SUMMARYOF PRODUCT CHARACTERSITICS

1. Name of the medicinal product
AHISTON Tablets

2. Qualitative and quantitative composition
Each tablet contains: Chlorpheniramine maleate 2 mg

Excipients with known effect:
Lactose content: 118 mg/tablet.
Sodium content: 0.14-0.21 mg/tablet.

For a full list of excipients, see section 6.1.

3. Pharmaceutical form
Tablet

Yellow, round tablet, scored in half on one side, engraved "IKA" on the other.

4. Clinical particulars
4.1 Therapeutic indications
Symptomatic relief of perennial and seasonal allergic rhinitis, vasomotor rhinitis, allergic conjunctivitis, mild uncomplicated urticaria and angioedema, amelioration of allergic reactions to blood or plasma, dermatographism, adjunctive therapy in anaphylactic reactions.

4.2 Posology and method of administration
Oral Administration only.
Do no exceed the stated dose or frequency of dosing.
It is recommended that this medicine be taken with or after food.

The adult dosage is 1-2 tablets, 3-4 times daily, as needed.
The dosage in children 6-12 years of age is 1/2-1 tablet 3-4 times daily, as needed.

Not recommended for children under 6.

4.3 Contraindications
Chlorphenamine is contra-indicated in patients who are hypersensitive to antihistamines or to any of the other ingredients.
The anticholinergic properties of chlorphenamine are intensified by monoamine oxidase inhibitors (MAOIs). Chlorphenamine 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 intra-ocular pressure including glaucoma, prostatic hypertrophy; severe hypertension or cardiovascular disease; bronchitis, bronchiectasis and 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). Avoid use in elderly patients with confusion.

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.

Concurrent use with drugs which cause sedation such as anxiolytics and hypnotics may cause an increase in sedative effects, therefore medical advice should be sought before taking chlorphenamine concurrently with these medicines.

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, total 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, concurrent use of alcohol may have a similar effect 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 contraindications Section 4.3).

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.

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 may seriously affect patients` ability to drive and use machinery.

4.8 Undesirable effects
The following convention has been utilised for the classification of the frequency of adverse reactions: very common (>1/10), common (>1/100 to <1/10), uncommon (>1/1000 to <1/100), rare (>1/10,000 to <1/1000) and very rare (<1/10,000), not known (cannot be estimated from available data).
Adverse reactions identified during post-marketing use with chlorphenamine are listed below. As these reactions are reported voluntarily from a population of uncertain size, the frequency of some reactions is unknown but likely to be rare or very rare:

System Organ Class	**Adverse Reaction**	**Frequency**
Nervous system disorders*	Sedation, somnolence	Very common
	Disturbance in attention, abnormal coordination, dizziness headache	Common
Eye disorders	Blurred Vision	Common
	Nausea, dry mouth	Common

Gastrointestinal disorders	Vomiting, abdominal pain, diarrhoea, dyspepsia	Unknown
Immune system disorders:	Allergic reaction, angioedema, anaphylactic reactions	Unknown
Metabolism and nutritional disorders	Anorexia	Unknown
Blood and lymphatic system disorders	Haemolytic anaemia, blood dyscrasias	Unknown
Musculoskeletal and connective tissue disorders	Muscle twitching, muscle weakness	Unknown
Psychiatric disorders	Confusion*, excitation*, irritability*, nightmares*, depression	Unknown
Renal and urinary disorders	Urinary retention	Unknown
Skin and subcutaneous disorders	Exfoliative dermatitis, rash, urticaria, photosensitivity	Unknown
Respiratory, thoracic and mediastinal disorders	Thickening of bronchial secretions	Unknown
Vascular disorders	Hypotension	Unknown
Hepatobiliary disorders	Hepatitis, including jaundice	Unknown
Ear and labyrinth disorders	Tinnitus	Unknown
Cardiac disorders	Palpitations, tachycardia, arrythmias	Unknown
General disorders and administration site conditions	Fatigue	Common
	Chest tightness	Unknown

* 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. Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form https://sideeffects.health.gov.il/

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.

Treatment

Management should be as clinically indicated or as recommended by the national poisons centres where available.

Symptomatic and supportive measures should be provided with special attention to cardiac, respiratory, renal and hepatic functions, and fluid 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
ATC Code: R06AB04
Chlorphenamine is potent antihistamine (H1 antagonist).
Antihistamines diminish or abolish the actions of histamine in the body by competative reversible blockade of histamine H1-receptor sites on tissues. Chlorphenamine also has anticholinergic activity.

Antihistamines act to prevent the release of histamine, prostaglandins and leukotrines and have been shown to prevent the migration of inflammatory mediators. The actions of chlorphenmine include inhibition of histamine on smooth muscle, cappillary permeability and hence reduction of oedma and wheal in hypersneitivity reactions such as allergy and anaphylaxis.

5.2 Pharmacokinetic properties
Chlorphenamine is well absorbed from the gastro-intestinal tract, following oral administration. The effect 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 – 15 hours.
Chlorphenamine is metabolised to the monodesmethyl and didesmethyl derivative. About 22% of an oral dose is excreted unchanged in the urine.

5.3 Preclinical safety data
No additional data of relevance.

6. Pharmaceutical particulars
6.1 List of excipients
Lactose monohydrate, starch, sodium starch glycolate, povidone, magnesium stearate, color D&C Yellow No.10.

6.2 Incompatibilities
Not applicable.

6.3 shelf life
The expiry date of the product is indicated on the packaging materials.

6.4 Special precautions for storage
Store in a dry place below 25°C.

6.5 Nature and contents of container
Ahiston Tablets is available in PVC/Aluminium blister.
Each blister contains 20 tablets.

6.6 Special precautions for disposal and other handling
For detailed instructions for use refer to the Patient Information Leaflet in every pack.

7. LICENCE HODER AND MANUFACTURER
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7. Registration Number:
051 69 24231
The leaflet was revised in December 2021 according to MOHs guidelines.