SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Haymine Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains chlorphenamine maleate 10 mg and ephedrine hydrochloride 15 mg.

Excipients with known effect
Each tablet contains 0.7 mg hydrogenated castor oil, 0.193 mg methyl parahydroxybenzoate (E218), 0.054 mg ethyl parahydroxybenzoate (E214), 0.026 mg propyl parahydroxybenzoate (E216), 0.051 mg butyl parahydroxybenzoate and 0.026 mg isobutyl parahydroxybenzoate.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Modified release tablet

Yellow, circular bevelled edge tablets with ‘H’ on one face.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Relief of symptoms caused by allergic conditions such as hay fever, allergic rhinitis, perennial rhinitis, urticaria etc., which are responsive to antihistamine.

4.2 Posology and method of administration

Posology

Adults, elderly and children over 12 years of age
One or two tablets daily. One tablet should be taken in the morning on rising and a further tablet may be taken at night if required.

Paediatric population
Not recommended in children under 12 years of age.

Method of administration

Oral administration.

4.3 Contraindications

Hypersensitivity to the active substances or to any of the excipients listed in section 6.1.

Use in patients with coronary thrombosis, hypertension, thyrotoxicosis and those on treatment with monoamine oxidase inhibitors.

4.4 Special warnings and precautions for use

Haymine Tablets should be swallowed whole and not sucked or chewed. Do not exceed the stated dose. Asthmatics should consult their doctor before using this product. May cause drowsiness, if affected do not drive or operate machinery. Avoid alcoholic drink.

Excipients
This medicine contains hydrogenated castor oil which may cause stomach upset and diarrhea.
This medicine contains methyl parahydroxybenzoate (E218), ethyl parahydroxybenzoate (E214), propyl parahydroxybenzoate (E216), butyl parahydroxybenzoate and isobutyl parahydroxybenzoate which may cause allergic reactions (possibly delayed).

4.5 Interaction with other medicinal products and other forms of interaction

Alcoholic drinks and certain other central nervous system depressants can potentiate any sedative effect.

4.6 Fertility, pregnancy and lactation

Haymine Tablets are contra-indicated during pregnancy and during breast-feeding.

4.7 Effects on ability to drive and use machines

Haymine Tablets have a moderate influence on the ability to drive and use machines.

4.8 Undesirable effects

Although the combination of ephedrine with the anti-histamine chlorphenamine is intended to reduce side-effects, slight drowsiness may occur. Side effects of ephedrine are rare at the low dose employed in this preparation, however in particularly susceptible patients, effects such as giddiness, palpitations and muscular weakness may be experienced transiently.

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 or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Management
Treatment should include gastric lavage. In the event of convulsions sedate with intramuscular paraldehyde. Respiratory depression may necessitate mechanical ventilation. Symptomatic treatment of cardiovascular dysfunction should be given with careful patient monitoring. The physician should be aware that tablets in the intestine will continue to release the active ingredients for a period of hours.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antihistamines for systemic use, substituted alkylamides, ATC code: R06AB54

Mechanism of action
Chlorphenamine is a potent H_1-blocking drug. It antagonises the pharmacological actions of histamine released by antigen-antibody reaction in allergic diseases, thus providing symptomatic relief. Chlorphenamine alone is less effective when pollen counts are high, allergen exposure is prolonged and nasal congestion has become prominent.

Ephedrine has mild CNS stimulant properties which counteract any drowsiness produced by chlorphenamine. In addition, it produces a decongestant action on nasal mucosal surfaces relieving mucosal congestion in conditions such as hay fever and allergic rhinitis.

5.2 Pharmacokinetic properties

Chlorphenamine is readily absorbed after oral administration and may undergo enterohepatic re-circulation in man. It is eliminated with a t½ of 12-15 hours. Ephedrine is completely absorbed following oral administration and is eliminated with a t½ of 3-6 hours.

5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber which are additional to that already included in other sections of the SmPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hypromellose
Quinoline yellow (E104)
Hydrogenated castor oil
Magnesium stearate
Methyl parahydroxybenzoate (E218)
Ethyl parahydroxybenzoate (E214)
Propyl parahydroxybenzoate (E216)
Butyl parahydroxybenzoate
Isobutyl parahydroxybenzoate

6.2 Incompatibilities

Not known.

6.3 Shelf life

4 years

6.4 Special precautions for storage

This medicinal product does not require any special storage condition.

6.5 Nature and contents of container

Alu/Alu blisters.
Pack sizes of 10 and 30 tablets.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Chemidex Pharma Limited
8a Crabtree road, Egham
Surrey, TW20 8RN
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 17736/0117

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 9 March 1978
Date of latest renewal: 22 May 2003

10 DATE OF REVISION OF THE TEXT

27/03/2026