SUMMARY OF PRODUCT CHARACTERISTICS (SPC)

1. NAME OF THE MEDICINAL PRODUCT

GG COLD (CHLORPHENIRAMINE MALEATE AND PHENYLEPHRINE HYDROCHLORIDE CAPSULES)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Batch size: 10, 00, 000 Capsules

Sr. No.	Name of Ingredient	Spec.	Qty. in mg/ Cap	Qty. in kg/ Batch	Ovg.
1	Pellets of Chlorpheniramine Maleate 4 mg and Phenylephrine Hydrochloride IH 5 mg	IHS	260.000	260.000	--
2	EHG.CAPS. SIZE"2" Printed GG COLD on Pink/ Clear Transparent Coloured cap/body	IHS	1 no	10,00,000 nos	--
		TOTAL	**260.000**		--

IHS: In House Specification

Net content per capsule **:** 260.000 mg ± 5 %

Average weight of filled capsule **:** 325.000 mg ± 5 %

3. PHARMACEUTICAL FORM

Capsule

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

This product is indicated for the temporary relief of nasal congestion due to the common cold, hay fever, or other respiratory allergies and associated sinusitis.

4.2 Posology and Method of Administration

Route of administration: Oral

Adults and children over 12 years:

1 Capsule every 4 to 6 hourly.

Maximum daily dose: 6 Capsules 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.

Children aged 6 - 12 years:

Maximum daily dose: 3 Capsules in any 24 hours.

Not recommended for children under the age of 6 years.

4.3 Contraindications

i) This product is contraindicated in patients with hypersensitivity to antihistamines and/or sympathomimetics.

ii) Antihistamines are contraindicated in patients receiving antihypertensive or antidepressant drugs containing monoamine oxidase (MAO) inhibitors since these agents may prolong and intensify anticholinergic and CNS depressant effects of antihistamines

iii) Antihistamines should not be used to treat lower respiratory tract symptoms or be given to premature or newborn infants.

iv) This product is contraindicated in patients with severe hypertension or severe coronary artery disease.

v) Risk-benefit should be considered when the following medical problems exist: hyperthyroidism, diabetes mellitus, glaucoma, prostatic hypertrophy, urinary retention and asthma (although antihistamines may decrease allergen induced bronchoconstriction, their anticholinergic drying effects may cause thickening of secretions and impair expectoration during an acute episode of asthma).

4.4 Special Warnings and Precautions for use

i) 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).

ii) 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.

iii) 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

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

v) Keep out of the sight and reach of children.

4.5 Interaction with other medicinal products and other forms of interaction

i) 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.

ii) Chlorphenamine inhibits phenytoin metabolism and can lead to phenytoin toxicity.

iii) The anticholinergic effects of chlorphenamine are intensified by MAOIs

iv) This medicine should not be taken together with vasodilators, beta-blockers or enzyme inducers such as alcohol.

4.6 Pregnancy and Lactation

Pregnancy

Pregnancy category C. It is not known whether this product can cause fetal harm when administered to a pregnant woman. This product should be given to pregnant woman only if clearly needed.

Lactation

Because of the higher risk of intolerance of antihistamines in infants in general, and in newborns in particular, this product is contraindicated in nursing mothers.

4.7 Effects on ability to drive and use machines

The anticholinergic properties of chlorphenamine may cause drowsiness, dizziness, blurred vision and psychomotor impairment which can seriously hamper the patient's ability to drive and use machinery.

4.8 Undesirable Effects

Blood and lymphatic system disorders:

Unknown: haemolytic anaemia, 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, diarrhoea, dyspepsia

Hepatobiliary disorders:

Unknown: hepatitis, jaundice

Skin and subcutaneous disorders:

Unknown: exfoliative 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

4.9 Overdose

Signs and symptoms:

Overdosage with antihistamines may cause hallucinations, convulsions or possibly death, especially in infants and children. Antihistamines are more likely to cause dizziness, sedation, and hypotension in elderly patients. Overdosage with sympathomimetic amines can cause cardiac arrhythmias, cerebral hemorrhage and pulmonary edema. It can also cause palpitations, tremor, dizziness, vomiting, fear, labored breathing, headache, pallor, weakness, hallucinations, and delirium.

Recommended treatment:

Since there is no specific antidote for overdose with this product, treatment is symptomatic and supportive with possible utilization of the following:

i) If the amount ingested is considered dangerous or excessive induce vomiting with ipecac syrup unless the patient is convulsing, comatose, or has lost the gag reflex, in which case perform gastric lavage.

ii) Gastric lavage (isotonic or 0.45% sodium chloride solution) if patient is unable to vomit within 3 hours of ingestion.

iii) Saline cathartics (milk of magnesia) are sometimes used

iv) Vasopressors to treat hypotension, however, epinephrine should not be used since it may further lower blood pressure.

v) Oxygen and intravenous fluids

vi) Precaution against use of stimulants (analeptic agents) because they may cause seizures.

vii) For reflex bradycardia accompanying the pressor response to phenylephrine atropine may be used to block the effect.

viii)For excessive hypertensive effects, an alpha-adrenergic blocker, such as phentolamine, may be administered.

5.1 Pharmacodynamic Properties

Chlorphenamine is a potent histamine H1, receptor antagonist.

Antihistamines diminish or abolish the actions of histamine in the body by competitive reversible blockade of histamine H1-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 oedema and wheal in hypersensitivity reactions such as allergy and anaphylaxis.

Phenylephrine is a sympathomimetic agent with mainly direct effects on adrenergic receptors. It has predominantly alpha adrenergic activity and is without stimulating effects on the central nervous system. The sympathomimetic effect of phenylephrine produces vasoconstriction which in turn relieves nasal congestion.

5.2 Pharmacokinetic Properties

Chlorpheniramine maleate is almost completely absorbed after administration by mouth, peak plasma concentrations occurring at about 2.5 to 6 hours. The drug is widely distributed including passage into the CNS, with a volume of distribution of between 1 and 10L/KG. About 70% of chlorpheniramine in the circulation is protein bound. Chlorpheniramine undergoes some first pass metabolism and enterohepatic recycling. Chlorpheniramine is extensively metabolised, principally to inactive desmethylated metabolites which are excreted primarily in the urine, together with about 35% unchanged drug. Only trace amounts are excreted in the faeces. The mean elimination half life has been reported to be about 30 hours, with mean values ranging from 2 to 43 hours.

Phenylephrine is readily absorbed after oral administration but is subject to extensive presystemic metabolism, much of which occurs in the enterocytes. As a consequence, systemic bioavailability is only about 40%. Following oral administration, peak plasma concentrations are achieved in 1-2 hours. The mean plasma half life is in the range 2- 3 hours. Penetration into the brain appears to be minimal. Following absorption, the drug is extensively metabolised in the liver. Both phenylephrine and its metabolites are excreted in the urine. The volume of distribution is between 200 and 500 litres, but there are no data on the extent of plasma protein binding.

5.3 Preclinical Safety Data

The antihistaminic potency of chlorpheniramine is confined mainly to its (+)-isomer. The racemate is similarly or slightly more toxic because of the contribution of (-)- isomer. The toxicity may therefore be non- specific, perhaps attributable to local anaesthetic action and the toxic effects (excitation/sedation, coma, convulsions and death) resemble those of other classic H1antihistamines. Toxic doses may cause hypotension attributable to myocardial depression, an effect which is clearer with the (-)-isomer. The experimental data on the carcinogenicity and mutagenicity of chlorpheniramine indicate lack of these adverse effects, but the racemate and the (+)-isomer have shown some embryotoxicity in fertility tests.

Effective antihistaminic concentrations of chlorpheniramine in vitro are about 1-10μg/L and oral doses of 0.2-1 mg/kg antagonise histamine- induced bronchospasm in guinea pigs.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

EHG.CAPS. SIZE"2" Printed GG COLD on Pink/ Clear Transparent Coloured cap/body - IHS

6.2 Incompatibilities

None

6.3 Self Life

36 Months

6.4 Special Precautions for Storage

Store below 30°C.
Protect from direct sunlight, heat and moisture.
Keep all medicines out of reach of children.

6.5 Nature and contents of container

Blister Pack of 10 Capsules

6.6 Special precautions for disposal and other handling

No special requirement

7 MARKETING AUTHORIZATION HOLDER

Not applicable

8 MARKETING AUTHORIZATION NUMBER(S)

Not applicable

9 DATE OF FIRST AUTHORIZATION / RENEWAL OF THE AUTHORIZATION

Not applicable

10. DATE OF REVISION OF THE TEXT

As depends on requirement of updation of details