STACTIFED TABLETS

CHLORPHENIRAMINE MALEATE TABLETS 4mg

Summary of Product Characteristics

Document type:	Summary of Product Characteristics
Document status:	Final
Release date:	20th Feb. 2019
Number of pages:	6 pages

1 NAME OF THE MEDICINAL PRODUCT

Stactifed Tablets

Chlorpheniramine Maleate Tablets 4mg

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each uncoated tablets contains:

Chlorphenamine Maleate BP	4mg
Excipients	q.s.
(Approved colour used)	

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral Tablets.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indication.

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

4.2 Posology and method of administration.

The route of administration for chlorphenamine tablets is oral

Adults and the elderly

4mg 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 precaution 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 Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

Contains the colouring agent Sunset Yellow (E110), which can cause hypersensitivity reactions including asthma. Allergy is more common in those people who are allergic to aspirin.

Keep out of the sight and reach of children.

4.5 Interaction with other medicinal product 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 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 Effect on the ability to drive and use machine.

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 effect.

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.

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 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 Preclinical safety data.

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

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maize Starch,
Microcrystalline Cellulose,
Povidone,
Methyl Paraben,
Propyl Paraben,
Colour Tartrazine yellow,
Purified Talc,
Magenesium Stearate,
Sodium Starch Glycolate,
Aerosil,

6.2 Incompatibilities
unknown

6.3 Shelf-life
36 months

6.4 Special precautions for storage

Medicines should be kept out of the reach of children.

Store in a cool, dry place below 30°C. Do not allow to freeze. Protect from light.

6.5 Nature and composition of immediate packaging

10 tablets to be packed in a blister made up of printed aluminium foil / rigid, non-toxic PVC film. Such 10 blisters to be packed in a carton with a leaflet.

6.6 Special precautions for the disposal of unused medicinal products or waste materials

None.

7 MARKETING AUTHORISATION HOLDER

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