Legal Category

POM: Over The Counter

- **SmPC**

1. Name of the medicinal product

Coughcare + Syrup

2. Qualitative and quantitative composition

Each 5ml of the syrup contains

Ammonium chloride	100mg
Chlorpheniraime maleate	2mg
Sodium citrate	60mg
Menthol crystal	1.5mg

Pharmaceutical form

Liquid Syrup

3. Clinical particulars

3.1 Therapeutic indications

Coughcare+ Preparation is effective in the management of cough by soothing and prevention of irritation of upper respiratory tract. Also to relieve the symptoms associated with cold through nasal and bronchial decongestion.

Posology and method of administration

AGE	**DOSAGE**	**FREQUENCY**
Adults and children	1-2 teaspoonful	3-4 times daily
Over 12 years		
Children 6-12 years	1 teaspoonful	3-4 times daily
Children 1-5 years		3-4 times daily
Children below 1 year	Consult your physician	

3.2 Contraindications

Patients with a history of hypersensitivity to any of the product ingredients.

Patients who have been treated with monoamine oxidase inhibitors (MAOIs) within the previous fourteen days, as the anticholinergic properties of chlorpheniramine are intensified by MAOIs.

In patients with severe hepatic disease (e.g., cirrhosis or hepatitis) because drug retention and subsequent ammonium toxicity or hepatic coma can occur in these patients.

In patients with severe renal impairment (renal failure).

Should not be used in patients with metabolic acidosis or respiratory acidosis because these disease states can be worsened.

In patients when severe metabolic alkalosis due to vomiting of hydrochloric acid is accompanied by a significant loss of sodium (hyponatremia, and excretion of sodium bicarbonate in the urine).

Should not be used in patients with preexisting hyperchloremia.

Special warnings and precautions for use

Chlorpheniramine, in common with other drugs having anticholinergic effects, should be used with caution in epilepsy, severe hypertension and cardiovascular disease, raised intra -ocular pressure including glaucoma; prostatic hypertrophy; bronchitis, bronchiectasis and bronchial asthma. The anticholinergic properties of chlorpheniramine may cause drowsiness, dizziness, blurred vision and psychomotor impairment in some patients which may seriously affect ability to drive and use machinery.

Precautions

4. Children and the elderly are more likely to experience neurological anticholinergic effects and paradoxical excitation (e.g. increased energy, restlessness, nervousness). Avoid use in elderly patients with confusion.

4.1 Interaction with other medicinal products and other forms of interaction

Concurrent use of chlorpheniramine and hypnotics or anxiolytics may potentiate drowsiness. Concurrent use of alcohol may have a similar effect. (see 4.4 Special Warnings and Special Precautions for Use). Chlorpheniramine inhibits phenytoin metabolism and can lead to phenytoin toxicity. The anticholinergic effects of chlorpheniramine are intensified by MAOIs

4.2 Fertility, pregnancy and lactation

Pregnancy

There are no adequate data from the use of chlorpheniramine maleate in pregnant women. The potential risk for humans is unknown. There is no good evidence of an association between first trimester exposure to ammonium chloride and foetal abnormalities. Should not be used during pregnancy unless the benefit to the mother outweighs the potential risk to the foetus.

Lactation

Chlorpheniramine maleate may inhibit lactation and may be secreted in breast milk. The safety of use of ammonium chloride during lactation has not been established

4.3 Effects on ability to drive and use machines

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

4.4 Undesirable effects

Coughcare + may cause certain common side-effects such as headache, dizziness, nausea, fatigue, and dry mouth in some cases. Most of these side effects do not require medical attention and will resolve gradually over time. However, you are advised to talk to your doctor if you experience these side effects persistently.

4.5 Overdose Symptoms and signs

Chlorpheniramine maleate: Overdose is likely to result in effects similar to those listed under adverse reactions. Additional symptoms may include, toxic psychosis, convulsions, apnoea, dystonic reactions and cardiovascular collapse including arrhythmias. Ammonium chloride: Large doses may cause nausea, vomiting, thirst, headache, hyperventilation and progressive drowsiness and lead to profound acidosis and hypokalaemia. Treatment Management should be as clinically indicated

5. Pharmacological properties

5.1 Pharmacodynamic properties

Chlorpheniramine maleate

Pharmacotherapeutic group: Antihistamines for systemic use; ATC code: R06AB04

Antihistamines act to decrease antigen presentation, mediator release and diminish expression of

pro-inflammatory cytokines, cell adhesion molecules and chemotactic factors. The actions of chlorpheniramine include inhibition of histamine on smooth muscle, capillary permeability and hence reduction of oedema and wheal in hypersensitivity reactions such as allergy. Duration of action of 3 to 6 hours has been reported with significant intersubject variation in reported duration of action.

Ammonium chloride

Ammonium chloride has an irritant effect on mucous membranes and is considered to have expectorant properties.

Sodium Citrate

Sodium citrate is considered to increase bronchial secretion by salt action.

5.2 Pharmacokinetic properties

Chlorpheniramine maleate

Absorption

The peak plasma concentrations occur from about 2.5 to 6 hours after administration. The bioavailability is low: values of 25 to 50% have been reported.

Distribution

Approximately 70% of chlorpheniramine in the circulation is bound to plasma proteins. It is distributed in the body, including the CNS. Extensive uptake by lungs, kidneys, liver, and brain have been shown. Volume of distribution of 7.0 L/kg has been reported after oral dosing.

Metabolism

Chlorpheniramine undergoes considerable first-pass metabolism. Chlorpheniramine is extensively metabolized via demethylation in the liver, forming desmethyl- and didesmethylchlorpheniramine.

Elimination

The half-life varies from 2 to 43 hours. Unchanged drug and metabolites are excreted mainly in urine. Considerable intersubject variation (two- to fivefold differences in urinary metabolite excretion) in chlorpheniramine metabolism is found.

Ammonium Chloride

Ammonium salts are effectively absorbed from the gastrointestinal tract. The ammonium ion is converted into urea in the liver; the anion thus liberated into the bloodstream and extracellular fluid causes a metabolic acidosis and decreases the pH of the urine, this is followed by a transient diuresis.

Sodium Citrate

Absorption

Tmax of 98-130min 3.

Volume of distribution

19-39L 3.

Metabolism

Citrate is metabolized to bicarbonate in the liver and plays a role as an intermediate in the citric acid cycle 5 9.

Route of elimination

Largely eliminated through hepatic metabolism with very little cleared by the kidneys

5.3 Preclinical safety data

None.

6. Pharmaceutical particulars

6.1 List of excipients

Menthol, Sucrose, Methyl Paraben, Propyl Paraben, Citric acid monohydrate, sodium citrate, banana green flavor, purified water.

6.2 Incompatibilities

There are no significant incompatibilities with the product.

6.3 Shelf life

3 Years.

6.4 Special precautions for storage

Store in a cool, dark and dry place, below 30°C.

6.5 Nature and contents of container

100 ml amber PET Bottle provided with a measuring cup.

6.6 Special precautions for disposal and other handling

No special requirements for disposal.

7. Marketing authorisation holder

Krishat Pharma Industries Limited KM 15, Lagos-Ibadan Expressway, Ibadan, Oyo State, NIGERIA.

Email: info@krishatpharma.com

8. Marketing authorisation number(s)

NA

9. Date of first authorisation/renewal of the authorisation

NA

10. Date of revision of the text

NA

Company contact details

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