APPROVED PACKAGE INSERT:

AUSTELL-CETIRIZNE 5/10 mg

SCHEDULING STATUS

S2

PROPRIETARY NAME (AND DOSAGE FORM)

AUSTELL-CETIRIZINE 5 mg TABLETS

AUSTELL-CETIRIZINE 10 mg TABLETS

COMPOSITION

AUSTELL-CETIRIZINE 5 mg:

Each film coated tablet contains cetirizine dihydrochloride 5 mg.

AUSTELL-CETIRIZINE 10 mg tablets:

Each film coated tablet contains cetirizine dihydrochloride 10 mg.

PHARMACOLOGICAL CLASSIFICATION

A 5.7.1 Antihistaminics.

PHARMACOLOGICAL ACTION

AUSTELL-CETIRIZINE 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

AUSTELL-CETIRIZINE 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 patient's ability to perform hazardous activities requiring mental alertness or physical co-ordination 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

Adults or children 12 years of age or older: one 10 mg tablet once daily.

Children 6 to 12 years old: one 10 mg tablet once daily or 5 mg 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:

AUSTELL-CETIRIZINE 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. There is no specific antidote. Cetirizine is not effectively removed by dialysis.

FURTHER TREATMENT IS SYMPTOMATIC AND SUPPORTIVE.

IDENTIFICATION

AUSTELL–CETIRIZINE 5 mg:

White to creamish white capsule shaped film coated tablets with breakline and ‘B’ & ‘L’ embossed on either side of the breakline and ‘5’ embossing on the other side.

AUSTELL–CETIRIZINE 10 mg:

White to creamish white capsule shaped film coated tablets with scoreline and ‘B’ & ‘L’ debossed on either side of the scoreline and ‘10’ debossing on the other side.

PRESENTATION

AUSTELL–CETIRIZINE 5 mg:

Blister packs (Clear PVC/Aluminium foil) of 1 x 10, 3 x 10 and 10 x 10 tablets.

Bulk packs (White HDPE Jars) of 250, 500 and 1000 tablets.

AUSTELL–CETIRIZINE 10 mg:

Blister packs (Clear PVC/Aluminium foil) of 1 x 10, 3 x 10 and 10 x 10 tablets.

Bulk packs (White HDPE Jars) of 250, 500 and 1000 tablets.

STORAGE INSTRUCTIONS

Store in a dry place below 25 °C. Protect from light.

Keep blister packs in carton until required for use.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

AUSTELL-CETIRIZINE 5 mg: 37/5.7.1/0579

AUSTELL-CETIRIZINE 10 mg: 37/5.7.1/0580

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

Austell Pharmaceuticals (Pty) Ltd

1 Sherborne Road

Parktown

JOHANNESBURG

2193

South Africa

Tel: 0860287835

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