SUMMARY OF PRODUCT CHARACTERISTICS:

1. Name of the medicinal product

Rinacet tablets

2. Qualitative and quantitative composition

Each film-coated tablet contains: Cetirizine Hydrochloride 10mg.

For the full list of excipients, see section 6.1.

3. Pharmaceutical form

Film-coated tablet.

White coloured biconvex oblong shaped tablet, scored on one side and plain on the reverse side.

4. Clinical particulars

4.1 Therapeutic 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.

4.2 Posology and method of administration

Method of administration: Oral route

Posology:

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.

4.3 Contraindications

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.

4.4 Special warnings and precautions for use

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 o alcohol.

4.5 Interaction with other medicinal products and other forms of interaction.

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.

4.6 Fertility, 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.

Caution should be exercised

4.7 Effects on ability to drive and use machines.

Objective measurements of driving ability, sleep latency and assembly line performance have not demonstrated any clinically relevant effects at the recommended dose of 10 mg.

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

4.8 Undesirable effects.

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.

4.9 Overdose

There is limited experience of overdosing. 20 mg to a 2-year-old, 30 mg to a 3-year-old and 40 mg to an 11-year-old did not give any symptoms. 60 mg to a 4-year-old gave mild intoxication, 400 mg to a 14-year-old gave mild symptoms, while 400 to 500 mg to an adult gave no symptoms at all.

Symptoms

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.

There is no specific antidote.

Cetirizine is not effectively removed by dialysis.

5. Pharmacological properties.

5.1 Pharmacodynamic properties.

Pharmacotherapeutic group: Antihistamine for systemic use, piperazine derivative.

ATC code: R06AE07

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.

5.2 Pharmacokinetic properties.

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.

5.3 Preclinical safety data

Preclinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, toxicity to reproduction, genotoxicity or carcinogenicity.

6. Pharmaceutical particulars

6.1 List of excipients

Maize starch, microcrystalline cellulose, colloidal silica anhydrous, magnesium stearate, Croscarmellose sodium, Hypromellose 6cps, propylene glycol, titanium dioxide, dichloromethane and isopropyl alcohol.

6.2 Incompatibilities

Not applicable

6.3 Shelf life

3 years.

6.4 Special precautions for storage

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

6.5 Nature and contents of container

PVC /Aluminium foil blisters.
Pack size: Blister pack of 2 x 5 x 10's tablets per unit box.

6.6 Special precautions for disposal and other handling

No special requirements.
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. Marketing authorisation holder

DAWA Limited
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P.O Box 16633-00620, Nairobi-Kenya.

8. Date of revision of the text

November 2017