SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Chlorphenamine 2 mg/5 ml Oral Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml of oral solution contains 2 mg of Chlorphenamine Maleate.

Excipients with known effect (in each 5 ml):
Maltitol Liquid (E965) 1.25 g
Sodium Methyl Parahydroxybenzoate (E219) 9.0 mg
Sodium Propyl Parahydroxybenzoate (E217) 2.0 mg
Propylene glycol (E1520) 4.8 mg.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral Solution
A clear, colourless liquid with a strawberry flavour.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the symptomatic control of all allergic conditions responsive to antihistamines, including hay fever, vasomotor rhinitis, urticaria, angioneurotic oedema, food allergy, drug and serum reactions, insect bites.

Also for the symptomatic relief of itch associated with chickenpox.

4.2 Posology and method of administration

Posology

Do not exceed the stated dose or frequency of dosing.

Adults and Children 12 years and over: 10ml (4mg) every 4 to 6 hourly. Maximum daily dose: 60ml (24mg) in any 24 hours.

Elderly: The elderly are more likely to experience neurological anticholinergic effects. Consideration should be given to using a lower daily dose (e.g. a maximum of 12 mg in any 24 hours).

Children aged 6 - 12 years: 5ml (2mg) every 4 to 6 hourly. Maximum daily dose: 30ml (12mg) in any 24 hours.

Children aged 2 - 6 years: 2.5ml (1mg) every 4 to 6 hourly. Maximum daily dose: 15ml (6mg) in any 24 hours.

Children aged 1 - 2 years: 2.5ml (1mg) twice daily. The minimum interval between the doses should be 4 hours. Maximum daily dose: 5ml (2mg) in any 24 hours.

Not recommended for children below 1 year.

Method of administration

Oral administration only.

4.3 Contraindications

Hypersensitivity to chlorphenamine maleate, any other antihistamines or to any of the excipients listed in section 6.1.

The anticholinergic properties of chlorphenamine are intensified by monoamine oxidase inhibitors (MAOIs). Chlorphenamine Oral Solution 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; renal impairment. Children and the elderly are more likely to experience the neurological anticholinergic effects and paradoxical excitation (eg. increased energy, restlessness, nervousness). Avoid use in elderly patients with confusion.

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.

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.

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.

Patients with rare hereditary problems of fructose intolerance should not take this medicine, as it contains maltitol liquid. Maltitol may also have a mild laxative effect. Each 5ml of this product contains 1.25g of maltitol liquid. Calorific value 2.3 kcal/g maltitol.

This medicine contains sodium methyl and propyl parahydroxybenzoates (E219 & E217) which may cause allergic reactions (possibly delayed).

This medicine contains 4.8 mg of propylene glycol (E1520) per 5ml which is equivalent to 0.96 mg/ml.

This medicine contains less than 1 mmol sodium (23mg) per 5ml dose, that is to say “essentially sodium free”.

Keep out of the sight and reach of children.

4.5 Interaction with other medicinal products and other forms of interaction

Anxiolytics and Hypnotics: concurrent use of chlorphenamine 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 chlorphenamine concurrently with these medicines.

Antiepileptics: chlorphenamine inhibits phenytoin metabolism and can lead to phenytoin toxicity.

Antidepressants: the anticholinergic effects of chlorphenamine are intensified by MAOIs (see section 4.3 contraindications)

4.6 Fertility, 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.

Breast-feeding

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

Chlorphenamine may have moderate influence on the 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 or 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 trials 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 tissue 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)

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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: R06A B02

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 leukotrines 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 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

Xanthan gum

Sodium methyl parahydroxybenzoate (E219)

Sodium propyl parahydroxybenzoate (E217)

Maltitol liquid (E965)

Sodium saccharin

Citric acid monohydrate

Strawberry flavour (contains nature identical flavouring substances and propylene glycol (E1520))

Purified water

6.2 Incompatibilities

None known

6.3 Shelf life

Unopened: 3 years

After first opening: 28 days

6.4 Special precautions for storage

Do not store above 25°C.

Keep the bottle in the outer carton in order to protect the medicine from light.

6.5 Nature and contents of container

Amber glass bottle with polypropylene child resistant tamper evident cap containing 150 ml. A syringe and neck fitting syringe adaptor are supplied with this product.

6.6 Special precautions for disposal

No special requirements.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

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