Hydroxyzine hydrochloride is unrelated chemically to the phenothiazines, reserpine, meprobamate, or the benzodiazepines.

Hydroxyzine hydrochloride is contraindicated in patients who have shown a previous hypersensitivity to it.

ADVERSE REACTIONS

A determination has not been made whether this drug is excreted in human milk. Since many drugs are so excreted, nursing mothers should be warned of this possibility and cautioned against the simultaneous use of other CNS depressant drugs, and cautioned that the effect of alcohol may be increased.

The effectiveness of hydroxyzine as an anxiolytic agent for conditions such as chronic depression and anxiety has not been established. Involuntary motor activity including rare instances of tremor and convulsions have been reported. In a few cases, particularly in patients with severe mental depression, it has been necessary to discontinue the use of the drug temporarily until such extrapyramidal effects have disappeared.

Skin and Appendages:

Keep out of the reach of children.

Disorders of the CNS include headache, dizziness, nervousness, insomnia, agitation, and anxiety. These effects are generally mild and transient and usually can be managed with dosage reduction. 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, sedative-hypnotics, tranquilizers, or antipsychotics have been given concomitantly, they also may be removed by dialysis.

Disorders of the GIT include nausea, vomiting, dryness of mouth, dyspepsia, constipation, diarrhea, and GI cramps. These effects are usually mild and reversible on discontinuation of the drug. The oral preparation may cause local irritation of the GIT and occasionally mild GI disturbances such as diarrhea or dyspepsia, constipation, or Pruritus ani have been reported. If symptoms are severe, the drug should be discontinued.

As with all medications, the dosage should be adjusted upon reduction of the dose. The patient should be informed that drowsiness may occur with use of this drug and should be warned to avoid operating machinery or engaging in activities involving mental alertness or physical dexterity until reaction to the drug is known. The physician should remain in close touch with the patient and the dosage should be adjusted accordingly.

Geriatric Use:

The effectiveness of hydroxyzine as an anxiolytic agent for chronic depression and anxiety is not known. In a recent double-blind placebo-controlled study, there was no evidence of a significant difference between hydroxyzine and placebo in reducing the severity of symptoms of depression and anxiety in elderly patients. Therefore, when central nervous system depressants are administered concomitantly with hydroxyzine, their dosages should be reduced.

CONTRAINDICATIONS

It may also contain alcohol 0.5%; liquid sugar; methylparaben; peppermint oil; phenytoin; sodium citrate dihydrate for pH adjustment. The pH range is 2.0 to 4.3.

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/s/

ROBERT L WEST
06/03/2014
Deputy Director, Office of Generic Drugs, for Kathleen Uhl, M.D.