Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Piriton Allergy 4mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 4mg Chlorphenamine maleate.
Excipients: contains lactose monohydrate 94.5mg
For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet
Yellow, circular, biconvex tablets with a breakline on both sides. They are engraved with a "P" to one side of the breakline, on one face.
The tablet can be divided into equal halves.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

The tablets are indicated for symptomatic control of allergic conditions responsive to antihistamines, including hay fever, vasomotor rhinitis, urticaria, food allergy, drug and serum reactions, insect bites. Also indicated for the symptomatic relief of itch associated with chickenpox.

4.2 Posology and method of administration

Oral use.

Adults and children 12 years and over:
The usual dose is 1 tablet every 4 - 6 hours (maximum of 6 tablets in 24 hours).

In the elderly:
The usual dose is 1 tablet every 4 - 6 hours (maximum of 3 tablets in 24 hours).
Dosage should be as low as possible in view of greater susceptibility to anticholinergic central nervous system effects with a maximum of 12mg (3 tablets) in 24 hours.

Children 6 - 12 years:
The usual dose is 0.1mg/kg or ½ a tablet every 4 - 6 hours (maximum of 6 half tablets in 24 hours).

Children under 6 years:
Not recommended for children under the age of 6 years.

Do not exceed the stated dose or frequency of dosing. Minimum dosing interval 4 hours.

Do not use continuously for more than two weeks without consulting a doctor.

Patients with severe renal or hepatic impairment should seek doctor's advice prior to taking this medicine. (See Section 4.4 Special warnings and precautions for use).

4.3 Contraindications

1. Use in patients hypersensitive to the active ingredient or any other constituents.
2. Pre-coma states.
3. Use in patients who have been on recent MAO inhibitor therapy, within the previous 14 days (as the anticholinergic properties of chlorphenamine are intensified by MAOIs).

4.4 Special warnings and precautions for use

This product may act as a cerebral stimulant in children and occasionally in adults, giving rise to insomnia, nervousness, hyperpyrexia, tremors and epileptiform convulsions.

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

Chlorphenamine, 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, severe hepatic impairment, severe renal impairment, bronchitis, thyrotoxicosis, bronchiectasis and bronchial asthma.

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

Chlorphenamine may increase the effects of alcohol and therefore concurrent use should be avoided.

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.

Avoid use in elderly patients with confusion.

Should not be used with other anti-histamine containing products, including anti-histamine containing cough and cold preparations.

This medicinal product contains lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

Keep out of the sight and reach of children.

4.5 Interaction with other medicinal products and other forms of interaction

Chlorphenamine 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 chlorphenamine.

The effects of anti-cholinergics e.g. some psychotropic drugs and atropine, may be potentiated by this product giving rise to tachycardia, mouth dryness, gastrointestinal disturbances e.g. dyskinesia, colic, urinary retention and headache.

As monoamine oxidase inhibitor therapy intensifies the anticholinergic effects of chlorphenamine, concurrent therapy is contra-indicated.

Chlorphenamine inhibits phenytoin metabolism and can lead to phenytoin toxicity.

4.6 Fertility, pregnancy and lactation

This product should not be used during pregnancy or lactation unless considered essential by the physician. Animal studies have not been conducted nor are there specific studies in human beings. Use during the third trimester may result in reactions in the newborn or premature neonates.
Small amounts of anti-histamines are excreted in breast milk.
Use by nursing mothers is not recommended because of the risks of adverse effects in the infant. Antihistamines may inhibit lactation.

4.7 Effects on ability to drive and use machines

The anticholinergic properties of chlorphenamine may cause drowsiness, dizziness, blurred vision and psychomotor impairment in some patients which may seriously affect ability to drive and use machinery.
Do not drive whilst taking this medicine until you know how this medicine affects you.

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 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	Uncommon
General disorders and administration site conditions	Fatigue	Common
	Chest tightness	Unknown
Blood and Lymphatic system disorders	Haemolytic anaemia, thrombocytopenic purpura. Other blood dyscrasias including agranulocytosis, anaemia, aplastic anaemia, eosinophilia, leucopenia and thrombocytopenia	Very rare
Hepatobiliary disorders	Hepatitis including jaundice	Very rare
Immune system disorders	Allergic reactions, angioedema, anaphylactic reactions	Unknown
Metabolism and nutritional disorders	Anorexia	Unknown
Musculoskeletal and connective tissue disorders	Muscle twitching, muscle weakness	Unknown
Psychiatric disorders	Confusion*, excitation*, irritability*, nightmares*	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

*Children and the elderly are more susceptible to neurological anticholinergic effects and paradoxical excitation (e.g. 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 professional are asked to report any suspected adverse reactions via HPRA Pharmacovigilance website: www.hpra.ie.

4.9 Overdose

The estimated lethal dose of Piriton is 25 to 50mg/kg body weight.

Symptoms and Signs
Overdose is likely to result in effects similar to those listed under adverse reactions. Symptoms and signs include sedation, paradoxical stimulation of CNS, toxic psychosis, seizures, apnoea, convulsions, 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 should include gastric lavage or induced emesis.

Following these measures activated charcoal and cathartics may be administered to minimise absorption. In cases of suspected overdose, symptomatic and supportive therapy should be given as appropriate.

Convulsions and marked CNS stimulation should be treated with parenteral diazepam.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Mode of Action:
Chlorphenamine maleate is a potent antihistamine (H1-receptor antagonist). Antihistamines diminish or abolish the actions of histamine in the body by competitive reversible blockade of histamine 1 receptor sites on tissues. Chlorphenamine also has anticholinergic activity.

Chlorphenamine maleate is a potent antihistamine (H_1-antagonist).

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. Only trace amounts have been found in the faeces.

5.3 Preclinical safety data

No preclinical data presented.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate
Maize starch
Pregelatinised maize starch
Yellow iron oxide (E172)
Magnesium stearate

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 30ºC.

6.5 Nature and contents of container

Piriton Tablets are supplied in polypropylene containers (securitainers) of 500, with tamper-evident snap-on polyethylene lids or cartons of 30, containing three blister packs of 10 tablets or two blister packs of 15 tablets, cartons of 45 containing 3 blister packs of 15 tablets or cartons of 60 containing 4 packs of 15 tablets.

The packs comprise PVDC coated white opaque PVC blisters, sealed to a bilayer of Aluminium foil/paper/LDPE lacquered child resistant aluminium foil.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Haleon Ireland Limited
12 Riverwalk
Citywest Business Campus
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER

PA0678/080/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 10 June 1985

Date of last renewal: 10 June 2010

10 DATE OF REVISION OF THE TEXT

January 2024