Cetirizine hydrochloride

Ricam
5 mg / 5 mL Syrup
Antihistamine

FORMULATION
Each 5 mL contains:
Cetirizine hydrochloride ..... 5 mg

DESCRIPTION
Clear colourless syrup having mixed fruit flavour base.

ACTIONS AND PHARMACOLOGY
Cetirizine is used in the treatment of allergy and acts by competing with histamine for H_1-receptor sites on effector cells. It antagonizes, in varying degrees, most of the pharmacological effects of histamine, including urticaria and pruritus. Also, the anticholinergic action of Cetirizine provides a drying effect on the nasal mucosa. Cetirizine has been shown to cause mild bronchodilation and thereby blocking histamine-induced bronchoconstriction in asthmatic patients. Due to its inhibition of late-phase eosinophil recruitment after local allergen challenge, Cetirizine has been shown to be more effective, in higher doses, than other antihistamines in reducing the symptoms of pollen-induced asthma. Cetirizine has minimal anticholinergic activity by preventing responses to acetylcholine that are mediated via muscarinic receptors.

PHARMACOKINETICS
After oral administration, Cetirizine is well absorbed. Food may delay the rate, but not the extent of Cetirizine absorption. Protein binding of Cetirizine is 93%. Antihistamines are usually metabolized by the hepatic cytochrome P-450 system while a certain percentage is metabolized by the kidney. However, Cetirizine is minimally metabolized and excreted unchanged primarily through the kidneys. The half-life of Cetirizine is almost 8 hours. For dialysis patients, the half-life is almost 20 hours whereas children require between 4.1 to 6 hours. Peak concentration of Cetirizine is achieved in 1 hour. Approximately 60% of the total dose administered is excreted unchanged in urine within 24 hours and about 10% is excreted in faeces. For patients with moderate renal impairment, the clearance is decreased by 70% compared to normal subjects.

INDICATIONS
For the symptomatic treatment of seasonal and perennial allergic rhinitis and urticaria of allergic origin.

CONTRAINDICATIONS
Contraindicated for patients of:
- Hypersensitivity to the active substance or to any of the excipients, to Hydroxyzine or to any piperazine derivatives
- Patients with severe renal impairment at less than 10ml/min creatinine clearance
- Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take Cetirizine

PREGNANCY AND LACTATION
Adequate and well-controlled studies in humans have not been conducted. The extent of distribution into human breast milk is unknown. Use is not recommended in nursing mothers because of the risk of adverse effects, such as unusual excitement or irritability, in infants.

WARNINGS & PRECAUTIONS
Caution in epileptic patients and patients at risk of convulsion is recommended.

Patients intending to drive, engaging in potentially hazardous activities or operating machinery should not exceed the recommended dose and should take their response to the medicinal product into account. In these sensitive patients, concurrent use with alcohol or other CNS depressants may cause additional reductions in alertness and impairment of performance.

INTERACTION WITH OTHER MEDICAMENTS AND OTHER FORMS OF INTERACTION
- No interaction is observed for Cetirizine with Pseudoephedrine, Cimetidine, Ketoconazole, Erythromycin and Azithromycin.
- Small decrease in Cetirizine clearance is observed when Theophylline (400mg once daily) is taken with Cetirizine. However, disposition of Theophylline was not altered by concomitant Cetirizine administration.
- Concomitant administration of Cetirizine and macrolides or Ketoconazole has never resulted clinically relevant ECG changes.
- Extent of exposure to Cetirizine was increased by 40% when Ritonavir is taken with Cetirizine.
- Disposition of Ritonavir was slightly altered further to concomitant Cetirizine administration.

ADVERSE EFFECTS
Cetirizine causes minimal sedative effects. Incidences more frequent seen are drowsiness and dryness of mouth, nose, or throat. Anaphylaxis (cough; difficulty in swallowing; dizziness; increased heartbeat; hives; itching; puffiness or swelling of the eyelids or around the eyes, face, lips or tongue; shortness of breath; skin rash; tightness in chest; unusual tiredness or weakness; wheezing), cardiac arrhythmias/palpitations/tachycardia, cholestasis, hepatitis or other hepatic function abnormalities, convulsions or seizures, edema are less frequently found. However, medical attention is required in such cases. Confusion, difficult or painful urination, drowsiness, dizziness, and dryness of mouth, nose, or throat are more likely to occur in the elderly. Nightmares, unusual excitement, nervousness, restlessness, or irritability is more likely to occur in children and elderly patients.

OVERDOSE
Symptoms
Symptoms observed after an overdose of Cetirizine are mainly associated with CNS effects that could suggest an anticholinergic effect. Adverse effects reported after an intake of at least 5 times the recommended daily dose are: confusion, diarrhea, dizziness, fatigue, headache, malaise, mydriasis, pruritus, somnolence, tachycardia, restlessness, sedation, tremor and urinary retention.

Treatment
There is no specific antidote for Cetirizine. Should overdose occur, symptomatic or supportive treatment is recommended. Gastric lavage should be considered following ingestion of a short occurrence. Cetirizine is not effectively removed by dialysis.

DOSAGE AND ADMINISTRATION
Adult
Oral, 1 to 2 teaspoons once daily.
A dose of 5 mg once a day is recommended for patients with reduced creatinine clearance (<31mL per min) and with hepatic impairment.

Children
Age 2 to 6 years old: Oral, 1/2 teaspoon daily, may be increased to maximum daily dose of 1 teaspoon.
Cetirizine use is not recommended if patient of age 2 to 6 years has renal or hepatic dysfunction.

Age 6 years and older
Oral, 1 to 2 teaspoons once daily.
Lower dosage of 5mg once a day should be used for patient age 6 years and older with renal or hepatic dysfunction.

Storage: Store at temperatures not exceeding 30˚C.
Protect from light.

Presentation / packing: Amber Polyethylene Terephtalate Bottle x 60 mL.

For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph

Seek medical attention immediately at the first sign of any adverse drug reaction.

Date of First Authorization / Renewal of the Authorization: 11 September 2019

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