CETIRIZINE HYDROCHLORIDE

IZEEN

5 mg/5 mL Syrup

ANTIHISTAMINE

Formulation:
Each 5 mL contains:
Cetirizine (as hydrochloride) .....5 mg

Indications:
It is used for the symptomatic relief of allergic conditions including rhinitis and chronic urticaria.

Contraindications:
Hypersensitivity to the drug, pregnancy and lactation.

Pharmacokinetics:
Cetirizine is rapidly absorbed from the gastrointestinal tract after oral doses, peak plasma concentrations being attained within about an hour. Food delays the time to peak plasma concentrations but does not decrease the amount of drug absorbed. Cetirizine is highly bound to plasma proteins and has an elimination half-life of about 10 hours. It has been detected in breast milk. Cetirizine is excreted primarily in the urine mainly as unchanged drug. It does not appear to cross the blood-brain barrier to a significant extent.

Uses and Administration:
Cetirizine hydrochloride, a piperazine derivative and metabolite of hydroxyzine, is described as a long-acting non-sedating antihistamine with some mast-cell stabilising activity. It appears to have a low potential for drowsiness in usual doses and to be virtually free of antimuscarinic activity. It is used for the symptomatic relief of allergic conditions including rhinitis and chronic urticaria.
In adults and children aged 6 years and over, cetirizine hydrochloride is given by mouth in a dose of 10 mg once daily or 5 mg twice daily. Children aged 2 to 5 years may be given cetirizine 5 mg once daily or 2.5 mg twice daily. In the USA, children aged 6 months to 2 years may be given a dose of 2.5 mg once daily, increased to a maximum of 2.5 mg twice daily in

those aged 12 months and over, for the treatment of perennial allergic rhinitis and chronic urticaria. It is also used with a decongestant such as pseudoephedrine hydrochloride.
Dosage of cetirizine should be reduced in patients with hepatic or renal impairment.

Reporting of Suspected Adverse Reactions:
To allow continued monitoring of the benefit/risk balance of the medicinal product, reporting of suspected adverse reaction is necessary. Healthcare professionals are encouraged to report any suspected adverse reactions directly to the importer/distributor and/ or report to FDA: www.fda.gov.ph.
Patients are advised to seek immediate medical attention at the first sign/s of adverse reactions.

Drug Interactions:
Sedating antihistamines may enhance the sedative effects of CNS depressants including alcohol, barbiturates, hypnotics, opioid analgesics, anxiolytic sedatives, and anti psychotics. Sedative interactions apply to a lesser extent with the non-sedating antihistamines; they do not appear to potentiate the effects of alcohol, but it should be avoided in excess.

Caution:
Foods, Drugs, Devices & Cosmetics Act prohibits dispensing without prescription.

Storage:
Store at temperatures not exceeding 30°C.
Keep out of reach of children.

Availability:
In 60 mL amber glass bottle.

FDA Reg. No.: DRP-4198-01
Date of First Authorization: 10 November 2016
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Mfg. Lic. No: 000024

Manufactured by:
Pharmatec Pakistan (Pvt.) Ltd.
D-86/A, S.I.T.E.,Pakistan.

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