RINACET®
(Cetirizine Hydrochloride)

Description
Cetirizine is a Piperazine derivative Histamine (H) receptor blocker.

Composition
Each tablet contains: Cetirizine Hydrochloride BP 10 mg.
Each 5ml syrup contains: Cetirizine Hydrochloride BP 5 mg.

Excipients:
Rinacet Tablets: Microcrystalline cellulose, maize starch, Aerosil 200, magnesium stearate, Croscarmellose sodium, Hypromellose 6 CPS, propylene glycol, titanium dioxide, dichloromethane, isopropyl alcohol.
Rinacet syrup: sodium benzoate, citric acid, sodium saccharin, sodium citrate, sodium methyl paraben, sodium propyl paraben, Bronopol, natrosol, Ponceau 4R, strawberry flavour and purified water.

Pharmacology
Cetirizine is non-sedating anti-histamine with a potent anti-allergic action. It possesses a strong affinity for histamine H_1receptors, and has no anti-cholinergic and anti-serotoninergic effects. Since it does not cross the blood-brain barrier. It does not cause sedation or interfere with mental alertness or memory function .It appears to have some mast-cell stabilizing activity.

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

Indications
For the treatment of perennial rhinitis, seasonal allergic rhinitis (hay fever) and chronic idiopathic urticaria in adults and children aged 6 years and over, and for seasonal rhinitis (hay fever) in children aged between 2 to 5 years.

Dosage and administration.
For oral route of administration.
In adults and children aged 6 years and over, Cetirizine 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.

Contra-indications
Cetirizine hydrochloride 10mg film coated tablets are contraindicated in:

- Patients with hypersensitivity to cetirizine hydrochloride or to any of the excipients
- In children under six years of age
- Patients with severe renal impairment.

Warning and precautions:
In some patients, long term treatment with cetirizine tablets may lead to an increased risk of caries due to mouth dryness. The patients should therefore be informed about the importance of oral hygiene. At impaired hepatic function and renal function, the elimination of cetirizine may be impaired. Caution should be exercised when administering cetirizine to these patients. Cetirizine may potentiate the effects of alcohol. Therefore caution is recommended at concomitant use of alcohol.

Drug interactions:
Allergy testing: use of cetirizine must be discontinued three days before allergy tests. Cetirizine may potentiate the effects of alcohol. Therefore caution is recommended at concomitant use of alcohol. Caution is recommended with the concomitant use of CNS depressants.

Pregnancy and lactation:
Data on limited number of exposed pregnancies indicate no adverse effects of cetirizine on pregnancy or on health of foetus/new born child. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/foetal development, parturition or post natal development hence caution should be exercised.

Effects on ability to drive and use machines.
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 sensitive patients, concurrent use with alcohol or other CNS depressants may cause additional reductions in alertness and impairment of performance.

Adverse reactions
Occasional gastrointestinal side-effects of antihistamines include nausea, vomiting, diarrhoea, or epigastric pain. Palpitations and arrhythmias have been reported occasionally with most antihistamines.
Antihistamines may sometimes cause rashes and hypersensitivity reactions (including bronchospasm, angioedema, and anaphylaxis) and cross-sensitivity to related drugs may occur
Other adverse effects that have been reported with the antihistamines include convulsions, sweating, myalgia, Paraesthesia, extra pyramidal effects, tremor, sleep disturbances, depression, confusion, tinnitus, hypotension, and hair loss.

Overdosage and treatment:
Symptoms observed after an overdose of cetirizine are mainly associated with CNS effects or with effects that could suggest an anticholinergic effect. Adverse events reported after an intake of at least 5 times the recommended daily dose are: confusion, diarrhoea, dizziness, fatigue, headache, malaise, mydriasis, pruritus, restlessness, sedation, somnolence, stupor, tachycardia, tremor, and urinary retention.
Management: There is no known specific antidote to cetirizine. Should overdose occur, symptomatic or supportive treatment is recommended. The patient should be kept under clinical observation for at least four hours after ingestion, and the blood pressure, heart rate and vital signs monitored until stable. In symptomatic cases, ECG should be performed. Gastric lavage should be considered following ingestion of a short occurrence. Oral activated charcoal (50 g for an adult, 10-15 g for a child) should be considered if more than 2.5 mg/kg cetirizine has been ingested within one hour. Cetirizine is not effectively removed by dialysis.

Presentation
Tablet: A folding carton pack containing a perforated blister pack of 2 x 5 x 10 tablets.
Syrup: A folding carton pack containing 30ml, 60ml or 100ml amber coloured bottles.

Shelf life:
Syrup: 3 years from the date of manufacture.
Tablet: 3 years from the date of manufacture

Storage condition.
Store in a dry place, below 30°C. Protect from direct sunlight.
Keep out of reach of children.

Distribution category: Prescription Only Medicine **(POM).**

Manufactured By:

DAWA	**DAWA Limited,** **Plot No. 7879/8, Baba Dogo Road, Ruaraka** **P. O. Box 16633 – 00620, Nairobi, Kenya.**

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