SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Chlorphenamine 4 mg Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains chlorphenamine maleate 4mg

Excipient(s) with known effect:

Each tablet contains 100 mg lactose (as monohydrate).

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablet

Yellow uncoated convex tablets with break-line on one side.

The tablet can be divided into two equal doses

4. CLINICAL PARTICULARS

4.1. Therapeutic Indications

The symptomatic control of allergic conditions which respond to anti-histamines including hay fever, urticaria, vasomotor rhinitis, food allergy, drug and serum reactions, pruritis vulvae, pruritis ani, and insect bites.

4.2. Posology and Method of Administration

The route of administration for chlorphenamine tablets is oral.

Adults and the elderly

4 mg every 4-6 hours (maximum of 24mg daily).

Children

6 - 12 years: 2mg every 4-6 hours (maximum of 12mg daily).

Not recommended for use in children under 6 years of age.

4.3 Contraindications

The tablets are contraindicated in patients who are hypersensitive to antihistamines or any of the other tablet ingredients.

The anticholinergic properties of chlorphenamine are intensified by monoamine oxidase inhibitors (MAOIs). Chlorphenamine is therefore contraindicated in patients who have been treated with MAOIs within the last fourteen days.

4.4 Special warnings and precautions for use

In common with other drugs having anticholinergic effects, chlorphenamine should be used with caution in conditions such as 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 (e.g increased energy, restlessness, nervousness). 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.

Excipients
Contains lactose. Patients with rare hereditary problems of galactose intolerance, the total 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

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 Fertility, 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 essential 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 in some patients which may seriously affect 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 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 reactions identified during post-marketing use is unknown.

Blood and lymphatic system disorders: Unknown: Blood dyscrasias including haemolytic anaemia

Immune system disorders: Unknown: Hypersensitivity, angioedema, anaphylactic reactions

Metabolism and nutrition disorders: Unknown: Anorexia

Psychiatric disorders: Unknown: Depression, confusion*, excitation*,irritability*, nightmares*

Nervous system disorders:*
Very common: sedation, somnolence

Common: disturbance in attention, headache, dizziness, abnormal co-ordination,

Eye disorders: Common: Blurred vision

Ear and labyrinth disorders: Unknown: Tinnitus

Cardiac disorders: Unknown: Tachycardia, palpitations, cardiac arrhythmias

Vascular disorders: Unknown: Hypotension

Respiratory, thoracic or mediastinal disorders: Unknown: thickening of bronchial secretions

Gastrointestinal disorders: Common: Nausea, Dry mouth,
Unknown: dyspepsia, vomiting, diarrhoea, abdominal pain

Hepatobiliary disorders: Unknown: Hepatitis, jaundice

Skin and subcutaneous disorders: Unknown: Skin rash, urticaria, exfoliative dermatitis, photosensitivity

Musculoskeletal and connective tissue disorders: Unknown: Muscle twitching, muscular weakness

Renal and urinary disorders: Unknown: Urinary retention

General disorders:
Common: Fatigue
Unknown: Chest tightness

*Children and the elderly are more likely to experience 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 professionals are asked to report any suspected adverse reactions via Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

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

5.1 Pharmacodynamic properties

ATC code R06AB02
Mechanism of action

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

Pharmacodynamic effects

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

Absorption

Chlorphenamine is well absorbed from the gastrointestinal tract and following oral administration the effects develop within 30 minutes, and are maximal within 1 to 2 hours and last about 4 to 6 hours. The plasma half life has been estimated to be 12 to 15 hours.

Distribution

The drug is widely distributed throughout the body including the CNS.

Biotransformation

The main site of metabolic transformation is in the liver. Chlorphenamine is metabolised to the monodesmethyl and didesmethyl derivatives. About 22% of an oral dose is excreted unchanged in the urine.

Elimination

Little if any is excreted unchanged in the urine; most appears there as degradation products that are almost completely excreted within 24 hours. The drug is eliminated more rapidly by children than by adults.

5.3. Pre-clinical Safety Data

No data of relevance which is additional to that already included in other sections of the SPC.

6.1 List of excipients

Lactose
Maize starch
Magnesium stearate
Colloidal silicon dioxide
Quinoline yellow E104

6.2. Incompatibilities

Not applicable.

6.3. Shelf Life

3 years.
Do not use after the expiry date given on the pack.

6.4. Special Precautions for Storage

Store below 25°C, protect from light.

6.5 Nature and contents of container

Al/PVC blister strips enclosed in an outer carton
Pack sizes of 28, 30, 100, 250, 500 and 1000 tablets

Not all pack sizes may be marketed.

6.6. Instructions for Use/Handling

Not applicable.

7. MARKETING AUTHORISATION HOLDER

Strides Pharma UK Ltd
Unit 4 The Metro Centre
Dwight Road

Watford WD18 9SS
United Kingdom

8. MARKETING AUTHORISATION NUMBER(S)

PL 13606/0043

9. DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

21st October 1996

10 DATE OF REVISION OF THE TEXT

02/09/2024