

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Histasin

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Cetirizine dihydrochloride 10 mg

For excipients see 6.1

3. PHARMACEUTICAL FORM

Film coated, white or almost white convex, elliptical tablets, 5.7 x 11.4 mm, scored on one side.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Histasin is indicated for the symptomatic treatment of allergic rhinitis, rash and urticaria due to histamine release.

4.2 Posology and method of administration

Dosage for adults:

One tablet (10 mg) daily.

Dosage for children:

Children 12 years of age and over:

One tablet (10 mg) daily.

Children aged between 6 to 12 years, weighing more than 30 kg:

One tablet once daily or ½ tablet (5 mg) mornings and evenings.

Children aged between 6 to 12 years, weighing less than 30 kg:

½ tablet (5 mg) once daily.

The drug is not recommended for children below 6 years of age.

If sedation occurs the tablets can be taken in the evening.

4.3 Contra-indications

Histasin is contra-indicated in patients with a history of hypersensitivity to cetirizine or any of the excipients.

Patients with severe renal impairment should not take the drug.

4.4 Special warnings and special precautions for use.

In some patients, prolonged use of the drug may lead to increased risk of dental caries because of dryness of the mouth. Therefore the importance of mouth hygiene should be emphasized.

Histasin tablets contain lactose. The medicine is contra-indicated in patients with lactose intolerance, galactose intolerance or insufficient absorption of glucose/galactose.

In renal or hepatic insufficiency the elimination of cetirizine may be reduced. Therefore the drug should be administered with caution to such patients (see 4.2. Posology and method of administration and 4.3. Contra-indications). Caution is recommended if Histasin is used together with CNS depressants.

4.5 Interactions with other medicinal products and other interactions

Allergy test: The use of cetirizine should be stopped 3 days prior to skin test procedures.

Cetirizine may increase the effects of alcohol. Therefore caution is required when alcohol is used concomitantly.

Caution is recommended when drugs with inhibiting effects on the CNS are administered concurrently with cetirizine.

4.6 Pregnancy and lactation

Pregnancy

Data on limited number of exposed pregnancies indicate no adverse effects of cetirizine on pregnancy or on health of foetus/new born child. To date no other relevant epidemiological data are available. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonic/foetal development, parturition or post natal development (see 5.3 Preclinical safety data). Caution is recommended when the drug is prescribed to pregnant women.

Lactation

The medicine passes into breast milk and can affect the breast-fed baby. Don't use Histasin during breast-feeding unless it has been prescribed for you by a doctor.

4.7 Effects on ability to drive and use machines

Rarely cetirizine can have sedating effects and impair patients' alertness and reaction time. This should be considered when extra alertness is required, as when driving or operating machines.

Cetirizine may potentiate the effects of alcohol and CNS inhibitors.

4.8 Undesirable effects

Common (>1/100, <1/10):

Gastrointestinal tract: Dry mouth.

Nervous system: Tiredness and sleepiness.

Uncommon (>1/1000, <1/100):

Gastrointestinal tract: Gastric discomfort and gastrointestinal disorders.
Nervous system: Headache, dizziness, restlessness.

Very rare (<1/10.000):

Immune system: allergic reactions such as cutaneous reactions and quinke's oedema.

4.9 Overdose

There is limited information regarding overdosage. In cases where 20 mg were taken orally by a 2 year old child, 30 mg were taken orally by a 3 year old child and 40 mg were taken orally by an 11 year old child, no symptoms occurred. A 4 year old child who took 60 mg orally experienced mild toxic effects. A 14 year old who took 400 mg orally developed mild symptoms but an adult who took 400-500 mg orally developed no symptoms at all.

Symptoms that have been reported in association with overdosage of antihistamines:

Drowsiness, unconsciousness and/or agitation (mainly in children). Ataxia, tremor, headache, hallucinations, convulsions, dry mouth, rash, hyperthermia, mydriasis, urine retention, tachycardia and in case of massive overdosage a drop in blood pressure and arrhythmia may occur. Nausea and vomiting. Extrapyrimal symptoms may also occur. Cetirizine has mild sedating and anti-cholinergic effects. Sedation can be a symptom of overdosage and it can occur after a single dose below 50 mg.

Treatment: An antidote is not known. The experience of overdosage is limited and so far no serious poisoning has been reported. If required the initial treatment should be gastric lavage and charcoal. In case of acute poisoning, symptomatic treatment should be given, e.g. diazepam for convulsions or acute dystonia.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antihistamine for systemic use.

ATC group: R06A E07

Cetirizine inhibits H1-receptors but has negligible effects on H2-receptors. The drug has minor anti-cholinergic, adrenergic and serotonin like effects. Cetirizine inhibits the histamine-mediated early phase of the allergic reaction and reduces the affinity of eosinophils and the release of various mediators during the late allergic response. The onset of action of cetirizine occurs after approximately 25 minutes after administration, reaches a maximum after 4 hours and lasts for 24 hours.

5.2 Pharmacokinetics

Cetirizine is rapidly absorbed from the gastro-intestinal tract and peak plasma concentration is obtained after 1 hour. Plasma protein binding is about 93%. Plasma half-life of cetirizine is about 10 hours in adults but 6 hours in children aged 6-12 years. The drug is excreted mainly unchanged in the urine. The pharmacokinetics do not vary very much with increasing age but the half life is increased in renal failure. Hepatic dysfunction also reduces the elimination rate.

5.3 Preclinical safety data

Preclinical data does not indicate any special risk for humans, based on conventional studies of pharmacological safety, toxicity after repeated doses, genotoxicity, carcinogenic effects and reproductive toxicity.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Microcrystalline cellulose *Ph. Eur.*

Lactose monohydrate *Ph. Eur.*

Crospovidone *Ph. Eur.*

Anhydrous colloidal silica *Ph. Eur.*

Magnesium stearate *Ph. Eur.*

Hypromellose *Ph. Eur.*

Macrogol stearate *Ph. Eur.*

Propylene glycol *Ph. Eur.*

Titanium dioxide (E171) *Ph. Eur.*

Purified water *Ph. Eur.*

6.2 Incompatibilities

None reported

6.3 Shelf life

3 years.

6.4 Special precautions for storage

No special precautions for storage.

6.5 Nature and contents of container

Blister pack (aluminium/PVC) and HDPE glass with LDPE cap.
10, 30 and 100 10 mg tablets.

Not all pack sizes might be marketed.

6.6 Instructions for use and handling (and disposal)

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Actavis hf
Reykjavíkurvegi 76-78,
220 Hafnarfirdi,
Iceland

8 MARKETING AUTHORISATION NUMBER

950211 (IS)

9 DATE OF FIRST AUTHORISATION/RENEWAL OF AUTHORISATION

June 1, 1997

10 DATE OF REVISION OF THE TEXT

July 13, 2004