APPROVED PROFESSIONAL INFORMATION

SCHEDULING STATUS: S2

PROPRIETARY NAME (AND DOSAGE FORM):

TANTRIN TABLETS 5 mg (Tablet)

TANTRIN TABLETS 10 mg (Tablet)

COMPOSITION:

TANTRIN TABLETS 5 mg

Each film-coated tablet contains 5 mg cetirizine dihydrochloride. Contains lactose monohydrate.

TANTRIN TABLETS 10 mg

Each film-coated tablet contains 10 mg cetirizine dihydrochloride. Contains lactose monohydrate.

The inactive ingredients are crospovidone (type B), hypromellose (methocel E5 LV premium), macrogol 400, magnesium stearate, starch pregelatinised and titanium dioxide.

PHARMACOLOGICAL CLASSIFICATION:

A 5.7.1 Antihistaminics

PHARMACOLOGICAL ACTION:

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.

A high proportion of cetirizine is bound to human plasma proteins.

INDICATIONS:

TANTRIN TABLETS is indicated for symptomatic relief of allergic conditions such as allergic rhinitis, and allergic skin conditions such as urticaria.

CONTRA-INDICATIONS:

Hypersensitivity to **TANTRIN TABLETS** or 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 simultaneous intake of alcohol or other central nervous system depressant agents. The patient's 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"**). Cetirizine is excreted in breast milk.

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 one 5 mg tablet twice daily. This dosage form is not suitable for children younger than 6 years.

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:

Immune system disorders:

Less frequent:

Anaphylaxis, angioedema.

Blood and lymphatic system disorders:

Less frequent:

Agranulocytosis, leucopenia, haemolytic anaemia and thrombocytopenia.

Psychiatric disorders:

The following side effects have been reported and frequencies are unknown:

Agitation, anxiety, nervousness.

Nervous system disorders:

Frequent:

Drowsiness.

Less frequent:

Dizziness, fatigue, confusion, convulsions, tremor, anorexia, paraesthesia. The following side effect has been reported and frequency is unknown: Headache.

Eye disorders:

Less frequent:

Blurred vision.

Ear and labyrinth disorders:

Less frequent:

Tinnitus.

Cardiac disorders:

Less frequent:

Palpitations, arrhythmias.

Respiratory, thoracic and mediastinal disorders:

The following side effect has been reported and frequency is unknown: Thickening of

mucous, pharyngitis

Gastrointestinal disorders:

Less frequent:

Nausea, increased appetite, dry mouth, vomiting, diarrhoea, constipation.

The following side effect has been reported and frequency is unknown: Gastro-intestinal discomfort.

Hepato-biliary disorders:

Less frequent:

Cholestasis, hepatitis or other hepatic function abnormalities.

Skin and subcutaneous tissue disorders:

Less frequent:

Skin rash, photosensitivity, sweating.

The following side effects have been reported and frequencies are unknown: Urticaria, pruritus.

Renal and urinary disorders:

Less frequent:

Urinary difficulty.

General disorders and administrative site conditions:

The following side effects have been reported and frequencies are unknown: Malaise, asthenia

Special precautions:

TANTRIN TABLETS lack 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 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 overdose. Overdose in children may produce agitation, somnolence, pruritus, rash, urinary retention, fatigue, tremor, and tachycardia. In the case of massive overdose, 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:

TANTRIN TABLETS 5 mg:

White, film-coated, off-rectangular tablets, debossed with “X” on one side with ‘21’ on the other side. Score line between ‘2’ and ‘1’.

TANTRIN TABLETS 10 mg:

White, film-coated, off-rectangular tablets, debossed with “X” on one side with ‘20’ on the other side. Score line between ‘2’ and ‘0’.

PRESENTATION:

TANTRIN TABLETS 5 mg:

PVC / PVdC Pack:

Tablets are packed in 250 micron clear PVC coated with 60 g/m^2 PVdC and printed aluminium foil with 7 g/m^2 heat seal lacquer.

Pack size: 10's – Each carton contains 1 blister of 10 tablets each. 30's – Each carton contains 3 blisters of 10 tablets each.

TANTRIN TABLETS 10 mg:

PVC / PVdC Pack:

Tablets are packed in 250 micron white opaque PVC coated with 60 g/m^2 PVdC and printed aluminium foil with 7 g/m^2 heat seal lacquer.

Pack size: 10's – Each carton contains 1 blister of 10 tablets each. 30's – Each carton contains 3 blisters of 10 tablets each.

HDPE Container Pack:

Tablets are packed in 40 ml white opaque HDPE container of 33 neck finish (OFC 51ml) with 33 mm-400 RS white opaque polypropylene closure with induction seal wad.

Pack size: 30's – One HDPE container of 30 tablets.

STORAGE INSTRUCTIONS:

Store at or below 25 °C.

Keep tablets in a dry place.

Keep the blisters in the carton until required for use. Keep the HDPE containers tightly closed.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

TRANTRIN TABLETS 5 mg: 43/5.7.1/0645

TRANTRIN TABLETS 10 mg: 43/5.7.1/0646

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

Aurogen South Africa (Pty) Ltd

Woodhill Office Park, Building 1,

53 Phillip Engelbrecht Avenue

Meyersdal, Ext. 12, 1448

Johannesburg, South Africa

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