SUMMARY OF PRODUCT CHARACTERSTICS

1. Name of the medicinal product

Piriton Expectorant Linctus

2. Qualitative and quantitative composition

Each 5 ml of syrup contains

Chlorphenamine maleate.....2mg

Ammonium Chloride.....100mg

Sodium Citrate.....44mg

3. Pharmaceutical form

Linctus

4. Clinical particulars

4.1 Therapeutic indications

Piriton Expectorant linctus 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

Do not exceed the stated dose or frequency of dosing

Adults and children 12 years and over: 10ml three to four times a day

Children aged 6 - 12 years: 5ml to 10ml three to four times a day

Children aged 2 - 5 years: 2.5ml to 5 ml three times a day

Children aged 1 - 2 years: 2.5ml twice a day. **Not recommended for children below 1 year**

Elderly: As in adults but such types of patients are prone to confusional psychosis and other neurological anticholinergic effects.

4.3 Contraindications

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

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

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.

Piriton expectorant contains 3.8% v/v ethanol. Harmful for those suffering from alcoholism. To be taken into account in pregnant and breast feeding women, children and high risk groups such as patients with liver disease or epilepsy.

Piriton Expectorant contains 3.9 g of sugar per 10 ml. 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.

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 the reach and sight 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 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 essential by a physician.

Lactation

Chlorphenamine maleate and other antihistamines 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 events 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, diarrhoea, dyspepsia

Hepatobiliary disorders:

Unknown: hepatitis including jaundice

Skin and subcutaneous disorders:

Unknown: exfoliative dermatitis, rash, urticaria, photosensitivity,

Musculoskeletal and connective tissue disorders:

Unknown: muscular 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 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.

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

Chlorphenamine is a potent antihistamine (H_1-antagonist).

Antihistamines diminish or abolish the actions of histamine in the body by competative 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 leukotrines and have been shown to prevent the migration of inflammatory mediators. The actions of chlorphenmine include inhibition of histamine on smooth muscle, cappillary permeability and hence reduction of oedma and wheal in hypersneitivity 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 metabolised to the monodesmethyl and didesmethyl derivatives. About 22% of an oral dose is excreted unchanged in the urine.

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

5.3 Preclinical safety data

No additional data of relevance.

6. Pharmaceutical particulars

6.1 List of excipients

Sodium Citrate BP
Glycerol BP
Sugar BP
Liquid Glucose BP
Alcohol BP 96%
Citric acid Anhydrous BP
Liquorice Liquid Extract B.P

Levomenthol B.P
Vanillin B.P
Cherry Morella Flavour
Essence of Creme De Menthe
Aniseed Oil B.P
Nipasept
Purified Water BP/USP

6.2 Incompatibilities
None known

6.3 Shelf life
3 years.

6.4 Special precautions for storage
Store below 25ºC. Protect from light

6.5 Nature and contents of container
Amber glass bottle containing 100ml Piriton expectorant.

6.6 Special precautions for disposal and other handling
For detailed instructions for use refer to the Patient Information Leaflet in every pack.

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