

## **SUMMARY OF PRODUCTS CHARACTERISTICS**

**1. Name of the Finished Pharmaceutical Product**

**1.1 Name of the medicinal product**

**Product Name:** Aspi-M

**Generic Name:** Chlorphenamine Tablets BP 4 mg

**1.2 Strength**

4 mg

**1.3 Pharmaceutical form**

Tablets

**2. Qualitative and quantitative composition**

Chlorphenamine Maleate
Microcrystalline cellulose
Maize starch
Lactose
Sodium starch glycolate
Colour tartrazine yellow
Purified water
Silicon dioxide
Magnesium stearate

**3. Pharmaceutical form**

**Dosage Form:** Uncoated Tablets

**Physical Characteristics:** Yellow to light yellow, uncoated, round tablet with flat face and bevelled edges, scoring with "C" and "4" separated by breakline on one side and other side Plain.

#### **4. Clinical particulars**

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

Chlorphenamine Maleate 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 reactions, insect bites.

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

##### **4.2 Posology and method of administration**

Oral Administration only.

Do not exceed the stated dose or frequency of dosing.

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

Not recommended for children under 6 years.

##### **4.3 Contraindications**

Chlorphenamine Maleate tablets are 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 Maleate tablets is therefore contra-indicated 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 intraocular 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

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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 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 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 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.

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#### **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**

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  $\geq 1\%$  to  $< 10\%$  of subjects) or very common (occurring in  $\geq 10\%$  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

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**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).

**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.

**Treatments**

Symptomatic and supportive measures should be provided with special attention to cardiac, respiratory, renal and hepatic functions and fluid and electrolyte balance. If overdose 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.

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CNS convulsions may be treated with i.e. diazepam. Haemoperfusion may be used in severe cases.

## **5.0 Pharmacological properties**

### **5.1 Pharmacodynamic properties**

**Pharmacotherapeutic group:** potent antihistamine (H1-antagonist).

**ATC code:** R06AB02.

#### **Mechanism of action**

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 well absorbed from the gastro-intestinal 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 has been estimated to be 12 to 15 hours.

Chlorphenamine is metabolised to the monodesmethyl and didesmethyl derivatives. About 22% of an oral dose is excreted unchanged in the urine.

### **5.3 Preclinical safety data**

No additional data of relevance.

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## 6. Pharmaceutical particulars

### 6.1 List of Excipients

Sr. No.	Name of Ingredients	Specification
01	Microcrystalline cellulose	BP
02	Maize starch	BP
03	Lactose	BP
04	Sodium starch glycolate	BP
05	Colour tartrazine yellow (supra)	IH
06	Purified water	BP
07	Silicon dioxide	USP
08	Magnesium stearate	BP

### 6.2 Incompatibilities

Not applicable

### 6.3 Shelf life

36 months

### 6.4 Special precautions for storage

Store below 30 °C, Protect from light.

Keep out of the reach and sight of children.

### 6.5 Nature and contents of container

10 x 10's Al/PVC Blister

### 6.6 Instruction for use and handling

Not applicable

## 7. Marketing Authorization Holder

Astra lifecare (India) Pvt. Ltd

Plot No. 57/P, Sarkhej – Bavla Highway,

Post. Rajoda –382220, Taluka: Bavla,

Dist. Ahmedabad, India.

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**8. Marketing Authorization Number(s)**

ASL/IND/004

04432/06899/REN/2018

**9. Date of first authorization/renewal of the authorization**

Date of first authorization : 14 Aug 2008

Date of latest renewal Apr 25, 2019

**10. Date of revision of the text**

Not applicable

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