Summary of Product Characteristics

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1. NAME OF THE MEDICINAL PRODUCT

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Chlorphenamine syrup BP 2 mg/5ml

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml contains:
Chlorphenamine Maleate BP 2 mg

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Oral syrup

Yellow Coloured Syrup

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

Chlorphenamine Oral Solution indicated for 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 indicated for the symptomatic relief of itch associated with chickenpox.

4.2 Posology and Method of administration

Adults and children over 12 years

Two 5ml doses every four to six hours up to a maximum of six doses in 24 hours as required.

Children 6 to 12 years

One 5ml dose every four to six hours up to a maximum of six doses in 24 hours as required.

Children 2 to 5 years

One 2.5ml dose every four to six hours up to a maximum of six doses in 24 hours as required.

Children 1 to 2 years

One 2.5ml dose twice a day up to a maximum of two doses in 24 hours as required.

Children under 1 year

Not recommended.

Elderly

The normal adult dose is appropriate for the elderly

Route of administration: Oral

4.3 Contraindications

Chlorphenamine Oral Solution contra-indicated in patients who are hypersensitive to antihistamines or to any of the tablet ingredients.

The anticholinergic properties of Chlorphenamine are intensified by monoamine oxidase inhibitors (MAOIs). Chlorphenamine Tablets is therefore contra-indicated in patients who have been treated with MAOIs within the last fourteen day

4.4 Special warnings and precautions for use

- Should be given with caution to patients with epilepsy, severe cardiovascular disorders, liver disorders, glaucoma, urinary retention, prostatic enlargement, pyloroduodenal obstruction, asthma, bronchitis, bronchiectasis, thyrotoxicosis and severe hypertension.
- Special care should be taken when using Chlorphenamine maleate in children and the elderly as they are more prone to developing neurological anticholinergic effects.
- Warning: May cause drowsiness. If affected do not drive or operate machinery. Avoid alcoholic drink.
- If symptoms do not go away within 5 days talk to your pharmacist or doctor.
- Keep all medicines out of the reach of children.
- Although most antihistamines should be avoided by patients with porphyria, Chlorphenamine maleate has been used and is thought to be safe.

4.5 Interaction with other medicinal products and other forms of interact.

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.

4.6 Fertility, Pregnancy and Lactation

Pregnancy:

There is inadequate evidence of safety in human pregnancy. Chlorphenamine should only be used in pregnancy when clearly needed and when the potential benefits outweigh the potential unknown risks to the foetus. Using during the third trimester may result in reactions in neonates and premature babies.

Lactation:

Chlorphenamine may be secreted in breast milk. The use of Chlorphenamine in breast feeding mothers is not recommended.

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

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:

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 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 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 EFDA yellow Card Scheme, online at https://primaryreporting.who-umc.org/ET or toll free call 8482 to Ethiopian food and drug authority (EFDA).

4.9 Overdose

Symptoms:

Symptoms and signs include sedation, paradoxical stimulation of CNS, toxic psychosis, seizures, apnoea, convulsions, anticholinergic effects, dystonic reactions and cardiovascular collapse including arrhythmias.

Treatment:

Treatment with activated charcoal should be considered provided there are no contraindications for use and the overdose has been taken recently.

5.0 Pharmacological Properties

5.1 Pharmacodynamic Properties

Pharmacotherapeutic group: Antihistamines

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.

Antihistamines act to prevent the release of histamine, prostaglandins and leukotriene 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 oedma and wheal in hypersensitivity reactions such as allergy and anaphylaxis.

5.2 Pharmacokinetic properties

Chlorphenamine maleate is almost completely absorbed after administration by mouth, peak plasma concentrations occurring at about 2.5 to 6 hours. The drug is widely distributed including passage into the CNS, with a volume of distribution of between 1 and 10L/KG. About 70% of Chlorphenamine in the circulation is protein-bound. Chlorphenamine undergoes some first pass metabolism and enterohepatic recycling. Chlorphenamine is extensively metabolised, principally to inactive desmethylated metabolites which are excreted primarily in the urine, together with about 35% unchanged drug. Only trace amounts are excreted in the faeces. The mean elimination half life has been reported to be about 30 hours, with mean values ranging from 2 to 43 hours

5.3 Preclinical safety data

Not Applicable

6.0 Pharmaceutical particulars

6.1 List of excipients

Sodium Benzoate, Disodium Edetate, Sucrose, Bronopol, Glycerol, Citric Acid Monohydrate BP, Flavour Mixed Fruit Flavour, Tartrazine Supra, Purified Water .

6.2 Incompatibilities

Not applicable

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Store at a temperature not exceeding 30°C in a dry place. Protect from light.

6.5 Nature and contents of container

100 ml oral solution packed in Amber coloured PET Bottle, PET bottle further packed in Unit Carton along with Leaflet.

6.6 Special precautions for disposal and other handling

No special requirements

7 Marketing Authorisation Holder

FECCOX PHARMACY AND GENERAL ENTERPRISES LTD,
JABA LAYOUT OFF AIRPORT RD KANO KANO

7. Number(s) in the national register of finished pharmaceutical products

Certificate No: 07898/3523/NMR/2017

8. Date of first authorisation/renewal of the authorisation

Oct 6, 2022

9. Date of revision of the text

August 2024