## 1. NAME OF THE MEDICINAL PRODUCT

(Piriton) Chlorpheniramine maleate BP Syrup

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml of Piriton Syrup contains: Chlorpheniramine maleate BP 2mg.

*(For a full list of actives and excipients, see section 6.1)*

## 3. PHARMACEUTICAL FORM

Light orange yellow liquid

Presentation: 60ml pet bottle in individual packs

## 4. CLINICAL PARTICULARS

### 4.1 Therapeutic indications

Piriton syrup is indicated for symptomatic control of all allergic conditions responsive to antihistamines, including hat fever, vasomotor rhinitis, angioneurotic oedema, food allergies, and drug and serum reactions, insect bites.

### 4.2 Posology and method of administration

The doses below are to be taken three to four times daily or as directed by your physician

Children (Below 6 years): Half to one teaspoonful (2.5-5ml) depending on age and weight.

(6-12 years): One to two teaspoonfuls (5-10ml)

Adults (Above 12 years): Two teaspoonfuls (10ml)

Method of administration

**Route of Administration:** Oral

### 4.3 Contraindications

Piriton is contraindicated in patients who are hypersensitive to antihistamines and those that have had a MOI (monoamine oxidase inhibitor) therapy within 14 days.

### 4.4 Special warnings and precautions for use

Chlorpheniramine may have an additive effect when used concurrently with hypnotics and anxiolytics causing potentiation of drowsiness.

A similar additive effect will result from concurrent usage of alcohol with Chlorpheniramine. Monoamine oxidase inhibitor therapy intensifies the anticholinergic effects of Chlorpheniramine. Chlorpheniramine inhibits phenytoin metabolism and can lead to Phenytoin toxicity. The anticholinergic properties of Chlorpheniramine may cause drowsiness, dizziness, blurred vision and psychomotor impairment, which can seriously hamper the patient's ability to drive and use machinery.

Piriton should only be used during pregnancy when clearly needed and when potential benefit outweighs the potential risks to the foetus.

## 4.5 Interaction with other medicinal products and other forms of interaction

Concurrent use of Chlorpheniramine and hypnotics or anxiolytics may cause an increase in sedative effects, concurrent use of alcohol may have a similar effect therefore medical advice should be sought before taking Chlorpheniramine concurrently with these medicines.

Chlorpheniramine inhibits phenytoin metabolism and can lead to phenytoin toxicity.

The anticholinergic effects of Chlorpheniramine are intensified by MAOIs.

## 4.6 Pregnancy and Lactation

**Pregnancy:**
There are no adequate data from the use of Chlorpheniramine 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:**
Chlorpheniramine 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 Chlorpheniramine 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

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).

Adverse reactions identified during post-marketing use with Chlorpheniramine 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 |
| Immune system disorders: | Allergic reaction, 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 (e.g. increased energy, restlessness, nervousness)

## 4.9 Overdose

**Symptoms and signs**

The estimated lethal dose of Chlorpheniramine 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**

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** Pharmacodynamics properties

**Pharmacotherapeutic group:** Anti-histamine, ATC code: { R06AB02}

**Mechanism of action**

Chlorpheniramine is a potent antihistamine (H1-antagonist).

Antihistamines diminish or abolish the actions of histamine in the body by competative reversible blockade of histamine H1-receptor sites on tissues. Chlorpheniramine 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, capillary permeability and hence reduction of oedema and wheal in hypersensitivity reactions such as allergy and anaphylaxis.

### 5.2 Pharmacokinetic properties

Chlorpheniramine is well absorbed from the gastro-intestinal tract, following oral administration. The effects develop within 30 minutes, are maximal within I to 2 hours and last 4 to 6 hours. The plasma half-life has been estimated to be 12 to 15 hours.
Chlorpheniramine is metabolised to the monodesmethyl and didesmethyl derivatives. About 22% of an oral dose is excreted unchanged in the urine.

### 5.3 Preclinical safety data

No additional data of relevance.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Sugar Granulated
Liquid Glucose SO2 Free
Glycerol
Chlorpheniramine Maleate
Nipasept
Methyl Paraben
Propyl Paraben
Peppermint Oil
Ethanol 96%
Sunset yellow Ariavit 311831
Hydrochloric Acid
Demin water (PURIFIED WATER)

**6.2 Incompatibilities:** Not applicable.

**6.3 Shelf life:** 3 years; use within 2 weeks after opening

### 6.4 Special precautions for storage

Store below 30°C away from light. Keep out of the reach of children

### 6.5 Nature and contents of container

Light orange yellow liquid
Presentation: 60ml pet bottle in individual packs

**6.6 Special precautions for disposal:** No special requirements.

## 7. APPLICANT/MANUFACTURER

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