Xyril®

Hydroxyzine Hydrochloride USP

Description: Hydroxyzine Hydrochloride (**Xyril®**) is a first-generation antihistamine, of the piperazine class that is an H1 receptor antagonist. Hydroxyzine Hydrochloride is unrelated chemically to the phenothiazines, reserpine, meprobamate or the benzodiazepines.

Mode of action: Hydroxyzine Hydrochloride (**Xyril®**) is not a cortical depressant, but it's action may be due to a suppression of activity in certain key regions of the subcortical area of the central nervous system. Primary skeletal muscle relaxation has been demonstrated experimentally. Bronchodilator activity, antihistaminic and analgesic effects have been demonstrated experimentally and confirmed clinically. An antiemetic effect, both by the apomorphine test and the veriloid test has been demonstrated. Hydroxyzine Hydrochloride in therapeutic dosage does not increase gastric secretion or acidity and in most cases has mild antisecretory activity.

Pharmacokinetics: Hydroxyzine Hydrochloride (**Xyril®**) is rapidly absorbed from the gastrointestinal tract and it's clinical effects are usually noted within 15 to 30 minutes after oral administration. About 93% bound to plasma proteins & bioavailability is high. Elimination half-life about 20 to 25 hours has been reported. Hydroxyzine Hydrochloride is excreted through both urine & feces.

Composition: Xyril® 10 Tablet: Each film coated tablet contains Hydroxyzine Hydrochloride USP 10 mg.
Xyril® 25 Tablet: Each film coated tablet contains Hydroxyzine Hydrochloride USP 25 mg.
Xyril® Syrup: Each 5 ml syrup contains Hydroxyzine Hydrochloride USP 10 mg.

Indications: *Generalized Anxiety Disorder:* For symptomatic relief of anxiety and tension associated with psychoneurosis and as an adjunct in organic disease states in which anxiety is manifested.
Pruritus:
Useful in the management of pruritus due to allergic conditions such as chronic urticaria and atopic and contact dermatoses and in histamine-mediated pruritus.
Pre-anesthetic adjunctive therapy:
As a sedative when used as premedication and following general anesthesia, Hydroxyzine Hydrochloride may potentiate meperidine and barbiturates, so their use in pre-anesthetic adjunctive therapy should be modified on an individual basis.
The effectiveness of Hydroxyzine Hydrochloride as an antianxiety agent for long term use, that is more than 4 months, has not been assessed by systematic clinical studies. The physician should reassess periodically the usefulness of the drug for the individual patient.

Dosage & administration: ***Tablet:*** *Pruritus:* initially 25 mg at night increased if necessary to 25 mg 3-4 times daily;
Child 6 months-6 years: initially 5-15 mg daily increased if necessary to 50 mg daily in divided doses;
Over 6 years: initially 15-25 mg daily increased if necessary to 50-100 mg daily in divided doses.
Generalized Anxiety Disorder (GAD): 50-100 mg 4 times daily.
Syrup: *Pruritus: Children (6 months-6 years):* 1/2-1 1/2 tea spoonful everyday or if necessary 1 1/4 tea spoonful in every 6 hours.
Children (6 years and over): 1 1/2-2 1/2 tea spoonful everyday or if necessary 1 1/2-2 1/2 tea spoonful in every 6 hours.
Adult (Over 12 years): 2 1/2 tea spoonful at night or if necessary 2 1/2 tea spoonful 3-4 times everyday.

Generalized Anxiety Disorder (GAD):
Children (6 months - 6 years): 1 1/4 tea spoonful in every 6 hours.
Children (6 years & over): 1 1/4-2 1/2 tea spoonful in every 6 hours.
Adult (Over 12 years): 2 1/2- 5 tea spoonful in every 6 hours.

Contraindications: Hydroxyzine Hydrochloride is contraindicated for patients who have shown a previous hypersensitivity to it.

Side effects: 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 the dose. Involuntary motor activity including rare instances of tremor and convulsions has been reported, usually with doses considerably higher than those recommended. Clinically significant respiratory depression has not been reported at recommended doses.

Use in pregnancy & lactation: Clinical data in human beings are inadequate to establish safety in early pregnancy. Until such data are available, Hydroxyzine Hydrochloride is contraindicated in early pregnancy. It is not known whether this drug is excreted in human milk. Since many drugs are so excreted, 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 depressants such as narcotics, non-narcotic analgesics and barbiturates. Therefore, when central nervous system depressants are administered concomitantly with Hydroxyzine Hydrochloride 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 Hydrochloride. Patients should be advised against the simultaneous use of other CNS depressant drugs and cautioned that the effect of alcohol may be increased.

Over dosage: The most common manifestation of Hydroxyzine Hydrochloride over-dosage is hypersedation. As in the management of over-dosage 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 nor-epinephrine or metaraminol. There is no specific antidote. It is doubtful that hemodialysis would be of any value in the treatment of over-dosage with Hydroxyzine Hydrochloride. However, if other agents such as barbiturates have been ingested concomitantly, hemodialysis may be indicated. There is no practical method to quantitate Hydroxyzine Hydrochloride in body fluids or tissue after its ingestion or administration.

Storage: Store in a cool (Below 25 ˚C temperature) and dry place protected from light.

Packaging: Xyril® 10 Tablet: Each carton contains 20X10 tablets in Alu-PVC blister pack.
Xyril® 25 Tablet: Each carton contains 20X10 tablets in Alu-PVC blister pack.
Xyril® Syrup: Each bottle contains 100 ml syrup with a measuring cup.

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