

## New Zealand Data Sheet

### 1. PRODUCT NAME

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Histafen elixir 2 mg/5 mL

### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

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Histafen elixir 2 mg/5 mL contains 0.4 mg/ml of chlorphenamine maleate (chlorpheniramine maleate)

#### **Excipient(s) with known effect**

Histafen elixir contains amaranth, ethanol and sorbitol. For the full list of excipients, see section 6.1.

### 3. PHARMACEUTICAL FORM

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Red thin liquid with the characteristic odour of raspberry.

### 4. CLINICAL PARTICULARS

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#### **4.1. Therapeutic indications**

Chlorphenamine maleate is indicated for allergic skin disorders including urticaria, pruritus, insect bites, some drug allergies and contact allergies to plants. It is also effective in relieving the symptoms of seasonal and perennial allergic rhinitis such as sneezing, nasal itch and conjunctivitis.

#### **4.2. Dose and method of administration**

Adults and children over six years of age: 5ml up to eight times daily.

#### **4.3. Contraindications**

- Hypersensitivity to Chlorphenamine maleate or any of the ingredients listed in section 6.1.
- Acute attacks of asthma.
- Do not use in children under six years of age.

#### **4.4. Special warnings and precautions for use**

Because of the antimuscarinic properties, antihistamines should be used with care in conditions such as narrow angle glaucoma, urinary retention and prostatic hypertrophy.

#### **4.5. Interaction with other medicines and other forms of interaction**

Administration of Histafen elixir with other CNS depressants such as alcohol, barbiturates, hypnotics, opioid analgesics, sedatives and antipsychotics may enhance sedation.

Histafen elixir will enhance the antimuscarinic action of atropine, tricyclic antidepressants and Monoamine Oxidase inhibitors (MAOIs).

There is evidence to suggest that antihistamines such as Chlorphenamine maleate could mask the warning signs of damage caused by ototoxic medicines such as aminoglycosides.

Histafen may suppress the cutaneous histamine response to allergen extracts. Its use should be stopped several days before skin testing.

#### **4.6. Fertility, pregnancy and lactation**

##### **Pregnancy and women of child bearing potential**

Class A. Antihistamines have been taken by a large number of pregnant women and women of childbearing age without any proven increase in the frequency of malformations or other direct or indirect harmful effects on the fetus having been observed.

##### **Breast-feeding**

Since Chlorphenamine maleate enters breast milk it is recommended that nursing mothers either stop the medicine or find an alternative method of infant feeding.

##### **Fertility**

No data available.

#### **4.7. Effects on ability to drive and use machines**

May cause drowsiness; patients so affected should not drive or operate machinery. Patients should abstain from alcohol.

#### **4.8. Undesirable effects**

Side effects vary in incidence and severity with each patient.

Sedation is not so common with Chlorphenamine maleate, but a significant proportion of patients can experience this, varying from slight drowsiness to deep sleep, and including lassitude, dizziness and incoordination.

Sedative effects, when they occur, may diminish after a few days.

Other side effects include gastrointestinal disturbances such as nausea, vomiting, diarrhoea or constipation, anorexia or increased appetite, and epigastric pain.

Antimuscarinic effects include blurred vision, difficulty in micturition, dysuria, dryness of the mouth, and tightness of the chest. Central effects include hypotension, muscular weakness, tinnitus, euphoria and occasionally headache. Paradoxical CNS stimulation may occur, with insomnia, nervousness, tachycardia, tremors and convulsions. Chlorphenamine maleate may precipitate epileptiform seizures in patients with local lesions of the cerebral cortex.

Chlorphenamine maleate may produce allergic reactions and cross-sensitivity to related drugs.

Grave complications such as leukopenia and agranulocytosis are very rare.

### **Reporting of suspected adverse reactions**

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected reactions <https://nzphvc.otago.ac.nz/reporting/>

## **4.9. Overdose**

### **Symptoms**

The main symptoms in children are ataxia, excitement, hallucinations, muscle tremor, convulsions, dilated pupils, dry mouth, flushed face, and hyperpyrexia. Deep coma, cardiorespiratory collapse, and death may occur within 18 hours.

In adults, the usual symptoms are of CNS depression with drowsiness, coma and convulsions. Hypotension may also occur. Elderly patients are more susceptible to the CNS depressant and hypotensive effects even at therapeutic doses.

### **Treatment**

In severe overdosage, the stomach should be emptied by aspiration and lavage. Emetics may be tried if the patient is alert and there are no symptoms of toxicity but may be ineffective due to the anti-emetic activity of the antihistamine. Activated charcoal and saline laxatives may also be given.

Convulsions may be controlled with diazepam given IV, although it has been suggested that sedatives should be avoided.

For advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764766).

## **5. PHARMACOLOGICAL PROPERTIES**

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### **5.1. Pharmacodynamic properties**

#### **Mechanism of action**

Chlorphenamine maleate is an alkylamine derivative and potent, long acting H<sub>1</sub>-receptor antagonist (an antihistamine). Chlorphenamine maleate diminishes the main actions of histamine in the body by competitive, reversible blockade of histamine receptor sites on tissues. Vasodilatation increased capillary permeability, flare and itch reactions in the skin are blocked by Chlorphenamine maleate. H<sub>1</sub>-antagonists also possess anticholinergic, serotonin-antagonising and local anaesthetic effects.

## **5.2. Pharmacokinetic properties**

### **Absorption**

Chlorphenamine maleate is rapidly absorbed from the gastrointestinal tract with peak plasma concentrations after 2 - 3 hours.

### **Biotransformation and elimination**

It is metabolised in the liver. It has a half-life of approximately 14 - 25 hours and a duration of effect of approximately 24 hours. Chlorphenamine maleate undergoes extensive gut and hepatic first pass effect. It is excreted usually as metabolites in the urine. Excretion is dependent on urinary pH and flow rate.

## **5.3. Preclinical safety data**

No data available.

## **6. PHARMACEUTICAL PARTICULARS**

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### **6.1. List of excipients**

Histafen contains Amaranth, Ethanol, Nipastat, Propylene glycol, Purified water, Raspberry flavour C3056, Saccharin sodium, Sodium cyclamate, Sorbitol, Vanillin.

### **6.2. Incompatibilities**

Not applicable.

### **6.3. Shelf life**

36 months.

### **6.4. Special precautions for storage**

Stored at or below 30°C.

### **6.5. Nature and contents of container**

Histafen elixir: plastic bottles 500 mL or 2 L.  
Not all pack sizes may be marketed.

## **6.6. Special precautions for disposal and other handling**

Any unused medicine or waste material should be disposed of in accordance with local requirements.

## **7. MEDICINE SCHEDULE**

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Restricted medicine

## **8. SPONSOR**

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Douglas Pharmaceuticals Ltd  
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Auckland 0651  
New Zealand  
Phone: (09) 835 0660

## **9. DATE OF FIRST APPROVAL**

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14 March 1973

## **10. DATE OF REVISION OF THE TEXT**

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23 January 2019

Summary table of changes

<b>Section Changed</b>	<b>Summary of new information</b>
All	SPC format