PRESCRIBING INFORMATION
PRODUCT MONOGRAPH

ATARAX SYRUP, 2MG/ML

Hydroxyzine Hydrochloride Syrup USP 10 mg/5 mL

ATARAX IM SOL 50MG/ML

Hydroxyzine Hydrochloride Injection USP 50 mg/mL
For Intramuscular Use Only

ATARAX CAPSULES 10 MG, 25 MG, 50 MG

Hydroxyzine Hydrochloride Capsules 10 mg, 25 mg, 50 mg

Anxiolytic - Antihistamine Agent

Erfa Canada Inc.
4545 Sherbrooke Ouest
Westmount, QC
Canada H3Z 1E8

Date of Preparation:
September 6, 2005

Control No. 100902

PRODUCT INFORMATION

ATARAX*

Hydroxyzine Hydrochloride Syrup USP 10 mg/5 mL

ATARAX*

Hydroxyzine Hydrochloride Injection USP 50 mg/mL

For Intramuscular Use Only

ATARAX*

Hydroxyzine Hydrochloride Capsules 10 mg, 25 mg, 50 mg

Anxiolytic - Antihistamine Agent

INDICATIONS

ORAL

ATARAX (hydroxyzine hydrochloride) is indicated in the management of anxiety and tension as in the preparation for dental procedures and in acute emotional problems. Also used in the management of anxiety associated with organic disturbances and as adjunctive therapy in alcoholism and allergic conditions with strong emotional overlay, such as in asthma.

ATARAX (hydroxyzine hydrochloride) is useful in the management of pruritus due to allergic conditions such as chronic urticaria and atopic and contact dermatoses.

ATARAX (hydroxyzine hydrochloride) is also useful in the control of nausea and vomiting, excluding nausea and vomiting of pregnancy (see CONTRAINDICATIONS section).

INTRAMUSCULAR

ATARAX (hydroxyzine hydrochloride) Injection I.M. is indicated in the treatment of the following types of patients when this route of administration is desirable:

1. The acute disturbed or hysterical patient.
2. The acute or chronic alcoholic with anxiety, withdrawal symptoms or delirium tremens.
3. As pre- and post-operative, and pre- and post-partum adjunctive medication to allay anxiety, and to permit substantial reduction in narcotic dosage and to control emesis, excluding nausea and vomiting of pregnancy (see CONTRAINDICATIONS section).

Patients may be started on parenteral therapy when indicated by the clinical situation. They should be maintained on oral therapy whenever this route is again practicable.

CONTRAINDICATIONS

ATARAX (hydroxyzine hydrochloride) is contraindicated in patients with known hypersensitivity to hydroxyzine hydrochloride and any component of this medication.

Use in Pregnancy

Hydroxyzine hydrochloride, when administered to the pregnant mouse, rat, and rabbit, induced fetal abnormalities in the rat and mouse at doses substantially above the human therapeutic range. Clinical data in human beings are inadequate to establish safety in early pregnancy. Until such data are available, **ATARAX** (hydroxyzine hydrochloride) is contraindicated in early pregnancy.

WARNINGS

Nursing Mothers: It is not known whether this drug is excreted in human milk. Since many drugs are so excreted, **ATARAX** (hydroxyzine hydrochloride) should not be given to nursing mothers.

PRECAUTIONS

The potentiating action of hydroxyzine hydrochloride must be considered when the drug is used in conjunction with central nervous system (CNS) depressants such as narcotics, non-narcotic analgesics, hypnotics, sedatives, psychotherapeutic agents, barbiturates or alcohol. Therefore when central nervous system depressants are administered concomitantly with **ATARAX** (hydroxyzine hydrochloride) their dosage should be reduced.

Administer **ATARAX** (hydroxyzine hydrochloride) cautiously to epileptic patients.

Since drowsiness may occur with use of this drug, patients should be cautioned against driving a car or operating dangerous machinery while taking **ATARAX** (hydroxyzine hydrochloride).

ADVERSE REACTIONS

Side effects reported with the administration of **ATARAX** (hydroxyzine hydrochloride) are usually mild and transitory in nature.

Anticholinergic: Dry mouth may be encountered at higher dosages.

Central Nervous System: Drowsiness.

Involuntary motor activity, including rare instances of tremor and convulsions, has been reported, usually with doses considerably higher than those recommended.

In post-marketing experience, the following additional undesirable effects have been reported: Body as a Whole: allergic reaction, Injection Site: localized pain, localized reaction, Nervous System: headache, Psychiatric: hallucination, Skin and Appendages: pruritus, rash, urticaria.

SYMPTOMS AND TREATMENT OF OVERDOSAGE

The most common manifestation of **ATARAX** overdosage is hypersedation. Other reported signs and symptoms were convulsions, stupor, nausea and vomiting. As in the management of overdosage with any drug, ingestion of multiple agents may have been taken.

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 vasopressors (such as norepinephrine). Do not use epinephrine as **ATARAX** counteracts its pressor action.

There is no specific antidote. It is doubtful that hemodialysis would be of any value in the treatment of overdosage with hydroxyzine. However, if other agents have been ingested concomitantly, hemodialysis may be indicated.

DOSAGE AND ADMINISTRATION

ORAL:

The dosage is dependent upon the intensity of the emotional disturbance rather than upon the weight of the patient.

Usual Oral Dosage

Adults: 25 mg to 100 mg three or four times daily.

Children: under 6 years of age: 30 to 50 mg daily in divided doses;

over 6 years of age: 50 to 100 mg daily in divided doses.

INTRAMUSCULAR

Psychiatric and emotional emergencies, including acute alcoholism:

Adults: 50 to 100 mg initially, repeated every 4 to 6 hours as needed.

Pre- and Post-operative Adjunctive Medication:

Adults: 25 to 100 mg.

Children: 1 mg/kg body weight.

Pre- and Post-partum Adjunctive Therapy:

25 to 100 mg.

Nausea and Vomiting:

Adults: 25 to 100 mg

Children: 1 mg/kg body weight.

When **ATARAX** (hydroxyzine hydrochloride) Injection I.M. is used as pre-operative or pre-partum adjunctive medication, narcotic requirements may be reduced by as much as 50%. Thus, when 50 mg of **ATARAX** (hydroxyzine hydrochloride) Injection I.M. is administered, meperidine dosage may be reduced from 100 to 50 mg.

ATARAX (hydroxyzine hydrochloride) Injection I.M. is intended only for intramuscular administration and should not, under any circumstances, be injected subcutaneously, intra-arterially or intravenously.

ATARAX (hydroxyzine hydrochloride) Injection I.M. may be administered without further dilution. It should be injected deep into the body of a relatively large muscle such as the upper out quadrant of the buttock or the lateral thigh.

Adults: The preferred site is the upper outer quadrant of the buttock, (i.e. gluteus maximus) or the mid-lateral thigh.

Children: It is recommended that intramuscular injections be given preferably in the mid-lateral muscles of the thigh. In younger children, the periphery of the upper outer quadrant of the gluteal region should be used only when necessary, such as in burn patients, in order to minimize the possibility of damage to the sciatic nerve. The deltoid area should be used only if well developed such as in certain adults and older children, and then only with caution to avoid radial nerve injury. Intramuscular injections should not be made into the lower and mid-third of the upper arm.

Aspiration and proper anatomical selection of injection sites should be observed as a precaution against inadvertent injection into a blood vessel or major nerve.

ATARAX Injection I.M. is physically compatible with parenteral solutions of morphine, atropine, papaverine, codeine, meperidine and scopolamine.

DOSAGE FORMS

Availability:

Pr **ATARAX** Syrup: Each 5 mL of mint-flavored syrup contains: hydroxyzine hydrochloride 10 mg, sodium benzoate 1.5 mg. Also contains sucrose, water, alcohol, menthol, spearmint oil, peppermint oil and hydrochloric acid (for pH adjustment). Energy: 67 kJ (16 kcal). Tartazine-free.

Available in bottles of 473 mL.

Pr **ATARAX** Injection I.M.: Each mL contains hydroxyzine hydrochloride 50 mg with benzyl alcohol 0.9 % (as preservative), sodium hydroxide to adjust to optimum pH, and water for injection, q.s. Available in 10 mL vials and 1 mL vials in boxes of 10.

Pr **ATARAX** Capsules:
10 mg: Each softgel capsule contains: hydroxyzine hydrochloride 10 mg, soybean oil, lecithin and wax mixture. Available in bottles with 100 capsules.

25 mg: Each softgel capsule contains: hydroxyzine hydrochloride 25 mg, soybean oil, lecithin and wax mixture. Available in bottles with 100 capsules.

50 mg: Each softgel capsule contains: hydroxyzine hydrochloride 50 mg, soybean oil, lecithin and wax mixture. Available in bottles with 100 capsules.

PHARMACEUTICAL INFORMATION

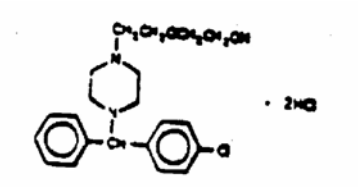
CHEMISTRY

(I) Drug Substance:

Proper Name(s): Hydroxyzine hydrochloride

Chemical Name(s): 1-(p-chlorobenzhydryl)4-2-(2-hydroxy-ethoxy)-ethylpiperazine dihydrochloride.

Structural Formula:



Molecular Formula: $C_{21}H_{27}ClN_2O_2.2HCl$

Molecular Weight: 447.83

Description: Hydroxyzine hydrochloride is a white odorless powder with bitter taste. M.p. 1968 to 2048 with decomposition. Soluble 1 in 1 of water, 1 in 4.5 of alcohol and 1 in 13 of chloroform, slightly soluble in acetone.

(ii) Composition: **ATARAX** Syrup: Each 5 mL of mint- flavored syrup contains: hydroxyzine hydrochloride 10 mg. Also contains sodium benzoate 1.5 mg, sucrose, water, alcohol, menthol, spearmint oil, peppermint oil and hydrochloric acid (for pH adjustment).

Energy: 67 kJ (16 kcal).

Tartrazine-free.

ATARAX Injection USP: Each mL contains:

Hydroxyzine hydrochloride	50 mg
Benzyl alcohol	0.9%
Sodium hydroxide (approx.) to adjust to optimum pH	0.46%

Water for injection to make 1 mL q.s.