

SCHEDULING STATUS: S2

PROPRIETARY NAME (AND DOSAGE FORM):

ALLECET (Tablets)

COMPOSITION:

Each film-coated **ALLECET** tablet contains 10 mg cetirizine dihydrochloride.

PHARMACOLOGICAL CLASSIFICATION:

A 5.7.1 Antihistaminics.

PHARMACOLOGICAL ACTION:

Cetirizine is an anti-allergic medicine. Experimental and clinical pharmacology has shown cetirizine to be a histamine H₁-receptor antagonist without any significant anticholinergic or antiserotonergic effects. The anti-allergic activity of cetirizine is mainly due to its ability to inhibit the release of certain mediators (especially histamine), as well as its selective blocking of H₁-receptors. In addition, cetirizine reduces eosinophil recruitment induced by antigen-antibody reactions.

Pharmacokinetics:

Cetirizine reaches peak blood levels within one hour after administration of oral doses. The terminal half-life in adults is approximately 10 hours, while in children it is 6 hours and 5 hours in those aged 6 to 12 years and 2 to 6 years, respectively. These findings are confirmed by the urinary excretion half-life of cetirizine. Approximately two thirds of a dose is excreted in the urine in both adults and children. The apparent plasma clearance is higher in children compared to adults. There is a linear relationship between plasma levels and dosage. Cetirizine is predominantly bound to plasma proteins in humans.

INDICATIONS:

ALLECET is indicated for the treatment of allergic conditions, which respond to histamine H₁-receptor antagonists:

- Cutaneous: Allergic skin conditions associated with pruritus, e.g., urticaria.
- Respiratory: Allergic rhinitis, hay fever.

CONTRA-INDICATIONS:

Known hypersensitivity to cetirizine or any of the other components in the formulation.

WARNINGS:

ALLECET may lead to drowsiness and impaired concentration, which may be aggravated by the simultaneous intake of alcohol or other central nervous system depressant agents. Patients should be warned against taking charge of vehicles or machinery or performing potentially hazardous tasks where loss of concentration may lead to accidents (see "**Special Precautions**").

INTERACTIONS:

Studies with diazepam and cimetidine have shown no evidence of interactions with **ALLECET**.

Excessive alcohol consumption should be avoided in conjunction with **ALLECET**.

ALLECET may enhance the sedative effects of central nervous system depressants, including anxiolytics, neuroleptics, opioid analgesics, hypnotics, barbiturates and alcohol.

ALLECET may have an additive antimuscarinic action when combined with other antimuscarinic medicines, such as atropine and tricyclic antidepressants, and monoamine oxidase inhibitors (MAOI's) may enhance the antimuscarinic effects of **ALLECET**.

It has been suggested that **ALLECET** could possibly mask the warning signs of damage caused by ototoxic medicines, such as aminoglycoside antibiotics.

ALLECET should be discontinued several days before allergic skin testing as it may suppress the cutaneous histamine response to allergen extracts.

PREGNANCY AND LACTATION:

The safety of **ALLECET** has not been established in pregnancy. Although some antihistamines have been associated with foetal abnormalities when taken during pregnancy, a number of large studies have failed to demonstrate any definite associations.

ALLECET is contra-indicated in breast feeding women as cetirizine has been shown to be excreted in breast milk.

DOSAGE AND DIRECTIONS FOR USE:

Adults and children 12 years and older: 10 mg (one tablet) daily.

Children 6 to 12 years: 10 mg (one tablet) once daily, or, alternatively, 5 mg (half a tablet) twice daily.

Elderly: Currently there are no data available to suggest that dose reduction is required in this population.

Renal impairment: The dosage should be reduced to half the usual recommended dose in these patients.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS:

Side-effects:

The following side-effects, including subjective adverse events, which are usually mild and transient, have been reported:

Blood and lymphatic system disorders:

The following side-effects have been reported and frequencies are unknown:

Haemolytic anaemia, agranulocytosis, leucopenia and thrombocytopenia, though rare, have been reported. These blood disorders may have an immune basis.

Immune system disorders:

The following side-effects have been reported and frequencies are unknown:

Some individuals may develop hypersensitivity reactions, including skin reactions and angioedema. Cross-sensitivity to related medicines

may occur. Photosensitivity has also been reported. Jaundice, which is observed rarely, may also be a hypersensitivity reaction.

Neuropsychiatric system disorders:

The following side-effects have been reported and frequencies are unknown:

Sedation in a small number of patients (see "**Special Precautions**"). Sedative effects may vary from slight drowsiness to deep sleep and may include other side-effects, such as lassitude, dizziness and incoordination. Sedation, when it occurs, may diminish after a few days of treatment. Alternatively, paradoxical central nervous system (CNS) stimulation may occur, especially in children. This may present with irritability, tremors, insomnia, euphoria, nervousness, and rarely, nightmares, convulsions and hallucinations. With high doses, the CNS stimulation may be due to antimuscarinic activity. Extrapyrmidal symptoms have been reported. Paraesthesiae have been reported rarely.

Other subjective side-effects include drowsiness, dizziness, headache, agitation, and nervousness.

Disorders of the special senses:

The following side-effects have been reported and frequencies are unknown:

Tinnitus has been reported rarely.

Cardiovascular system disorders:

The following side-effects have been reported and frequencies are unknown:

Hypotension has been reported rarely.

Gastrointestinal system disorders:

The following side-effects have been reported and frequencies are unknown:

Increased appetite, dry mouth, gastrointestinal discomfort, constipation, nausea, vomiting, diarrhoea, and epigastric pain have occurred.

Special Precautions:

ALLECET lacks significant sedative effects. A small number of patients may, however, experience sedation. Determination of individual responses to **ALLECET** is therefore recommended before patients drive vehicles or perform other complicated tasks. The simultaneous intake of alcohol or other central nervous system depressants may exacerbate this effect (see "**WARNINGS**").

Elderly patients have been shown to be more susceptible to many adverse effects of **ALLECET**, including sedation, antimuscarinic effects and hypotension.

ALLECET should be used with care in patients with urinary retention, prostatic hyperplasia, closed-angle glaucoma and pyloroduodenal obstruction, due to its antimuscarinic properties.

ALLECET should be used with caution in patients with epilepsy and severe cardiovascular disorders based on its side-effects.

ALLECET is not indicated for the treatment of asthma.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

Overdosage with cetirizine may be fatal, especially in infants and children. In infants and children, central nervous system stimulation usually predominates over central nervous system depression, leading to tremors, excitement, ataxia, psychoses, hallucinations and convulsions. Hyperpyrexia may also occur. This may be followed by deepening coma and cardiorespiratory collapse. Alternatively, in adults, central nervous system depression is more common, presenting with drowsiness, convulsions and coma, which may progress to respiratory failure or possible cardiovascular collapse.

In cases of massive overdose gastric lavage should be performed. Furthermore, standard symptomatic and supportive measures should be employed. No specific antidote has been identified to date.

IDENTIFICATION:

White, circular, biconvex, film-coated tablets with "A" embossed on one side and a deep score on the other.

PRESENTATION:

Blister strips of 10 tablets, packed in 10's and 30's.

STORAGE INSTRUCTIONS:

Store in a cool (below 25°C), dry place.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

37/5.7.1/0034

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

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