

CTD MODULE 1
ADMINISTRATIVE INFORMATION AND
PRODUCT INFORMATION

Product Name :	RENE-CPM TABLETS (Chlorpheniramine Maleate 4mg)
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Pack Insert

RENE-CPM TABLETS

Chlorphenamine Tablets BP 4 mg

Composition:

Each uncoated tablet contains Chlorphenamine Maleate BP 4 mg

Description:

Chlorphenamine maleate is an alkylamine derivative of histamine H₁ receptor antagonist, which is given in the tablet form for the symptomatic relief of hypersensitivity reactions and in pruritic skin disorders.

Pharmacology:

Chlorphenamine prevents rather than reverses the effects of histamine by competing with it for the receptor sites. It gives palliative relief from allergic symptoms. In usual therapeutic dose, it moderately produces depression and sedation of CNS. It has moderate anticholinergic activity which may be related to its usefulness in motion sickness.

Indications:

Symptomatic relief of hypersensitivity reaction including urticaria & angioedema, rhinitis, conjunctivitis and pruritic skin disorders.

Contra- Indications:

Patients should be warned about concomitant use of alcohol beverages. It should be used with caution in condition such as closed angle glaucoma, urine retention, prostatic hypertrophy or pyloroduodenal obstruction.

Precautions and Warnings:

It should not be given to premature infants or neonates. It may cause drowsiness therefore patients so affected should not drive or operate any machinery.

Adverse reactions:

Usually depression of CNS, dizziness, tinnitus, incoordination, diplopia and fatigue may develop. Very rarely central excitement, euphoria, insomnia, and tremors may occur.

Dosage:

Adults: 4 mg (1 tablet) every 4 to 6 hours upto a maximum of 24 mg daily.

Children: 1 to 2 years : 1 mg twice daily.

2 to 5 years : 1 mg every 4 to 6 hours (maximum 6 mg daily)

6 to 12 years : 2 mg every 4 to 6 hours (maximum 12 mg daily)

Storage:

Store at a temperature not exceeding 30°C. Protect from light. Keep container tightly closed. Keep out of reach of children.

Presentation:

Blister pack of 10x10's Tablets

1000's Tablets in a well closed HDPE Container.

MANUFACTURED BY
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A Milestone to Golden Health