SAM C.P.M. TABLETS

Chloropheniramine Maleate B. P 4mg

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

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1. NAME OF THE MEDICINAL PRODUCT

SAM C. P. M TABLETS 4MG

2. QUALITATIVE AND QUANTITATIVE COMPOSITIONS

Each tablet contains 4mg of Chlorphenamine Maleate

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORMS

A round, circular, biconvex, white tablets with '4' marked one side and the reverse face has a plain only.
Oral Tablets

4. CLINICAL PARTICULARS

4.1 Therapeutic Indication.

Chlorphenamine Maleate is used to treat allergy reactions; articaria, seasonal hay fever, pruritus ani, pruritus vulvae, puritus of jaundice and drug rashes, contact dermatitis insect bites, emesis and sedation.

4.2 Posology and method of administration.

Oral Administration only

Adults and children 12 years and over: 1 tablet 4 to 6 hourly. Maximum daily dose: 6 tablets (24 mg) in any 24 hours

Elderly: The elderly are more likely to experience neurological anticholinergic effects. Consideration should be given to using a lower daily dose (e.g. a maximum of 12 mg in any 24 hours).

Children aged 6 - 12 years: ½ tablets 4 to 6 hourly. Maximum daily dose: 3 tablets (12mg) in any 24 hours

Not recommended for children under 6 years

4.3 Contraindications

Chlorphenamine Maleate should not be administered with iodipamide meglumine injection, phenytoin of alcohol.

4.4 Special warnings and precaution for use.

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

Chlorphenamine Maleate should not be used with other antihistamine containing products, including antihistamine containing cough and cold medicines.

Keep out of reach of children.

4.5 Interaction with other medicinal product 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.

4.6 Pregnancy and Lactation.

Pregnancy

There are no adequate data from the use of chlorphenamine maleate 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 antihistamine may inhibit lactation and may be secreted in breast milk. Not to be used during lactation unless considered essential by a physician.

4.7 Effect on the ability to drive and use machine.

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 effect.

Chlorphenamine Maleate causes agranulocytosis, aplastic aneamia, its long term use cause progressive left-side facial dyskinesia

4.9 Overdose.

In severe overdosage, the stomach should be emptied by aspiration and lavage. Emetica should not be used.
The patient should be kept quiet to minimise the excitation which occurs particularly in children.
Convulsions may be controlled with diazepam given intravenously.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties.

Chlorphenamine is a potent antihistamine.

Antihistamines act to prevent the release of histamine, prostaglandins and leukotrienes and have been shown to prevent the migration of inflammatory mediators. The actions of chlorphenamine include inhibition of histamine on smooth muscle, capillary 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 1 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.

Product is not a new chemical entity therefore this section is not applicable.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Di-calcium Phosphate

Maize Starch

Purified Talcum.

Magnesium Stearate

Gelatine

Methyl Paraben

Propyl Paraben

6.2 Incompatibilities

None known

6.3 Shelf-life

36 Months

6.4 Special precautions for storage

Protect from heat and light and store in a cool dry place below 30^0C

6.5 Nature and composition of immediate packaging

Bulk pack tablet whose quality has been approved by the quality control department in polythene bags in 1000's by weight. Seal the bags and place them in previously cleaned 350cc plastic securi-containers.

7. MARKETING AUTHORISATION HOLDER

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8. MARKETING AUTHORISATION NUMBER(S)

04 – 0271.

9. AUTHORISATION/RENEWAL OF THE AUTHORISATION

Renewal date: 27th April 2021

10. DATE OF REVISION OF THE TEXT

17th August 2025