Hydroxyzine hydrochloride, USP has the chemical name of 2-[2-[4-([D]-chloro-o-phenyl)ethyl]-1-piperaziney]ethanol dihydrochloride.

**DESCRIPTION**
Hydroxyzine hydrochloride, USP occurs as a white, odorless powder which is very soluble in water.

**PRECAUTIONS**

**THE POTENTIATING ACTION OF HYDROXYZINE MUST BE CONSIDERED WHEN THE DRUG IS USED IN CONJUNCTION WITH CENTRAL NERVOUS SYSTEM DEPRESSANTS SUCH AS NARCOTICS, NON-NARCOTIC ANALGESICS AND BARBITURATES.** Therefore, when central nervous system depressants are administered concomitantly with hydroxyzine their dosage should be reduced.

Since drowsiness may occur with use of this drug, patients should be warned of this possibility and cautioned against driving a car or operating dangerous machinery while taking hydroxyzine. Patients should also be advised against the simultaneous use of other CNS depressant drugs, and cautioned that the effects of alcohol may be increased.

**Geriatric Use**
A determination has not been made whether controlled clinical studies of hydroxyzine included sufficient numbers of subjects aged 65 and over to define a difference in response from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal or cardiac function, and of concomitant disease or other drug therapy.

The extent of renal excretion of hydroxyzine has not been determined. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selections.

Sedating drugs may cause confusion and over sedation in the elderly; elderly patients generally should be started on low doses of hydroxyzine and observed closely.

**ADVERSE REACTIONS**

**Skin and Appendages:** Oral hydroxyzine hydrochloride is associated with fixed drug eruptions in postmarketing reports.

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

**Anticholinergic:** Dry mouth.

**Central Nervous System:** Drowsiness is usually transitory and may disappear in a few days of continued therapy or upon reduction of dose. Involuntary motor activity including rare instances of tremor and convulsions have been reported, usually with doses considerably higher than those recommended. Clinically significant respiratory depression has not been reported at recommended doses.

In postmarketing experience, the following additional undesirable effects have been reported:

**Body as a Whole:** Allergic reaction.

**Nervous System:** Headache.

**Psychiatric:** Hallucination.

**Skin and Appendages:** Pruritus, rash, urticaria.

**OVERDOSAGE**
The most common manifestation of hydroxyzine overdosage is hypersedation. Other reported signs and symptoms were convulsions, stupor, nausea and vomiting. 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, 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 levarterenol or metaraminol. Do not use epinephrine as hydroxyzine 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 such as barbiturates have been ingested concomitantly, hemodialysis may be indicated. There is no practical method to quantitate hydroxyzine in body fluids or tissue after its ingestion or administration.

**DOSAGE AND ADMINISTRATION**

For symptomatic relief of anxiety and tension associated with psychoneuroses and as an adjunct in organic disease states in which anxiety is manifested: adults, 50 to 100 mg daily in divided doses; children over 6 years, 50 to 100 mg daily in divided doses.

As a sedative when used as a premedication and following general anesthesia: 50 to 100 mg for adults and 0.6 mg/kg of body weight in children.

When treatment is initiated by the intramuscular route of administration, subsequent doses may be administered orally.

As with all potent medication, the dosage should be adjusted according to the patient’s response to therapy.

**HOW SUPPLIED**

Hydroxyzine Hydrochloride Tablets USP, 10 mg are available as white, round, film-coated, convex tablets, debossed with “TV” on one side and “307” on the other side, containing 10 mg hydroxyzine hydrochloride, USP packaged in bottles of 100, 500, and 1000 tablets.

Hydroxyzine Hydrochloride Tablets USP, 25 mg are available as white, round, film-coated, convex tablets, debossed with “TV” on one side and “308” on the other side, containing 25 mg hydroxyzine hydrochloride, USP packaged in bottles of 100, 500 and 1000 tablets.

Hydroxyzine Hydrochloride Tablets USP, 50 mg are available as white, round, film-coated, convex tablets, debossed with “TV” on one side and “309” on the other side, containing 50 mg hydroxyzine hydrochloride, USP packaged in bottles of 100, 500 and 1000 tablets.

Dispense in a tight container as defined in the USP, with a child-resistant closure (as required).

**KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.**

Manufactured In Croatia By:

PLIVA HRVATSKA d.o.o.
Zagreb, Croatia

Manufactured For:

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/s/

ROBERT L WEST
06/05/2014
Deputy Director, Office of Generic Drugs, for Kathleen Uhl, M.D.