UCGOD CHLORPHENAMINE TABLET 4MG.

1. Name of the medicinal product

UCGOD chlorphenamine tablet 4mg.

2. Qualitative and quantitative composition

Each tablet contains 4 mg of Chlorphenamine maleate.

For the full list of excipients, see section 6.1.

3. Pharmaceutical form

Tablet

A white round biconvex tablet plain on one side and a dividing line on the reverse side.

4. Clinical particulars

4.1 Therapeutic indications

The tablets are indicated for symptomatic control of all allergic conditions responsive to antihistamines including hay fever, vasomotor rhinitis, urticaria, angioneurotic oedema, food allergies, drug and serum reactions and insect bites.

Also indicated for the symptomatic relief of itch associated with chickenpox.

4.2 Posology and method of administration

Posology

Adults and children over 12 years:

1 tablet (4mg) every 4 to 6 hourly.

Maximum daily dose: 6 tablets (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:

½ tablet (2mg) 4 to 6 hourly.

Maximum daily dose: 3 tablets (12mg) in any 24 hours.

Not recommended for children under the age of 6 years.

Method of administration

For oral administration only

Do not exceed the stated dose or frequency of dosing.

4.3 Contraindications

• Hypersensitivity to the active substance, antihistamines or to any of the excipients listed in section 6.1.

• The anti-cholinergic properties of chlorphenamine are intensified by monoamine oxidase inhibitors (MAOIs). The tablets are therefore contraindicated 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).

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.

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 section 4.3).

4.6 Fertility, pregnancy and lactation

Pregnancy

There is 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 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 patient's 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: 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, 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 (e.g. increased energy, restlessness, nervousness).

4.9 Overdose

Symptoms and signs

The estimated lethal dose of chlorphenamine is 25 to 50mg per kg body weight. Symptoms and signs include sedation, paradoxical excitation of the CNS, toxic psychosis, apnoea, convulsions, 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). Hypotension and arrhythmias should be treated 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: R06AB04

Chlorphenamine is a potent histamine H1, receptor 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 readily absorbed from the GI 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 is estimated to be 12 – 15 hours.

There is significant plasma protein binding. The drug is largely inactivated in the liver and excreted as metabolites in the urine. Chlorphenamine is metabolised to the monodesmethyl

and didesmethyl derivative. About 22% of an oral dose is excreted unchanged in the urine. Only trace amounts have been found in the faeces.

5.3 Preclinical safety data

None stated.

6. Pharmaceutical particulars

6.1 List of excipients

Lactose

Corn starch

Methyl Paraben

Propyl Paraben

Talcum powder

Magnesium Stearate

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Do not store above 30°C.

Store in the original package for blister packs.

Keep container tightly closed for bottles.

6.5 Nature and contents of container

Blister packs PVC: 250microns, Aluminium foil 20 microns

6.6 Special precautions for disposal and other handling

No special requirements

7. Marketing authorization holder

Distributed by

UCGOD Pharmaceutical Ltd.

6, Oba T.T, Dada Avenue, Dental Bus Stop, Along Idiroko Road, Ota, Ogun State Nigeria

UCGOD CHLORPHENAMINE TABLET 4MG.

Manufactured by

Daily Sun Pharmaceutical Company Limited

Plot 3 & 4, Tomori Industrial Estate, Off Idi-Iroko Road, Ota, Ogun State, Nigeria.