APPROVED PACKAGE INSERT:

ZELARY 10

SCHEDULING STATUS

S2

PROPRIETARY NAME (AND DOSAGE FORM)

ZELARY 10 Tablets

COMPOSITION

Each film-coated tablet contains 10 mg cetirizine dihydrochloride.

PHARMACOLOGICAL CLASSIFICATION

A 5.7.1 Antihistaminics

PHARMACOLOGICAL ACTION

PHARMACOKINETICS

ZELARY 10 is a metabolite of hydroxyzine. It is a second - generation reversible, competitive inhibitor of histamine at the histamine-1 (H_1) receptor. Cetirizine competes with histamine for the H_1 receptor site. Cetirizine prevents but does not reverse, pharmacological responses mediated by histamine, at the H_1 receptor.

Pharmacokinetics

Cetirizine is well absorbed from the gastro-intestinal tract and peak plasma concentrations are reached within 1 hour after oral administration.

Pharmacokinetics are linear, with plasma concentrations increasing proportionately with increasing doses.

The terminal half – life in adults is approximately 10 hours, in children aged 6 to 12 years, 6 hours, in children aged 2 to 6 years, 5 hours.

Cetirizine is eliminated faster in children, and slower in patients with hepatic or renal impairment (creatinine clearance < 40 ml/min), with a resultant increase in half-life and decrease in clearance. Cetirizine does not undergo extensive first-pass metabolism. The cumulative urinary excretion represents about two thirds of the dose given in both adults and children.

INDICATIONS

ZELARY 10 is indicated for the symptomatic relief of allergic conditions such as allergic rhinitis, and allergic skin conditions such as urticaria.

CONTRA-INDICATIONS

Hypersensitivity to any of the ingredients.

Hypersensitivity to hydroxyzine.

Lactating women, since the active ingredient is excreted in breast milk.

Pregnancy, as safety has not been established.

Children under the age of two years, as safety and efficacy have not been demonstrated.

WARNINGS

This medicine may lead to drowsiness and impaired concentration, which may be aggravated by the simultaneous intake of alcohol or other central nervous system depressant agents.

The patients ability to perform hazardous activities requiring mental alertness or physical coordination such as driving or operating machinery may be impaired.

Porphyria: Use With Caution.

INTERACTIONS

Concomitant use of alcohol and other sedating agents should be avoided.

There is no evidence of an interaction between cetirizine and cimetidine, ketoconazole, erythromycin, azithromycin, diazepam, glipizide and pseudoephedrine.

PREGNANCY AND LACTATION

Safety in pregnancy and lactation has not been established (see **CONTRA-INDICATIONS**)

DOSAGE AND DIRECTIONS FOR USE

Tablets:

Adults or children 12 years of age or

Older: one 10 mg tablet daily,

Children 6 to 12 years old: one 10 mg tablet once daily or 5 mg (half a tablet)

twice daily.

No dose adjustment is necessary in healthy elderly patients with normal

renal function.

Dosage in Renal impairment:

In patients with renal impairment, where the creatinine clearance is less than

40 ml/min, the recommended daily dose of cetirizine should be halved.

Dosage in Hepatic impairment:

In moderate to severe hepatic impairment half the recommended daily dose should be used.

SIDE EFFECTS AND SPECIAL PRECAUTIONS

Side effects:

Gastro-intestinal system:

Nausea, gastro-intestinal discomfort, increased appetite and dry mouth have been reported.

Respiratory system:

Thickening of mucous.

Central Nervous System:

Drowsiness, fatigue, dizziness, headache, anxiety, nervousness, malaise and asthenia have been reported.

Hypersensitivity reactions:

Urticaria, skin rash, pruritus, and angioedema, may develop.

Special precautions:

ZELARY 10 lacks significant sedative effects. Patients should be warned, however, that a small number of individuals may experience sedation. It is therefore advisable to determine individual response before driving or performing complicated tasks (see **WARNINGS**).

This effect may be compounded by the simultaneous intake of alcohol or other central nervous system depressants (see **INTERACTIONS**).

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

Drowsiness is an expected symptom of overdosage. Overdosage in children may produce agitation, somnolence, pruritus, rash, urinary retention, fatigue, tremor and tachycardia.

In the case of massive overdosage gastric lavage should be performed together with the usual supportive measures. To date there is no specific antidote.

Cetirizine is not effectively removed by dialysis.

FURTHER TREATMENT IS SYMPTOMATIC AND SUPPORTIVE.

IDENTIFICATION

ZELARY 10 Tablets:

White, circular biconvex film-coated tablets with a score line on one side.

STORAGE INSTRUCTIONS

Store at or below 25 °C. Protect from light.

KEEP OUT OF THE REACH OF CHILDREN

Keep blisters in carton until required for use.

REGISTRATION NUMBER

37/5.7.1/0428

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

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