1.3.1.1 PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

SCHEDULING STATUS:

S5

PROPRIETARY NAME (AND DOSAGE FORM):

ATERAX® 25MG (tablet)

ATERAX® SYRUP

COMPOSITION:

Aterax 25 mg:

Each film-coated tablet contains 25mg hydroxyzine hydrochloride.

Excipients:

Colloidal silicon dioxide, lactose monohydrate, magnesium stearate, microcrystaline cellulose, opadry white 85F28751, povidone, purified talc, purified water

Contains sugar:

Lactose monohydrate 51,25 mg

Aterax syrup:

Each 5 ml of Aterax Syrup contains 10 mg hydroxyzine hydrochloride.

Excipients:

Hazelnut flavour, purified water, sodium benzoate, sodium citrate (for pH-adjustment), sucrose.

Preservative: Sodium benzoate 0,03 % w/v

Contains sugar: Sucrose 3,75 g

CATEGORY AND CLASS:

A 2.6.3 Tranquillisers: Diphenylmethane and its derivatives.

PHARMACOLOGICAL ACTION:

Hydroxyzine is a piperazine derivative. ATERAX® has sedative and mild anti-anxiety activities. Hydroxyzine is chemically unrelated to the phenothiazines, reserpine, meprobamate, or the benzodiazepines. Primary skeletal muscle relaxation has been demonstrated experimentally. Secondary skeletal muscle relaxation due to ataraxia should be regarded as additive to this primary effect. ATERAX® has been shown experimentally to have anti-spasmodic properties, apparently due to its anti-cholinergic and antihistaminic activity.

Antihistamine effects have been demonstrated experimentally and confirmed clinically. An anti-emetic effect, both by the apomorphine test and the veriloid test has been demonstrated in animals.

ATERAX's® sedative action may be due to a suppression of activity in certain key regions of the subcortical area in the central nervous system.

The exact mechanism of anxiolytic action is not fully understood.

Pharmacokinetics:

Hydroxyzine is extensively metabolised and the elimination half-life is about 20 hours.

INDICATIONS:

ATERAX® is indicated in the short-term management of anxiety, tension and psychomotor agitation in conditions of emotional stress.

ATERAX® is also useful for alleviating the manifestations of anxiety and tension in situations in which the causative stress is temporary, as in the preparation for dental and other minor surgical procedures and in acute emotional problems. In addition, it has been used as adjunctive therapy in allergic conditions with strong emotional overlay, as in urticaria and pruritus.

The efficacy of ATERAX® as adjunctive pre- and postoperative sedative medication has also been well established, especially as regards its ability to allay anxiety, control emesis, and reduce the amount of opioid analgesic required

CONTRA-INDICATIONS:

ATERAX® is contra-indicated in patients who have shown previous hypersensitivity to it.

Acute intermittent porphyria.

ATERAX® is contra-indicated in respiratory failure.

USAGE IN PREGNANCY:

The safety of ATERAX® in pregnancy has not been established (Also see sections on the effects on neonates and premature infants under Side effects and Special Precautions).

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.

Patients should be warned not to drive a vehicle or take charge of machinery.

DOSAGE AND DIRECTIONS FOR USE:

Dosage varies with individual requirements and ranges from 25 mg three times daily to 100 mg four times daily.

As patients' response to ATERAX® may be variable, it is recommended, especially in elderly patients, to start treatment with low doses and to increase them progressively until an adequate response is obtained.

Geriatric patients may be more sensitive to the effects of the adult dose.

Anxiety:

Adults: 50 - 100 mg 4 times daily

Children over 6 years: 15 to 25 mg daily, increased if necessary, to 50 to 100 mg daily in divided doses.

Children under 6 years: 5 to 15 mg daily, increased if necessary, to 50 mg daily in divided doses.

Other indications:

Adults: 25 -100 mg four times daily.

For pruritus an initial dose of 25 mg may be given at night, increased to 25 mg three or four times daily.

Children over 6 years: 15 to 25 mg daily, increased if necessary, to 50 to 100 mg daily in divided doses.

Children under 6 years: 5 to 15 mg daily, increased if necessary, to 50 mg daily in divided doses.

Pre- and postoperative adjunctive medication:

Adults: 50 -100 mg

Children: 0,6 mg/kg body weight.

For indications where oral administration is not practical, the intramuscular dose in children is
1,1 mg/kg body weight.

SIDE EFFECTS AND SPECIAL PRECAUTIONS:

Side effects of hydroxyzine include drowsiness, dizziness, fatigue and dryness of the mouth. Tremor and convulsions have been reported, less frequently.

Side effects which have been reported include sedation, varying from slight drowsiness to deep sleep, dizziness and inco-ordination. Sedative effects may diminish after a few days of treatment.

Paradoxical central nervous system stimulation may occur, especially in children, with insomnia, nervousness, irritability, tremors, nightmares, hallucinations and convulsions. Extrapyramidal symptoms may occur.

Due to antimuscarinic properties of hydroxyzine, side effects such as dryness of the mouth, thickened respiratory-tract secretions and tightness of the chest, blurred vision, urinary difficulty and retention, constipation and increased gastric reflux may occur. In high doses, transient bradycardia followed by tachycardia with palpitations and arrhythmias have been observed.

Gastro-intestinal disturbances such as nausea, vomiting, diarrhoea or epigastric pain may occur. Hypersensitivity reactions, particularly of the skin and cross-sensitivity to related medicines may occur. Photosensitivity has also been reported. Jaundice, observed less frequently, may also be a hypersensitivity reaction.

Blood disorders, including agranulocytosis, leucopenia, haemolytic anaemia and thrombocytopenia have been reported; these may have an immune basis.

Other side effects reported include hypotension, tinnitus, headache and paraesthesias.

Isolated cases of hypotonic syndrome in neonates have occurred with chronic use of ATERAX® during late pregnancy. (Refer to section on use in pregnancy under Contra-indications.)

Precautions:

Hydroxyzine should not be given to premature infants or neonates as this group of patients has an increased susceptibility to antimuscarinic effects. Elderly patients are more susceptible to many adverse effects of hydroxyzine, including antimuscarinic effects, sedation and hypotension.

Because of the antimuscarinic effects, hydroxyzine should be used with care in patients with closed-angle glaucoma, urinary retention, prostatic hypertrophy, and pyloroduodenal obstruction. Caution should be exercised in patients with epilepsy and severe cardiovascular disorders.

Interactions:

Hydroxyzine potentiates the sedative effects of central nervous system depressants such as alcohol, barbiturates, hypnotics, opioid analgesics, anxiolytics, neuroleptics and other depressants of the central nervous system. Dosages must be tailored accordingly if ATERAX® and central nervous system depressants are given concomitantly.

The antimuscarinic effects of hydroxyzine may be enhanced by monoamine oxidase inhibitors and could also have an additive effect with other medicines such as atropine and tricyclic antidepressants.

Hydroxyzine counteracts the anti-convulsant efficacy of phenytoin.

It has been suggested that warning signs of damage caused by ototoxic medicines such as the aminoglycoside antibiotics could be masked. Positive skin test results may be suppressed and treatment with hydroxyzine should be stopped several days before the test.

When anticoagulants are administered, it is recommended that haemostasis be controlled at the beginning of treatment. The administration of hydroxyzine may interfere with the measurement of urinary 17-hydroxycorticosteroids.

The cardiac glycosides are not affected by ATERAX®.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

Overdosage is associated with antimuscarinic, extrapyramidal, gastro-intestinal and central nervous system effects. In infants and children central nervous system stimulation predominates over central nervous system depression, causing ataxia, tremors,

excitement, psychoses, hallucinations and convulsions followed by deepening coma and cardiorespiratory collapse. Hyperpyrexia may also occur. In adults central nervous system depression is more common, with drowsiness, coma and convulsions, progressing to respiratory failure or possibly cardiovascular collapse. Treatment is symptomatic and supportive and may include artificial respiration, external cooling for hyperpyrexia and intravenous fluids.
Adrenaline should not be used.

IDENTIFICATION:

ATERAX® 25 mg: A white, film-coated, oblong, breakable tablet.

ATERAX® Syrup: A clear, colourless to brownish yellow coloured solution with hazelnut flavor.

PRESENTATION:

ATERAX® 25mg:

100 tablets are packed in a clear polyvinylchloride film sealed with an aluminium foil backing. There are 10 tablets per blister strip. The blister strips are packed into an outer cardboard carton together with a leaflet.

ATERAX® Syrup:

100 ml is packed in a amber, polyethylene terephthalate (PET) bottle and sealed with a white polypropylene child resistant cap with an EPE wad. The bottle is placed in an outer cardboard carton together with a leaflet.

100 ml is packed in a amber glass bottle and sealed with a white polypropylene child resistant cap with an EPE wad. The bottle is placed in an outer cardboard carton together with a leaflet.

Not all packs and pack sizes are necessarily marketed.

STORAGE INSTRUCTIONS:

Store at or below 30 °C. Protect from light.
Keep in original packaging until required for use.
KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

ATERAX® 25 mg: B787 (Act 101 of 1965)

ATERAX® Syrup: B785 (Act 101 of 1965)

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

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE:

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