SUMMARY OF PRODUCT CHARACTERSTICS

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1. Name of the medicinal product

Piriton Expectorant

2. Qualitative and quantitative composition

Each 5 ml contains:

Chlorphenamine maleate B.P. 2mg

Ammonium Chloride B.P. 100mg

3. Pharmaceutical form

It is a clear brownish-yellow viscous liquid with an odour of cherries.

4. Clinical particulars

4.1 Therapeutic indications

Piriton Expectorant is indicated for the symptomatic relief of upper respiratory disorders accompanied by productive cough, including the common cold and bronchitis.

4.2 Posology and method of administration

Oral Administration only

For the relief of cold symptoms: Do not use continuously for more than one week without consulting a doctor.

For symptomatic control of allergic conditions and relief of itch associated with chickenpox: Do not use continuously for more than two weeks without consulting a doctor.

For all indications: Do not exceed the stated dose or frequency of dosing.

Minimum interval between the doses should be 4 hours.

Adults and Children aged 12 years and over: Two 5ml spoonful's every 4 to 6 hours. (Daily max: 24mg i.e. 60ml). Children between 6-11 years: one 5ml spoonful every 4 to 6 hours. (Daily max: 12mg i.e. 30ml).

Children between 2 to 5 years (under medical advice): One dose of 2.5 ml every 4 to 6 hours (daily max: 6 mg i.e., 15ml)

Infants under 2 years: Not recommended.

Elderly: 10ml (4mg) every 4 to 6 hours (daily max 12mg i.e. 30ml).

4.3 Contraindications

Piriton expectorant is contra-indicated in patients who are hypersensitive to antihistamines or to any of the ingredients.

The anticholinergic properties of chlorphenamine are intensified by monoamine oxidase inhibitors (MAOIs). Piriton expectorant 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

Caution is required when there is concurrent usage of alcohol as the expectorant contain 3-4% v/v ethanol

(alcohol). This should be taken into consideration as it is harmful for those suffering from alcoholism. To be taken into account in pregnant or breast-feeding women, children and patients at higher risk of alcohol associated problems, such as patients with liver disease or epilepsy.

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; thyrotoxicosis, hepatic impairment.

Long term treatment with Piriton Expectorant increases the risk of dental caries and it is essential that adequate dental hygiene is maintained. As Piriton expectorant contains 1.95 g of sucrose per 5ml it should be administered with care to patients with diabetes mellitus.

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

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

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.

Ammonium salts are contra-indicated in patients with hepatic or renal impairment.

Methyl, ethyl and propyl hydroxybenzoates may cause allergic reactions (possibly delayed).

Keep out of sight and reach of children.

4.5 Interaction with other medicinal products and other forms of interaction

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 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.

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 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 trails 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: 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, arrythmias

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, 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

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

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via EFDA yellow Card Scheme, online at https://primaryreporting.who-umc.org/ET or toll free call 8482 to Ethiopian food and drug authority (EFDA).

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

ATC Code R06AB02

Chlorphenamine is a potent antihistamine (H_1-antagonist).

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 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 metabolized to the monodesmethyl and didesmethyl derivatives. About 22% of an oral dose is excreted unchanged in the urine. Only trace amounts have been found in the faeces.

5.3 Preclinical safety data

No additional data of relevance.

6. Pharmaceutical particulars

6.1 List of excipients

Sodium Citrate
Glycerol
Sugar
Liquid Glucose
Alcohol 96%
Citric acid Anhydrous
Liquorice Liquid Extract
Levomenthol
Vanillin
Cherry Morella Flavour
Essence of Creme De Menthe
Aniseed Oil
Nipasept
Purified Water

6.2 Incompatibilities

Not Applicable

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Store below 30°C Protect from light.

6.5 Nature and contents of container

Packed in 100 ml round amber colour bottle made of type III glass.

6.6 Special precautions for disposal and other handling

For detailed instructions for use refer to the Patient Information Leaflet in every pack.

7 MARKETING AUTHORISATION HOLDER

GlaxoSmithKline (Kenya) Ltd

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P.O. Box 78392 – 00507

Nairobi

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8 MARKETING AUTHORISATION NUMBER

Certificate No: 05789/07361/REN/2020

9 DATE OF FIRST AUTHORISATION

Mar 18, 2021

10 DATE OF REVISION OF THE TEXT

August 2023