SUMMARY OF PRODUCT CHARACTERISTICS

Chlorphenamine 4mg Tablets

Summary of Product Characteristics (SmPC) Updated 04/06/2020| Phyto-Riker (GIHOC) Pharma. L.t.d.

1. NAME OF THE MEDICINAL PRODUCT

Chlorphenamine 4mg Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains Chlorphenamine maleate 4mg BP
For a full list of excipients, see Section 6.1.

3. PHARMACEUTICAL FORM

Yellowish flat tablets with breakline on one side.

4. Clinical particulars

4.1 Therapeutic indications

Chlorphenamine is indicated for symptomatic control of all allergic conditions responsive to antihistamines. Thus it provides temporary relief of sneezing, watery and itchy eyes, and runny nose due to hay fever, vasomotor rhinitis, urticaria, angioneurotic oedema, food allergies, drug and serum reactions, insect bites and other upper respiratory allergies.

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: 1 tablet 4 to 6 hourly. Maximum daily dose: 6 tablets (24 mg) 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: ½ tablet 4 to 6 hourly. Maximum daily dose: 3 tablets (12mg) in any 24 hours
Not recommended for children under 6 years

Method of administration

For oral use only

4.3 Contraindications

Contraindicated in patients with a history of hypersensitivity to chlorphenamine or any component of this drug.
The anticholinergic properties of chlorphenamine are intensified by monoamine oxidase inhibitors (MAOIs). Chlorphenamine is therefore contra-indicated in patients who have been treated with MAOIs within the last fourteen days. It is also contraindicated in patients with narrow-angle glaucoma.

4.4 Special warnings and precautions for oral use

Keep all medicines out of the reach and sight of children.

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).

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.
Patients with rare hereditary problems of galactose intolerance, Lapp lactase deficiency or glucose-galactose
malabsorption should not take this medicine,

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 maleate in pregnant women. The potentisl 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 essentially 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, 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 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 Sytem Organ Class. The frequency of other adverse reactions 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, arrhythmias

Vascular disorders:
Unnown: 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: muscle 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 likely to experience the neurological anticholinergic effects and paradoxical excitation (eg. increased energy, restlessness, nervousness).

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after marketing authorization of a medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare providers and patients are asked to report any suspected adverse reactions to Chlorphenamine via info@phyto-riker.com.gh or www.phyto-riker.com.gh or using the patient report form

4.9 Overdose

Symptoms and signs
The estimated lethal dose of chlorphenamine is 25 to 50mg/kg body weight. Symptoms and signs include dry mouth, flushed skin, dilated pupils, 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 R06AB02

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.
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

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
Lactose, Mannitol, Maize Starch, Gelatin, Methylhdroxybenzoate, Stearic Acid, D&C Yellow, Purified Talcum.

6.2 Incompatibilities

There are no relevant data available.

6.3 Shelf life

4 years

6.4 Special precautions for storage

Store away from light in a cool dry place (below 30^0c).

6.5 Nature and contents of container

2000's, 1500, 1000, 500, 100 Bulk pack
100X15, 100X10, 50X10, 10X10 PVC and Aluminium foil blister packs
Not all pack sizes may be marketed

6.6 Special precautions for disposal
No special requirements
Any unused product or waste material should be disposed of in accordance with local requirements

7. APPLICANT

Phyto-Riker (GIHOC) Pharmaceuticals Ltd.
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8. FDA REGISTRATION NUMBER

FDA/GD.04-7051

9. DATE OF RENEWAL OF REGISTRATION

17/04/2020

10. DATE OF REVISION OF THE TEXT

04/06/2020

Reference List

Summary of Product Characteristics Template by the FDA, Document No: FDA/DRI/DER/TP-SPC/2013/03, Version No: 02.

Piriton tablets Summary of Product Characteristics, GlaxoSmithKline Consumer Healthcare (UK) Trading Limited. Available at: https://www.medicines.org.uk/emc/product/20/smpc

Chlorpeniramine tablets Summary of Product Characteristics, Bristol Laboratories Limited, UK. Available at: *https://www.medicines.org.uk/emc/product/2887/smpc*

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