

SCHEDULING STATUS: S2

PROPRIETARY NAME (and dosage form):

ALLECET SYRUP (Syrup)

COMPOSITION:

Each 1 ml of ALLECET SYRUP contains
1 mg Cetrizine dihydrochloride.

Preservatives:

Methyl parahydroxybenzoate: 0.2 % m/v

Propyl parahydroxybenzoate: 0.02 % m/v

PHARMACOLOGICAL CLASSIFICATION:

A 5.7.1 Antihistamines.

PHARMACOLOGICAL ACTION:

ALLECET SYRUP is an anti-allergic medicine. Experimental and clinical pharmacology of cetirizine have demonstrated histamine H1-receptor antagonism without any significant anticholinergic and antiserotonergic effects. Current research into the mode of action of cetirizine has shown that the anti-allergic activity seems to be exerted mainly via the effects of cetirizine on the release of certain mediators (mainly histamine) in association with a selective action on the H1-receptors. Furthermore, cetirizine has been shown to reduce eosinophil recruitment induced by an antigen-antibody reaction.

INDICATIONS:

ALLECET SYRUP is indicated for the treatment of allergic conditions responding to a histamine H1-receptor antagonist:

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

CONTRA-INDICATIONS:

History of hypersensitivity to any of the components of the formulation.

INTERACTIONS:

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

Antihistamines have an additive antimuscarinic action when combined with other antimuscarinic medicines, such as atropine and tricyclic antidepressants, and MAOI's may enhance the antimuscarinic effects of antihistamines.

It has been suggested that antihistamines could possibly mask the warning signs of otic damage caused by ototoxic drugs such as aminoglycoside antibiotics. Antihistamines should be stopped several days before skin tests as they may suppress positive skin test results.

PREGNANCY AND LACTATION:

The safety of cetirizine has not been established in pregnancy.

ALLECET SYRUP is contra-indicated in breastfeeding women since cetirizine is excreted in breast milk.

DOSE AND DIRECTIONS FOR USE:

Adults and children 12 years or older: 10 mg or 10 ml (two medicine measures) once daily.

Children 6 to 12 years: 10 mg daily, either as a single 10 ml dose (two medicine measures), or as two divided doses of 5 ml (one medicine measure) each in the morning and in the evening respectively.

Children 2 to 6 years: 5 mg (one medicine measure) daily, either as a single dose (5 ml) or as two divided doses of 2.5 ml (half a medicine measure) each in the morning and in the evening respectively.

Elderly: At present there are no data to suggest that the dose needs to be reduced in this population.

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

SIDE-EFFECTS AND SPECIAL PRECAUTIONS:

Side-effects:

Neurological: **ALLECET SYRUP** lacks significant sedative effects. However, patients should be warned that a small number of individuals may experience sedation and it is therefore advised that an individual's response should be determined before driving or performing complicated tasks. This potential sedative effect may be exacerbated by the simultaneous intake of alcohol or other central nervous system depressants. Sedative effects may vary from slight drowsiness to deep sleep and may include other side-effects such as lassitude, dizziness and in-coordination. Sedation, when it occurs, may diminish after a few days of treatment.

Alternatively, paradoxical 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.

Extra-pyramidal symptoms have been reported. There have also been occasional reports of mild and transient subjective adverse effects such as nervousness, agitation, increased appetite and dry mouth.

Gastro-intestinal: Constipation, nausea, vomiting, diarrhoea, and epigastric pain have occurred.

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

Hypersensitivity reactions: Skin reactions especially, and angioedema, as well as cross-sensitivity to related medicines may occur. Photosensitivity has also been reported. Jaundice, which is observed rarely, may also be a hypersensitivity reaction.

Other: Tinnitus, headache, paraesthesias and hypotension have been reported rarely.

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

Special Precautions:

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

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

Antihistamines are not indicated for the treatment of asthma.

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.

Excessive alcohol consumption should be avoided when taking antihistamines.

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. Treatment is symptomatic and supportive.

IDENTIFICATION:

A clear, colourless, pineapple and sweet orange flavoured syrup with a sweet taste.

PRESENTATION:

Packed in 150 ml amber PET bottles.

STORAGE INSTRUCTIONS:

Store in a cool dry place below 25°C. Protect from light.
KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

37/5.7.1/0153

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

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