Formulation

WHAT IS THIS MEDICINE USED FOR?

Chlorphenamine maleate is used for symptomatic relief of allergic conditions including urticaria and angioedema, rhinitis, and conjunctivitis, and in pruritic skin disorders. For symptomatic treatment of cough and the common cold.

HOW MUCH AND HOW OFTEN SHOULD YOU USE THIS MEDICINE?

Chlorphenamine maleate is given in oral doses of 4 mg every 6 hours up to a maximum of 24 mg daily.
1 - 2 years old : 1 mg (2.5 mL) twice daily
2 - 5 years old : 1 mg (2.5 mL) 4 - 6 hours (maximum of 6 mg daily)
6 - 12 years old : 2 mg (5 mL) every 4- 6 hours (maximum of 12 mg daily) or as prescribed by the physician.

WHEN SHOULD YOU NOT TAKE THIS MEDICINE?

If you are allergic to chlorphenamine, or any of the other ingredients of this medicine.
- Any medicine containing chlorphenamine or other antihistamines.

CARE THAT SHOULD BE TAKEN WHEN TAKING THIS MEDICINE?

Chlorphenamine should be used with care in conditions such as angle-closure glaucoma, urinary retention, prostatic hyperplasia, or pyloroduodenal obstruction. Avoid operating vehicles or machinery. Hypersensitivity, cardiovascular diseases, cardiac arrhythmias, hypertension, hyperthyroidism, pheochromocytoma, diabetes.

PHARMACOKINETICS:

Chlorphenamine maleate is absorbed relatively slowly from the gastrointestinal tract, peak plasma concentrations occurring about 2.5 to 6 hours after oral doses. Bioavailability is low, values of 25 to 50% having been reported. Chlorphenamine appears to undergo considerable first-pass metabolism. About 70% of chlorphenamine in the circulation is bound to plasma proteins. There is wide interindividual variation in the pharmacokinetics of chlorphenamine, values ranging from 2 to 43 hours have been reported for the half-life. Chlorphenamine is widely distributed in the body, and enters the Central Nervous System.

UNDESIRABLE EFFECTS:

Common adverse effect of the of antihistamine is Central Nervous system depression, from slight drowsiness to deep sleep, and including lassitude, dizziness, headache, psychomotor impairment, and antimuscarinic effects, such as dry mouth, thickened respiratory tract secretions, blurred vision, urinary difficulty or retention, constipation, and increased gastric reflux. Gastrointestinal adverse effects of antihistamine include nausea, vomiting, diarrhea or epigastric pain.

WHAT OTHER MEDICINE OR FOOD SHOULD BE AVOIDED WHILE TAKING THIS MEDICINE?

Sedating antihistamines may enhance the sedative effects of Central Nervous System depressants including alcohol, barbiturates, hypnotics, opioid analgesics, anxiolytic sedatives, and antipsychotics.

WHAT SHOULD YOU DO IF YOU MISS A DOSE?

If you miss a dose, just take the next dose and subsequent doses at the usual recommended schedule. Do not take a double dose to make up for the dose that you missed.

SIGNS AND SYMPTOMS OF OVERDOSE:

Overdosage with sedating antihistamines is associated with antimuscarinic, extrapyramidal, and CNS effects. When CNS stimulation predominates over CNS depression, which is more likely in children or the elderly, it causes ataxia, excitement, tremors, psychoses, hallucinations, and convulsions; hyperpyrexia may also occur. Deepening coma and cardiorespiratory collapse may follow. In adults, CNS depression is more common with drowsiness, coma, and convulsions, progressing to respiratory failure and cardiovascular collapse.

WHAT TO DO IF HAVE TAKEN MORE THAN THE RECOMMENDED DOSAGE?

Immediately telephone your doctor or the Poisons Information Center if you think that you or anyone else may have taken too much FAHRENAL. Do this even if there are no signs of discomfort or poisoning.

HOW SHOULD YOU KEEP THIS MEDICINE?

Store at temperatures not exceeding 30°C

ADR REPORTING STATEMENT:

For suspected adverse drug reaction, report to FDA: www.fda.gov/ph
Patient must seek medical attention immediately at the first sign of any adverse drug reactions.

REGISTRATION NO.: 7338

DATE OF FIRST AUTHORIZATION /RENEWAL OF THE AUTHORIZATION

September 20, 2020

DATE OF REVISION OF PATIENT INFORMATION LEAFLET:

July 20, 2023



Manufactured by:
SAN MARINO Laboratories CORP.
1 Crisanto delos Reyes Street, Brgy Javalera
General Trias, Cavite
For:
JOHNTANN INTERNATIONALE PHARMACEUTICAL CORP.
25 Kabinayan Street, Quezon City