

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Histek Allergy 10 mg Film-coated Tablets.

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Cetirizine dihydrochloride 10 mg

Excipients include: Lactose monohydrate 117mg.

For a full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Film coated tablet.

Film-coated, white or almost white convex, oval shaped, tablets.

Scored on one side. The tablets are marked “C” on one side, “J” and “E” on either side of a central division line on the reverse.

The tablet can be divided into equal halves.

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic Indications

For the treatment of perennial rhinitis, seasonal allergic rhinitis (hay fever) and chronic idiopathic urticaria in adults and children aged 12 years and over.

### 4.2 Posology and method of administration

For oral use only.

Adults, the elderly and children aged 12 years and over: One 10mg tablet daily.

In patients with renal impairment (creatinine clearance 11 –31 ml/min), on haemodialysis (creatinine clearance < 7 ml/min) and in hepatically impaired patients, the dose should be reduced to 5mg daily.

### 4.3 Contraindications

Cetirizine is contra-indicated in patients who are hypersensitive to cetirizine, hydroxyzine or any constituent of the tablets.

Cetirizine has been reported to be excreted in human breast milk. Cetirizine is contra-indicated in lactating women, due to lack of evidence of safety (*see section 4.6 Pregnancy and Lactation*).

#### 4.4 Special warnings and precautions for use

Dosage adjustment is necessary in patients with moderate or severe renal impairment and in liver impairment (*see section 4.2 Posology and Method of Administration*).

Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

#### 4.5 Interaction with other medicinal products and other forms of interaction

Theophylline decreases the clearance of cetirizine although the disposition of theophylline is not affected.

In common with other antihistamines it is recommended that excessive alcohol consumption be avoided. Concurrent use of cetirizine with other CNS depressants should also be avoided as reduction in alertness and impairment of performance may occur.

No evidence of interactions with antipyrine, azithromycin, cimetidine, diazepam, erythromycin, ketoconazole and pseudoephedrine has been reported.

#### 4.6 Fertility, pregnancy and lactation

Animal studies have not revealed any adverse effects.

Use of cetirizine in human pregnancy has been limited. Although cetirizine does not appear to be associated with increased teratogenic risk, it is recommended that the use of cetirizine be avoided in pregnancy except where clearly needed.

As cetirizine has been reported to be excreted in breast milk, its use is contra-indicated in lactating women (*See also section 4.3. Contra-indications*).

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

At the recommended dose, alertness and reaction time should not be impaired. However, if patients expect to perform skilled tasks such as driving or operating machinery then the recommended dose should not be exceeded.

Concurrent use with alcohol or other CNS depressants may cause additional reductions in alertness and impairment of performance.

Please refer also to *section 4.8 Undesirable effects*.

#### 4.8 Undesirable effects

Clinical studies have shown that cetirizine at the recommended dosage has minor adverse effects on the CNS, including somnolence, fatigue, dizziness and headache. In some cases, paradoxical CNS stimulation has been reported.

Isolated cases of micturition difficulty, eye accommodation disorders and dry mouth have been reported.

For those patients who are affected the dosage should be halved and taken twice daily (i.e. take 5mg in the morning and 5mg in the evening).

Instances of abnormal hepatic function with elevated hepatic enzymes accompanied by elevated bilirubin have been reported. Mostly this resolves upon discontinuation of the drug.

The following adverse drug reactions have also been reported:

Abdominal pain, nausea, diarrhoea, pharyngitis and rhinitis.

Isolated cases of the following adverse drug reactions have been reported in post-marketing experience. Data are insufficient to support an estimate of their incidence in the population to be treated.

**Blood and lymphatic disorders:** thrombocytopenia.

**Cardiac disorders:** tachycardia.

**Eye disorders:** accommodation disorder, blurred vision.

**Gastro-intestinal disorders:** diarrhoea.

**General disorders and administration site conditions:** asthenia, malaise, oedema.

**Immune system disorders:** anaphylactic shock, hypersensitivity.

**Hepatobiliary disorders:** hepatic function abnormal (increased transaminases, alkaline phosphatase,  $\gamma$ -GT and bilirubin).

**Investigations:** weight increased.

**Nervous system disorders:** convulsions, dysgeusia, parathesia, syncope.

**Psychiatric disorders:** aggression, agitation, confusion, depression, insomnia.

**Renal and urinary disorders:** micturition difficulty.

**Skin and subcutaneous tissue disorders:** angioneurotic oedema, pruritus, rash, urticaria.

## 4.9 Overdose

Symptoms of overdosage in adults may include drowsiness; in children agitation or restlessness can occur followed by drowsiness.

Treatment of overdose should be symptomatic and supportive. Gastric lavage should be performed in the case of massive overdosage. There is no known specific antidote, and it is not effectively removed by dialysis.

## 5 PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

Pharmacotherapeutic classification:

R06A E07 (ATC classification system)

Cetirizine is a potent antihistamine, with selective H<sub>1</sub> receptor antagonist activity. The histamine-mediated 'early' phase of the allergic reaction is inhibited by cetirizine, which also reduces the migration of inflammatory cells and the release of mediators associated with the 'late' allergic responses. Effects on other receptors are negligible and consequently cetirizine is unlikely to cause undesirable anti-cholinergic and anti-serotonin effects. At the recommended therapeutic dose of 10mg daily, impairment of CNS function has not been found to be greater than with placebo.

### 5.2 Pharmacokinetic properties

Cetirizine is rapidly absorbed from the gastrointestinal tract; absorption is not reduced by food, though the rate may be decreased slightly. Apparent plasma clearance is greater in children than in adults: the terminal elimination half-life in healthy adult volunteers ranges between 6.7-10.7 hours; in children 6.1-7.1 hours; and in children aged under 4 years 5.55 hours.

Cetirizine is mainly excreted unchanged in the urine (approximately 70% over 5 days compared with 10% in the faeces). The half-life is increased in renal dysfunction: half lives of 19 and 21 hours in patients with mild and moderate renal impairment respectively have been reported. This may have implications for elderly patients. Cetirizine binds strongly to plasma proteins.

### 5.3 Preclinical safety data

Cetirizine has not been found to have teratogenic potential in animals or humans. In studies using rats and rabbits, no evidence of reproductive toxicity was shown at doses at least 20 times the human daily dose.

Long-term studies of 6 months to 1 year have been performed using rats, beagle dogs and monkeys. No-effect levels ranged from 75 to 125 times the recommended clinical dose, depending on species and duration of treatment.

Cetirizine is not carcinogenic *in vitro*, but some mutagenic potential has been observed in *in vitro* studies.

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

#### *Tablet core:*

Cellulose, microcrystalline  
Lactose monohydrate  
Crospovidone  
Silica, colloidal anhydrous  
Magnesium stearate

#### *Film coating:*

Hypromellose  
Macrogol stearate  
Cellulose, microcrystalline  
Propylene glycol  
Titanium dioxide E171

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf life

3 years.

### 6.4 Special precautions for storage

No special requirements.

### 6.5 Nature and contents of container

Blister packs made from 20µm aluminium and 45µm aluminium packed into a cardboard outer container.

Pack sizes: 7 and 30 tablets.

### 6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

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

## **7 MARKETING AUTHORISATION HOLDER**

Fannin Limited,  
Fannin House,  
South County Business Park,  
Leopardstown,  
Dublin 18

## **8 MARKETING AUTHORISATION NUMBER**

PA 1457/12/1

## **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 11 July 2003

Date of last renewal: 03 June 2008

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

August 2013