1 NAME OF THE MEDICINAL PRODUCT

Chlorphenamine Tablets 4 mg
Numark Antihistamine and Allergy Relief 4mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 4.00 mg chlorphenamine maleate.
For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Yellow, normal convex tablet engraved with company logo on one side, and a breakline and B094 on the other side.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications
Chlorphenamine tablets are indicated for symptomatic control of all allergic conditions responsive to antihistamines, including hay fever, vasomotor rhinitis, urticaria, angioneurotic oedema, food allergy, drug and serum reaction, pruritus am et vulvae, and insect bites.

4.2 Posology and method of administration

Adults and children 12 years and over: 1 tablet every 4-6 hours. Maximum daily dose 24mg (6 tablets) 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 daily dose of 12mg (3 tablets) in any 24 hours).

Children aged 6–12 years: ½ tablet every 4-6 hours. Maximum daily dose 12mg (3 tablets) in any 24 hours.

Children under 6 years: Not recommended.

4.3 Contraindications

Hypersensitivity to other antihistamines, chlorphenamine maleate or any of the other tablet ingredients.

The anticholinergic properties of chlorphenamine are intensified by monoamine oxidase inhibitors (MAOIs). Chlorphenamine tablets are therefore contra-indicated in patients who have been treated with MAOIs within the last fourteen days.
4.4 Special warnings and precautions for use

The sedative action of alcohol is potentiated when administered concomitantly with chlorphenamine.

Special care should be taken when using chlorphenamine maleate in children and the elderly as they are more prone to developing neurological anticholinergic effects such as drowsiness, dizziness, blurred vision, psychomotor impairment, sedation, confusion and hypotension. Paradoxical reactions characterised by hyperexcitability (e.g. increased energy, restlessness and nervousness) have also been reported in children and the elderly.

Chlorphenamine, in common with other drugs having anticholinergic effects, should be used with caution in epilepsy; raised intra-ocular pressure including glaucoma; pyloroduodenal obstruction; urinary retention; prostatic hypertrophy; severe hypertension or cardiovascular disease; bronchitis, bronchiectasis and asthma; hepatic disease and thyrotoxicosis.

Although most antihistamines should be avoided by patients with porphyria, chlorphenamine maleate has been used and is thought to be safe.

Should not be used with other antihistamine containing products, including antihistamine containing cough and cold medicines.

Patients with rare hereditary problems of galactose intolerance, the 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 administration of chlorphenamine with alcohol, antihypertensive agents with CNS depressant effect (such as clonidine and methyldopa), CNS depressants such as hypnotics, anxiolytics, sedatives, opioid analgesics, neuroleptics and tricyclic antidepressants may potentiate the CNS depressant effects of either of these medications or that of chlorphenamine.

Concurrent administration of chlorphenamine with drugs possessing antimuscarinic properties such as amantadine, antimuscarinics especially atropine and related compounds, haloperidol, phenothiazines or procainamide potentiate the antimuscarinic effects.

Concurrent use with ototoxic medication such as cisplatin, paromomycin, salicylates and vancomycin with chlorphenamine may mask the symptoms of ototoxicity.

Chlorphenamine inhibits phenytoin metabolism and can lead to phenytoin toxicity.

The anticholinergic effects of chlorphenamine are intensified by MAOIs (see Contraindications).

4.6 Fertility, pregnancy and lactation

There is no adequate data from the use of chlorphenamine in human pregnancy. The potential risk for humans is unknown. Use during the third trimester may result in reactions in the newborn or premature neonates. Chlorphenamine tablets should not be used during pregnancy unless considered essential by a physician.

Chlorphenamine maleate and other antihistamines 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
Administration of chlorphenamine may cause dizziness, drowsiness, blurred vision, and psychomotor impairment which can seriously hamper the patients’ ability to drive and use machinery therefore patients should be advised not to take charge of vehicles or 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 the lymphatic system disorders**
Unknown: blood dyscrasias (leucopenia, agranulocytosis), haemolytic anaemia

**Immune system disorders**
Unknown: drug allergy, allergic reactions including allergic dermatitis, angioedema, anaphylactic reactions.

**Metabolism and nutrition disorders**
Unknown: anorexia, loss of appetite

**Psychiatric disorders**
Unknown: euphoria, nervousness, insomnia, depression, sleep disturbances, nightmares*, irritability*, confusion*, paradoxical excitation*, confusional psychosis in the elderly

**Nervous system disorders**
Very common: sedation varying from slight drowsiness to deep sleep
Common: inability to concentrate, abnormal coordination, dizziness, headache
Unknown: lassitude, tremors, tingling

**Eye disorders**
Common: blurred vision
Unknown: diplopia

**Ear and labyrinth disorders**
Unknown: tinnitus

**Cardiac disorders**
Unknown: palpitations, tachycardia, arrhythmia

**Vascular disorders**
Unknown: hypotension

**Respiratory, thoracic and mediastinal disorders**
Unknown: dry throat and respiratory passages sometimes inducing cough, thickening of bronchial secretions

**Gastrointestinal disorders**
Common: nausea, dry mouth
Unknown: vomiting, epigastric distress, constipation, diarrhoea, , dyspepsia and abdominal pain

**Hepatobiliary disorders**
Unknown: hepatitis including jaundice

**Skin and subcutaneous tissue disorders**
Unknown: exfoliative dermatitis, photosensitisation, rash and urticaria

**Musculoskeletal and connective tissue disorders**
Unknown: muscle twitching, muscular weakness

**Renal and urinary disorders**
Unknown: urinary retention or frequency, dysuria

**General disorders and administration site conditions**
Common: fatigue
Unknown: drug fever, tightness of the chest, heaviness and weakness of the hands

*Children and the elderly are more likely to experience the 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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

### 4.9 Overdose

**Symptoms and signs**
The estimated lethal dose of chlorphenamine maleate is 25-50mg/kg body weight. Symptoms and signs include sedation, paradoxical stimulation of CNS, toxic psychosis, seizures, 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). 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
Pharmacotherapeutic classification: Substituted alkylamines; chlorphenamine ATC code: R06A B04
Chlorphenamine maleate is an alkylamine derivative with properties and uses of the antihistamines. Antihistamines used in the treatment of allergy act by competing with histamines for H₁-receptor sites on effector cells. They thereby prevent, but do not reverse, responses mediated by histamine alone. The antimuscarinic actions of most antihistamines provide a drying effect on the nasal mucosa.

5.2 Pharmacokinetic properties
Chlorphenamine is readily absorbed from the gastrointestinal tract. Following absorption, approximately 72 per cent of the drug is protein bound. Onset of action is in the range of 15-60 minutes with duration of action between 4-12 hours. Half-life of chlorphenamine is 12-15 hours. It is metabolised in the liver. Chlorphenamine induces hepatic microsomal enzymes and they may facilitate their own metabolism. It is excreted mainly as metabolites in the urine and is eliminated more rapidly in children than by adults.

5.3 Preclinical safety data
There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Lactose
Pregelatinised starch
Quinoline yellow lake (E104)
Magnesium stearate
Stearic acid
Maize starch

6.2 Incompatibilities
None

6.3 Shelf life
36 months in tablet containers
36 months in blister packs

6.4 Special precautions for storage
Store in the container provided. Do not store above 25°C.
6.5 Nature and contents of container
1. The product is packed in opaque plastic containers composed of polypropylene tubes and polyethylene tamper-evident closures in pack size of 28, 42, 50, 56, 84, 100, 112, 250, 500 and 1000 tablets.
2. The product is packed in opaque plastic containers composed of either, high density polypropylene or high density polyethylene with a tamper evident or child resistant tamper evident closure composed of high density polyethylene with a packing inclusion of standard polyether foam or polyethylene or polypropylene filler in pack sizes of 28, 42, 50, 56, 84, 100, 112, 250, 500 and 1000 tablets.
3. The product is packed in blister packs of aluminium/opaque PVC in pack sizes of 28, 42, 56, 84 and 112 tablets.

6.6 Special precautions for disposal
No special instructions for use/handling.

7 MARKETING AUTHORISATION HOLDER
Crescent Pharma Limited
Units 3 and 4
Quidhampton Business Units
Polhampton Lane
Overton
Hants
RG25 3ED
UK

8 MARKETING AUTHORISATION NUMBER(S)
PL 20416/0040

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
02/03/2004

10 DATE OF REVISION OF THE TEXT
11/11/2016