For the use only of Registered Medical Practitioners or a Hospital or a Laboratory

PIRITON EXPECTORANT

1. GENERIC NAME

Chlorpheniramine Maleate, Ammonium Chloride and Sodium Citrate Expectorant

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 mL (one teaspoonful) contains:

Chlorpheniramine Maleate IP	2.5 mg
Ammonium Chloride IP	125 mg
Sodium Citrate IP	55 mg

Colour: Sunset Yellow FCF
in a flavoured syrup base containing Menthol IP

List of Excipients

Sucrose, Sodium Benzoate, Sodium Saccharin, Citric Acid Monohydrate, Propylene Glycol, Menthol, Vanillin, Colour Sunset Yellow FCF, Flavour Ginger Beer RS -77777.

3. DOSAGE FORM AND STRENGTH

Syrup

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

For symptomatic treatment of cough.

4.2 Posology and Method of Administration

Do not exceed the stated dose or frequency of dosing.

Adults and children aged 12 years and over

8 mL every 6 hour.

Special Populations

Elderly
The elderly are more likely to experience neurological anticholinergic effects of chlorpheniramine maleate. Consideration should be given to using a lower daily dose.

Hepatic or Renal Impairment
Contraindicated in the presence of impaired hepatic or renal function.

4.3 Contraindications

PIRITON EXPECTORANT is contraindicated:

- Patients who are hypersensitive to antihistamines or other active substances or to any of the inactive ingredients in the formulation (see *List of Excipients, 4.8 Undesirable Effects*).
- Patients taking monoamine oxidase inhibitors (MAOIs) or in patients who have been treated with MAOIs within the last fourteen days.
- Impaired hepatic or renal function.
- Children under the age of 6 years

4.4 Special Warnings and Precautions for Use

PIRITON EXPECTORANT contains chlorphenamine, and hence should be used with caution in epilepsy; raised intra-ocular pressure including glaucoma; prostatic hypertrophy; severe hypertension or cardiovascular disease; bronchitis, bronchiectasis and asthma; urinary retention. Children and the elderly are more likely to experience the neurological anticholinergic effects and paradoxical excitation (e.g. increased energy, restlessness, nervousness). Avoid use in elderly patients with confusion.

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

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

Concurrent use with drugs which cause sedation such as anxiolytics and hypnotics may cause an increase in sedative effects, therefore medical advice should be sought before taking chlorphenamine concurrently with these medicines.

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

Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrose-isomaltase insufficiency should not take this medicine.

PIRITON EXPECTORANT contains sucrose. This should be taken into account in patients with diabetes mellitus.
Long term use increases the risk of dental caries and it is essential that adequate dental hygiene is maintained.

Keep out of the reach and sight of children.

4.5 Drug Interactions

Concurrent use of chlorpheniramine and hypnotics or anxiolytics may cause an increase in sedative effects. Concurrent use of alcohol may have a similar effect.

Chlorpheniramine inhibits phenytoin metabolism and can lead to phenytoin toxicity.

The anticholinergic effects of chlorpheniramine are intensified by MAOIs. Not to be used in patients taking MAOIs or within 14 days of stopping treatment as there is a risk of serotonin syndrome (see *4.3 Contraindications*).

4.6 Use in Special Population

Pregnancy
The potential risk for humans is unknown. Use during the third trimester may result in reactions in the newborn or premature neonates.
PIRITON EXPECTORANT should not be used during pregnancy unless considered essential by a physician.

Lactation
Chlorpheniramine maleate may inhibit lactation and may be secreted in breast milk.
Not to be used during lactation unless considered essential by a physician.

4.7 Effects on Ability to Drive and Use Machines

PIRITON EXPECTORANT may cause drowsiness, dizziness, blurred vision and psychomotor impairment, which can seriously hamper the patients' ability to drive and use machinery.
Refer to *4.4 Special Warnings And Precautions For Use*

4.8 Undesirable Effects

In absence of availability of adverse event data on the fixed dose combination of chlorpheniramine, ammonium chloride and sodium citrate, adverse event data of the individual ingredients (where available) is presented below.

The following convention has been utilised for the classification of the frequency of adverse reactions: very common (>1/10), common (>1/100 to <1/10), uncommon (>1/1000 to <1/100), rare (>1/10,000 to <1/1000) and very rare (<1/10,000), not known (cannot be estimated from available data).

Chlorpheniramine Maleate

Adverse reactions identified during post-marketing use with chlorphenamine are listed below. As these reactions are reported voluntarily from a population of uncertain size, the frequency of some reactions is unknown but likely to be rare or very rare:

System organ class	Adverse Reaction	Frequency
Nervous system disorders*	Sedation, somnolence	Very common
	Disturbance in attention, abnormal coordination, dizziness, headache	Common
Eye disorders	Blurred vision	Common
Gastrointestinal disorders	Nausea, dry mouth	Common
	Vomiting, abdominal pain, diarrhoea, dyspepsia	Unknown
	Fatigue	Common

System organ class	Adverse Reaction	Frequency
General disorders and administration site conditions	Chest tightness	Unknown
Immune system disorders	Allergic reactions, angioedema, anaphylactic reactions	Unknown
Metabolism and nutritional disorders	Anorexia	Unknown
Blood and lymphatic system disorders	Haemolytic anaemia, blood dyscrasias	Unknown
Musculoskeletal and connective tissue disorders	Muscle twitching, muscle weakness	Unknown
Psychiatric disorders	Confusion*, excitation*, irritability*, nightmares*, depression	Unknown
Renal and urinary disorders:	Urinary retention	Unknown
Skin and subcutaneous disorders	Exfoliative dermatitis, rash, urticaria, photosensitivity	Unknown
Respiratory, thoracic and mediastinal disorders	Thickening of bronchial secretions	Unknown
Vascular disorders	Hypotension	Unknown
Hepatobiliary disorders	Hepatitis, including jaundice	Unknown
Ear and labyrinth disorders	Tinnitus	Unknown
Cardiac disorders	Palpitations, tachycardia, arrythmias	Unknown
General Disorders and administration site conditions	Fatigue	Common
	Chest tightness	Unknown

*Children and the elderly are more susceptible to 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.
Large doses of ammonium chloride may cause nausea, vomiting, thirst, headache, hyperventilation and progressive drowsiness and lead to profound acidosis and hypokalaemia.

Treatment

Management should be as clinically indicated or as recommended by the national poisons centres where available. 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 Mechanism of Action/Pharmacodynamic Effects

Chlorpheniramine maleate

Chlorphenamine is a potent antihistamine (H1-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.

Ammonium chloride

Ammonium chloride has an irritant effect on the gastric mucous membrane.

5.2 Pharmacokinetic Properties

Chlorpheniramine maleate

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.

Ammonium Chloride

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

6. NONCLINICAL PROPERTIES

No additional data of relevance.

7. DESCRIPTION

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8. PHARMACEUTICAL PARTICULARS

8.1 Incompatibilities

There are no relevant data available.

8.2 Shelf Life

The expiry date is indicated on the label and packaging.

8.3 Packaging Information

Amber glass bottle.

8.4 Storage and Handling Instructions

Store in a well-closed container at temperature not exceeding 30°C, protected from direct sunlight.

Keep out of reach of children.

It is dangerous to take this preparation except under medical supervision.

9. PATIENT COUNSELLING INFORMATION

Registered Medical Practitioners may counsel their patients (and/or their patients' caregiver as applicable) about the special warnings and precautions for use, drug interactions, undesirable effects, and any relevant contra-indications of *PIRITON EXPECTORANT.* Patients (and/or patients' caregiver) may also be informed about posology, method of administration and storage/handling information as applicable.

10. DETAILS OF MANUFACTURER

The Manufacturing Site details are mentioned on the label and packaging.

For further information please contact:

GlaxoSmithKline Pharmaceuticals Limited.
Registered Office
Dr. Annie Besant Road, Worli,
Mumbai 400 030, India.

11. DETAILS OF PERMISSION OR LICENCE NUMBER WITH DATE

Manufacturing License number is indicated on the label and packaging.

12. DATE OF REVISION

05-FEB-2024

Trade marks are owned by or licensed to the GSK group of companies

Version: PIREX/PI/IN/2024/01

Adapted from:

- *Piriton Syrup SmPC (last updated on emc: 17 Apr 2023). Available from: https://www.medicines.org.uk/emc/product/3928)*
- *Numark Chesty Cough Expectorant SmPC on MHRA site dated 7 July 2021.*