National Agency for Food and Drug Administration and Control (NAFDAC)

SUMMARY OF PRODUCT CHARACTERISTICS

(As Per NAFDAC Template)

COFSTIFIED

(Chlorphenamine Maleate Tablets BP 4 mg)

Manufactured by:	**Marketed by** :
SURMOUNT LABORATORIES PVT.LTD A-2/4003, GIDC Ind. Estate, Ankleshwar-393002, Gujarat, INDIA Ph.: +91 2646-220582 Email: surmountlaborat@gmail.com	**SOMSONIKE INTEGRATED CO.,** 14, Nkpologwu str, Omagba Phase II Onitsha, Anambra State, Nigeria.

1. Name of the medicinal product

1.1 Product name

Generic Name or International Non-Proprietary Name (INN)

CHLORPHENAMINE MALEATE TABLETS BP 4 MG

Brand Name

COFSTIFIED

1.2 Dosage Strength

Composition:

Each Un-Coated Tablet Contains

Chlorphenamine Maleate BP……4 mg

Excipients……..q.s.

1.3 Dosage Form

Oral Tablets

2. Qualitative and Quantitative composition

2.1 Qualitative Declaration

Each Un-Coated Tablet Contains

Chlorphenamine Maleate BP……4 mg

Excipients……..q.s.

2.2 . Quantitative Declaration

SN	Raw Material	Specification	Mg / per Tablet	STD batch Qty 1,00,000 Tablet in Kg	Category
DRY MIXING –PART I					
1	Di Calcium Phosphate	BP	51.431	5.143	Disintegrant
2	Maize Starch	BP	35.55	3.55	Filler
BINDER PREPARATION					
3	Maize Starch	BP	93.42	9.342	Binder
4	Methyl Paraben	BP	0.098	0.009	Preservative
5	Propyl Paraben	BP	0.049	0.004	Preservative
6	Gelatin	IH	0.368	0.036	Binder
7	*Purified Water	BP	---	---	Vehicle
LUBRICANTION					
8	Chlorphenamine Maleate	BP	4.000	0.04	Active
9	Talcum	BP	3.924	0.039	Glidant
10	Magnesium Stearate	BP	2.450	0.245	Lubricant
11	Sod. Starch Glycolate	BP	2.450	0.245	Glidant
12	*Maize Starch (LOD)	BP	4.900	0.490	Glidant
13	Aerosil	BP	0.245	0.0245	Glidant
Average weight of uncoated tablet			**325.0 mg**	**32.50kg**	

Current edition of International Pharmacopoeia (PhI) , British Pharmacopoeia (BP) & IN HOUSE (IH) specification used.

Purified Water *were evaporated in manufacturing process.

3. Pharmaceutical form

White, circular shape plain uncoated tablets having break line on one side and plain on other side.

4. Clinical particulars

4.1 Therapeutic indications

Product Name:-

COFSTIFIED (CHLORPHENAMINE MALEATE TABLETS BP 4 MG)

Strength: - Chlorphenamine Maleate 4 mg

Dosage Form: - Oral Tablet

Chlorphenamine Maleate Tablets BP 4 mg are indicated for symptomatic control of all allergic conditions responsive to antihistamines, including hay fever, vasomotor rhinitis, urticaria, angioneurotic oedema, food allergy, drug and serum reactions, insect bites. Also indicated for the symptomatic relief of itch associated with chickenpox.

4.2 Posology and method of administration

Posology

Oral Administration only

Do not exceed the stated dose or frequency of dosing

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 tablet 4 to 6 hourly. Maximum daily dose: 3 tablets (12mg) in any 24 hours

Not recommended for children under 6 years

Method of administration

Tablets for oral administration.

4.3 Contraindications

Chlorphenamine Maleate Tablets BP 4 mg are contra-indicated in patients who are hypersensitive to antihistamines or to any of the tablet ingredients.
The anticholinergic properties of Chlorphenamine are intensified by monoamine oxidase inhibitors (MAOIs). Chlorphenamine Maleate Tablets BP 4 mg is therefore contra-indicated in patients who have been treated with MAOIs within the last fourteen days.

4.4 Special warnings and precautions for use

Chlorphenamine, in common with other drugs having anticholinergic effects, should be used with caution in epilepsy; raised intra-ocular pressure including glaucoma; prostatic hypertrophy; severe hypertension or cardiovascular disease; bronchitis, bronchiectasis or asthma; hepatic impairment; renal impairment. Children and the elderly are more likely to experience the neurological anticholinergic effects and paradoxical excitation (eg. increased energy, restlessness, nervousness).

The anticholinergic properties of Chlorphenamine may cause drowsiness, dizziness, blurred vision and psychomotor impairment in some patients which may seriously affect ability to drive and use machinery.

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

Should not be used with other antihistamine containing products, including antihistamine containing cough and cold medicines.

Patients with rare hereditary problems of galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine,

Keep out of sight and reach of children.

4.5 Interaction with other medicinal products and other forms of interaction
Contraindications of concomitant use

Concurrent use of Chlorphenamine and hypnotics or anxiolytics may cause an increase in sedative effects, therefore medical advice should be sought before taking Chlorphenamine concurrently with these medicines.

Chlorphenamine inhibits phenytoin metabolism and can lead to phenytoin toxicity.

The anticholinergic effects of Chlorphenamine are intensified by MAOIs (see Contra-indications).

4.6 Fertility, 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 essentially 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

Fertility

There is no information on the effects of Chlorphenamine maleateTablets on human fertility

4.7 Effects on ability to drive and use machines

Product Name:-
COFSTIFIED (CHLORPHENAMINE MALEATE TABLETS BP 4 MG)
Strength: - Chlorphenamine Maleate 4 mg
Dosage Form: - Oral Tablet

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 effects

Specific estimation of the frequency of adverse events for OTC products is inherently difficult (particularly numerator data). Adverse reactions which have been observed in clinical trials and which are considered to be common (occurring in ≥1% to <10% of subjects) or very common (occurring in ≥10% of subjects) are listed below by MedDRA System Organ Class. The frequency of other adverse reactions identified during post-marketing use is unknown.

Blood and lymphatic system disorders:

Unknown: hemolytic anemia, blood dyscrasias

Immune system disorders:

Unknown: allergic reaction, angioedema, anaphylactic reactions

Metabolism and nutritional disorders:

Unknown: anorexia

Psychiatric disorders:

Unknown: confusion*, excitation*, irritability*, nightmares*, depression

Nervous system disorders*:

Very common: sedation, somnolence

Common: disturbance in attention, abnormal coordination, dizziness headache

Eye Disorders:

Common: blurred vision

Ear and labyrinth disorders:

Unknown: tinnitus

Cardiac disorders:

Unknown: palpitations, tachycardia, arrhythmias

Vascular disorders:

Unknown: Hypotension

Respiratory, thoracic and mediastinal disorders:

Unknown: thickening of bronchial secretions

Gastrointestinal disorders:

Common: nausea, dry mouth

Unknown: vomiting, abdominal pain, diarrhea, dyspepsia

Hepatobiliary disorders:

Unknown: hepatitis, including jaundice

Skin and subcutaneous disorders:

Unknown: exfoliate dermatitis, rash, urticaria, photosensitivity

Musculoskeletal and connective tissue disorders:

Unknown: muscle twitching, muscle weakness

Renal and urinary disorders:

Unknown: urinary retention

General disorders and administration site conditions:

Common: fatigue

Unknown: chest tightness

*Children and the elderly are more likely to experience the neurological anticholinergic effects and paradoxical excitation (eg. increased energy, restlessness, nervousness).

4.9 Overdose

Symptoms and signs

The estimated lethal dose of chlorphenamine is 25 to 50mg/kg body weight. Symptoms and signs include sedation, paradoxical excitation of the CNS, toxic psychosis, convulsions, apnoea, anticholinergic effects, dystonic reactions and cardiovascular collapse including arrhythmias.

Treatment

Symptomatic and supportive measures should be provided with special attention to cardiac, respiratory, renal and hepatic functions and fluid and electrolyte balance. If overdosage is by the oral route, treatment with activated charcoal should be considered provided there are no contraindications for use and the overdose has been taken recently (treatment is most effective if given within an hour of ingestion). Treat hypotension and arrhythmias vigorously. CNS convulsions may be treated with i.v. diazepam. Haemoperfusion may be used in severe cases.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Chlorphenamine is a potent antihistamine (H1-antagonist).

ATC code: R06AB02

Mechanism of Action

This medication works by blocking a certain natural substance (histamine) that your body makes during an allergic reaction. By blocking another natural substance made by your body (acetylcholine), it helps dry up some body fluids to relieve symptoms such as watery eyes and runny nose.

Pharmacodynamic effects

Antihistamines diminish or abolish the actions of histamine in the body by competitive reversible blockade of histamine H_1-receptor sites on tissues. Chlorphenamine also has anticholinergic activity.

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 edema 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 metabolized to the monodesmethyl and didesmethyl derivatives. About 22% of an oral dose is excreted unchanged in the urine.

5.3 Preclinical safety data

No additional data of relevance.

6. Pharmaceutical particulars

6.1 List of excipients

Di Calcium Phosphate

Maize Starch

Methyl Paraben

Propyl Paraben

Gelatin

DM Water

Talcum

Magnesium Stearate

Sod. Starch Glycolate

Aerosil (Colloidal Silicone Dioxide)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years

6.4 Special precautions for storage

Do not store above 30°C.

6.5 Nature and contents of container

10 tablets packed in one Glassine strip. Such 10 strips packed in unit printed duplex board carton along with its package insert. Such cartons packed in export worthy shipper.

6.6 Special precautions for disposal

No special requirements

7. Marketing Authorisation holder

SOMSONIKE INTEGRATED CO.,
14, Nkpologwu str, Omagba Phase II
Onitsha, Anambra State, Nigeria.