

Summary of Product Characteristics

1. NAME OF THE MEDICINAL PRODUCT

ATARAX™

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Hydroxyzine hydrochloride 25mg

3. PHARMACEUTICAL FORM

25mg film coated tablets, coloured green and coded on one side with 'AX'.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Atarax is indicated to assist in the management of anxiety in adults.

Atarax is indicated for the management of pruritus associated with acute and chronic urticaria, including cholinergic and physical types, and atopic and contact dermatitis in adults and children.

4.2 Posology and method of administration

Method of administration: oral.

Dosage:

Anxiety

Adults 50-100mg four times daily.

Pruritus

Adults Starting dose of 25mg at night increasing as necessary to 25mg three or four times daily.

Use in the elderly Atarax may be used in elderly patients with no special precautions other than the care always necessary in this age group. The lowest effective maintenance dose and careful observation for side-effects are important.

Use in children From 6 months to 6 years 5-15mg rising to 50mg daily in divided doses and for children over 6 years, 15-25mg rising to 50-100mg daily in divided doses.

As with all medications, the dosage should be adjusted according to the patient's response to therapy.

Renal impairment The total daily dosage should be reduced by half (see 'Special Warnings and Precautions for Use').

4.3 Contraindications

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

4.4 Special warnings and precautions for use

Atarax should be used with caution in patients with impaired renal function (see 'Posology and Method of Administration'). It is uncertain whether the drug may accumulate or have other adverse effects in such patients. Atarax is completely metabolised and one of the metabolites is the active metabolite cetirizine. Cetirizine is renally excreted and clearance is reduced in patients with moderate renal impairment and on dialysis compared to normal volunteers.

Because of its potential anticholinergic effects, Atarax should be used with caution in patients with bladder outflow obstruction.

4.5 Interaction with other medicinal products and other forms of interaction

Patients should be warned that Atarax may enhance their response to alcohol, barbiturates and other CNS depressants.

4.6 Pregnancy and lactation

Atarax is contra-indicated in early pregnancy. Hydroxyzine, when administered to the pregnant mouse, rat and rabbit, induced foetal abnormalities at doses substantially above the human therapeutic range. Clinical data in humans are inadequate to establish safety in early pregnancy. There is inadequate evidence of safety in the later stages of pregnancy. Use in pregnancy only when there is no safe alternative or when the disease itself carries risks for the mother or child.

Use in nursing mothers It is not known whether Atarax is excreted in human milk. Since many drugs are so excreted, Atarax should not be given to nursing mothers.

4.7 Effects on ability to drive and use machines

Patients should be warned that Atarax may impair their ability to perform activities requiring mental alertness or physical co-ordination such as operating machinery or driving a vehicle.

4.8 Undesirable effects

Therapeutic doses of Atarax seldom produce marked impairment of mental alertness. Drowsiness may occur; if so, it is usually transitory and may disappear after a few days of continued therapy or upon reduction of the dose. Dryness of the mouth may be encountered at higher doses. Dizziness, weakness, headache and confusion, and urinary retention have been reported.

Extensive clinical use has substantiated the absence of toxic effects on the liver or bone marrow when administered for over four years of uninterrupted therapy. The absence of side-effects has been further demonstrated in experimental studies in which excessively high doses were administered.

Involuntary motor activity, including rare instances of tremor and convulsions, have been reported, usually with doses considerably higher than those recommended. Continuous therapy with over 1g/day has been employed in some patients without these effects having been encountered.

4.9 Overdose

The most common manifestation of Atarax overdosage is hypersedation. As in the management of overdosage with any drug, it should be borne in mind that multiple agents may have been taken. If vomiting has not occurred spontaneously in conscious patients it

should be induced. Immediate gastric lavage is also recommended. General supportive care, including frequent monitoring of the vital signs and close observation of the patient is indicated. Hypotension, though unlikely, may be controlled with intravenous fluids and noradrenaline, or metaraminol. Adrenaline should not be used in this situation as Atarax counteracts its pressor action.

There is no specific antidote. It is doubtful whether haemodialysis has any value in the treatment of overdosage with Atarax. However, if other agents such as barbiturates have been ingested concomitantly, haemodialysis may be indicated.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Atarax is unrelated chemically to phenothiazine, reserpine and meprobamate.

Atarax has been shown clinically to be a rapid-acting anxiolytic with a wide margin of safety. It induces a calming effect in anxious tense adults. It is not a cortical depressant, but its action may be due to a suppression of activity in certain key regions of the subcortical area of the central nervous system.

Antihistamine effects have been demonstrated experimentally and confirmed clinically; it is highly effective in alleviating pruritus.

5.2 Pharmacokinetic properties

Atarax is rapidly absorbed from the gastro-intestinal tract and effects are usually noted within 15 to 30 minutes after oral administration.

5.3 Preclinical safety data

None stated.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core:

- Lactose (anhydrous)
- Calcium Hydrogen Phosphate Anhydrous
- Starch, Pregelatinised.
- Magnesium Stearate
- Sodium Laurilsulphate
- Silica, colloidal anhydrous.

Tablet coating:

Opadry II Green 85G24674 (25mg only) -contains:

- Poly (vinyl alcohol)
- Talc
- Macrogol 3350
- Quinoline yellow (E104)
- Titanium dioxide (E171)
- Brilliant blue (E1331)
- Indigo carmine (E132)

- Lecithin (E322).

6.2 Incompatibilities

None stated.

6.3 Shelf life

24 Months.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

White opaque 250/5/120 micron PVC/TE/PVdC - 20 micron aluminium foil blister strips containing 28 x 25mg tablets (2 blister strips per carton).

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7. MARKETING AUTHORISATION HOLDER

Alliance Pharmaceuticals Limited
Avonbridge House
Chippenham
Wiltshire
SN15 2BB
United Kingdom

8. MARKETING AUTHORISATION NUMBER

Atarax 25mg Tablets PL 16853/0095

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Atarax 25mg Tablets 24 July 1985/24 July 2002

10. DATE OF REVISION OF THE TEXT

October 2008