CENE TABLETS

(Cetirizine 10 mg)

COMPOSITION

Each tablet contains Cetirizine 10 mg (as Cetirizine Hydrochloride). Other ingredients: as per the approved product formulation.

DESCRIPTION

Cetirizine is a second-generation, selective peripheral histamine H1-receptor antagonist with antihistaminic and antiallergic activity. It provides relief from histamine-mediated symptoms of allergic conditions.

CLINICAL PHARMACOLOGY

Cetirizine inhibits the action of histamine at peripheral H1 receptors, helping reduce sneezing, itching, runny nose and wheals. Onset of action is generally within one hour, and its effect lasts approximately 24 hours. Cetirizine is predominantly eliminated through the kidneys.

INDICATIONS

Symptomatic relief of nasal and ocular symptoms of seasonal and perennial allergic rhinitis, including sneezing, rhinorrhoea, nasal or eye itching and watery eyes. Relief of symptoms of chronic idiopathic urticaria (hives), including itching and wheals.

DOSAGE AND ADMINISTRATION

Adults and adolescents aged 12 years and over: one tablet (10 mg) once daily. Children aged 6–12 years: use according to a physician's recommendation; certain licensed regimens use 5 mg twice daily, for which a suitable 5 mg dosage form is needed. Swallow with water, with or without food. Do not exceed the prescribed dose.

SPECIAL POPULATIONS

Elderly: no adjustment is generally required with normal renal function. Renal impairment: dose or dosing interval should be adjusted according to kidney function by a physician; severe end-stage renal disease requiring dialysis may be a contraindication under relevant product information. Hepatic impairment: use with medical advice, particularly when renal impairment coexists.

CONTRAINDICATIONS

Known hypersensitivity to cetirizine, hydroxyzine, other piperazine derivatives or any component of the formulation. Severe renal impairment may preclude use; refer to approved local product information.

WARNINGS AND PRECAUTIONS

Cetirizine can cause somnolence, fatigue or dizziness. Use caution in persons predisposed to urinary retention (e.g., spinal cord lesions or prostatic enlargement), and in patients with epilepsy or increased risk of convulsions. Exercise caution in patients with kidney disease. Avoid exceeding recommended doses.

DRIVING AND MACHINERY

Although cetirizine is generally less sedating than first-generation antihistamines, individual sensitivity varies. Patients should assess their response before driving, operating machinery or performing work requiring alertness.

DRUG INTERACTIONS

Alcohol, sedatives and other central nervous system depressants may increase impairment or drowsiness. Patients should inform their healthcare professional about other medicines being taken. Clinically significant interactions are relatively uncommon at recommended doses.

PREGNANCY

Available human data have not identified a clear increase in major birth defects, but use during pregnancy should be based on the healthcare professional's assessment of necessity and potential risks.

LACTATION

Cetirizine passes into human breast milk. Consider potential effects on the breastfed infant and use only with professional guidance.

PEDIATRIC USE

This 10 mg tablet is not suitable for all pediatric dosing regimens. An age-appropriate formulation and dose should be selected for younger children. Do not give to children under 6 years unless directed by a physician.

GERIATRIC USE

Older adults may be more sensitive to adverse effects and are more likely to have decreased renal function. Dose selection should take kidney function into account.

ADVERSE REACTIONS

Commonly reported reactions include somnolence, fatigue, dry mouth, headache, dizziness and occasionally nausea. Children may experience headache, abdominal pain or fatigue.

UNCOMMON OR SERIOUS REACTIONS

Rarely, hypersensitivity reactions (including rash, urticaria, angioedema or anaphylaxis), agitation, confusion, palpitations, urinary retention, seizures or severe skin reactions may occur. Discontinue treatment and seek urgent medical assistance if swelling of the face or throat, breathing difficulty or severe allergic reactions occur.

OVERDOSAGE

Overdose may cause marked drowsiness, restlessness, agitation, confusion, dizziness, rapid heartbeat or urinary retention. Children may initially exhibit excitation followed by drowsiness. There is no specific antidote; treatment is symptomatic and supportive. Seek immediate medical attention in suspected overdose.

MISSED DOSE

Take the missed dose when remembered unless it is nearly time for the next dose. Do not take a double dose to make up for a missed one.

STORAGE CONDITIONS

Store in a dry place protected from excessive heat and moisture, under the temperature conditions approved for the marketed product. Keep out of the sight and reach of children.

PRESENTATION

Cene Tablets 10 mg: pack of 10 tablets.

PATIENT ADVICE

Use only as directed. Do not use if you have a known allergy to cetirizine or related antihistamines. Consult a healthcare professional if symptoms persist or worsen. Report troublesome adverse reactions.

MANUFACTURED BY

Vega Pharmaceuticals (Pvt.) Ltd.