Cezti 10

COMPOSITION

Active ingredient:

One Cezti 10 film-coated tablet contains Cetirizine dihydrochloride 10 mg.

PHARMACODYNAMICS

In experimental animals, Cetirizine has been shown to be an anti-H1 agent devoid of any significant anticholinergic or antiserotonin effects. At pharmacologically active doses, it induces neither sedation nor behavioral changes. This may be explained by the fact that Cetirizine does not cross the blood-brain barrier.

It was shown in human pharmacology studies that Cetirizine would inhibit certain effects produced by endogenous histamine released *in vivo* by an agent, e.g. 48/80.

Finally, it inhibits the cutaneous reaction induced by VIP (Vasoactive Intestinal Polypeptide) and substance P, neuropeptides that are believed to take part in the allergic reaction. Cetirizine markedly reduces bronchial hyper-reactivity to histamine in the asthmatic patients. It also reduces the allergic reaction induced by specific allergens.

These effects are obtained without any central effects being demonstrated either by psychometric test or by a quantified EEG.

PHARMACOKINETICS

Peak blood levels of the order of 0.3 µg/ml are reached between 30 and 60 minutes after administration of a 10 mg dose of Cetirizine. Its plasma half - life is approximately 11 hours.

Absorption is very consistent from one subject to the next. Its renal clearance is 30 ml/minute and the excretion half-life is approximately 9 hours. Cetirizine is strongly bound to plasma proteins.

INDICATIONS

Adult and children of 3 years or above: Symptomatic treatment of seasonal rhinitis, perennial allergic rhinitis and urticaria of allergic origin.

DOSAGE AND ADMINISTRATION

Administration

Cezti 10 need to be swallowed with a glass of liquid.

Dosage

The recommended dosage in children aged between 3 and 6 years old is 5 mg daily, either 2.5 mg twice daily or 5 mg once daily.

Adults and adolescents over 12 years of age: 1 tablet (10 mg) once daily.

If drowsiness occurs, the tablets can be administered in the evening.

Children 6-12 years: 1 tablet (10 mg) once daily or 1/2 tablet (5 mg) taken twice daily (morning and evening).

For children weighing less than 30 kg: 1/2 tablet (5 mg) taken once daily.

Clinical trials in children have not exceeded four weeks.

Cetirizine is contraindicated in patients with severe renal impairment. In patients with moderate renal impairment the dose should be adjusted to 5 mg (1/2 tablet). Caution should be exercised in patients with mild to moderate renal impairment or impaired liver function.

There is no evidence that the dose needs to be modified for healthy elderly patients. The duration of the treatment may vary depending on the symptoms.

CONTRAINDICATIONS

Patients with a history of hypersensitivity of any of Cetirizine's constituents.

PRECAUTIONS

At therapeutic doses, Cetirizine does not potentiate the effect of alcohol (at a blood level of 0.8 g/l). Care should, however be taken.

Activities requiring mental alertness: in clinical trials the occurrence of somnolence has been reported in some patients taking Cetirizine: due caution should therefore be exercised when driving a car or operating potentially dangerous machinery.

Pediatric Use

The safety and effectiveness of Cetirizine in pediatric patients under the age of 2 years have not been established.

DRUG INTERACTIONS

To date, there are no known interactions with other drugs. Nevertheless, cetirizine should be used with caution if sedatives are also being taken.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINE

Studies in healthy volunteers on 20 or 25 mg/day have not revealed effects on alertness or reaction time. Patient should be advised, however to take care not to exceed the recommended dose.

USE IN PREGNANCY AND LACTATION

Data on limited number of exposed pregnancies indicate no adverse effect of cetirizine on pregnancy or on health of foetus/new born child. To date no other relevant epidemiological data are available. Caution should be exercised when prescribing to pregnant women. No data concerning the excretion of cetirizine into human milk are available. Cetirizine should be avoided during lactation.

ADVERSE EFFECTS

When Cetirizine is administered at recommended doses any side effects that may occur, e.g. agitation, dry mouth, drowsiness or headache, do not differ significantly from placebo. Very occasionally, symptoms of hypersensitivity have been reported.

OVERDOSAGE

The acute lethal dose of cetirizine in humans is not known. Somnolence was reported in one adult who ingested 150 mg of cetirizine hydrochloride; no other adverse effects, including clinical manifestations, abnormal blood chemistry, or abnormal hematology occurred in this individual. Restlessness and irritability followed by drowsiness were reported in an 18-month old child who ingested about 180 mg of cetirizine hydrochloride.

In acute Cetirizine overdosage, treatment should include symptomatic and supportive measures, taking into account the possibility of any concomitantly ingested drugs. There is no specific antidote for overdosage of cetirizine. The drug is not effectively removed by dialysis, and therefore, dialysis would not be effective in acute overdosage of cetirizine, unless a drug that is removed by dialysis were ingested about 180 mg of cetirizine hydrochloride.

SHELF - LIFE AND STORAGE INSTRUCTIONS

The expiry date of this pack is printed on the box. Do not use this pack after this date.

Do not store above 30°C.

Keep all medicines out of reach of children.

PREPARATION AND PACK SIZES

Cezti 10 appears as white, caplet-shaped, film coated-tablet, biconvex, engraved logo "" on one side and scored on the other side.

Blister packed in PVC- Aluminium foil and packed in cardboard box (packs of 50's).

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STELLA

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