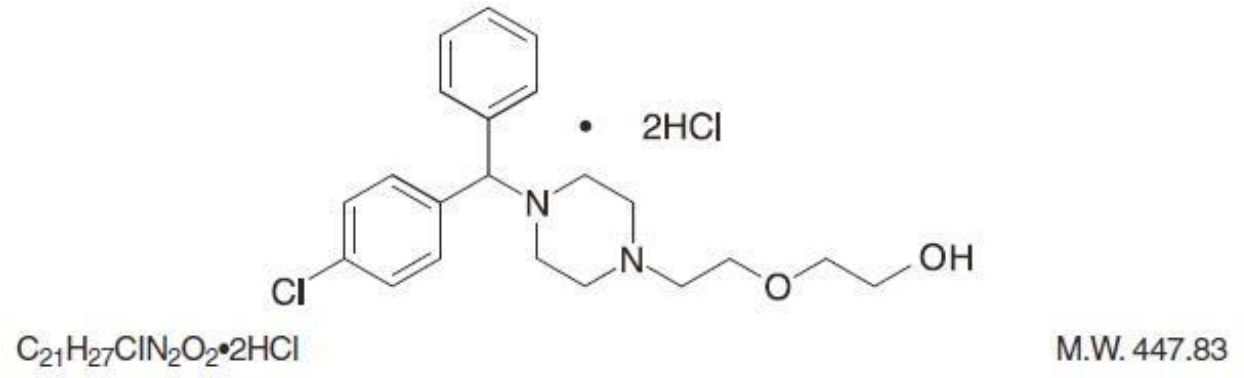
HYDROXYZINE HYDROCHLORIDE- hydroxyzine hydrochloride tablet, film coated
Aidarex Pharmaceuticals LLC

HYDROXYZINE HYDROCHLORIDE TABLETS, USP

DESCRIPTION

Hydroxyzine hydrochloride has the chemical name of 2-[2-[4-(*p*-Chloro-α-phenylbenzyl)-1-piperazinyl] ethoxy] ethanol dihydrochloride.



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

Each tablet for oral administration contains 10 mg, 25 mg or 50 mg hydroxyzine hydrochloride. Inactive ingredients include carnauba wax, colloidal silicon dioxide, crospovidone, lactose monohydrate, macrogol/polyethylene glycol 3350, magnesium stearate, microcrystalline cellulose, polyvinyl alcohol - part. hydrolyzed, talc and titanium dioxide.

CLINICAL PHARMACOLOGY

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

Primary skeletal muscle relaxation has been demonstrated experimentally. Bronchodilator activity, and 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.

Pharmacological and clinical studies indicate that hydroxyzine in therapeutic dosage does not increase gastric secretion or acidity and in most cases has mild antisecretory activity.

Hydroxyzine is rapidly absorbed from the gastrointestinal tract and hydroxyzine’s clinical effects are usually noted within 15 to 30 minutes after oral administration.

INDICATIONS AND USAGE

For symptomatic relief of anxiety and tension associated with psychoneurosis and as an adjunct in organic disease states in which anxiety is manifested.

Useful in the management of pruritus due to allergic conditions such as chronic urticarial and atopic and contact dermatoses and in histamine-mediated pruritus.

As a sedative when used as a premedication and following general anesthesia, **hydroxyzine may**

potentiate meperidine and barbiturates, so their use in pre-anesthetic adjunctive therapy should be modified on an individual basis. Atropine and other belladonna alkaloids are not affected by the drug. Hydroxyzine is not known to interfere with the action of digitalis in any way and it may be used concurrently with this agent.

The effectiveness of hydroxyzine 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.

CONTRAINDICATIONS

Hydroxyzine, 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, hydroxyzine is contraindicated in early pregnancy.

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

WARNINGS Nursing Mothers:

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

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

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.

OVERDOSAGE

The most common manifestation of hydroxyzine 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, 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 psychoneurosis and as an adjunct in organic disease states in which anxiety is manifested: Adults, 50 to 100 mg q.i.d.; children under 6 years, 50 mg daily in divided doses; children over 6 years, 50 to 100 mg daily in divided doses.

For use in the management of pruritus due to allergic conditions such as chronic urticarial and atopic and contact dermatoses and in histamine-mediated pruritus: adults, 25 mg t.i.d. or q.i.d.; children under 6 years, 50 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 are available as follows:

Hydroxyzine hydrochloride tablets, USP 50 mg are supplied as white, round, film coated, biconvex tablets debossed “K12” on one side and plain on the other side.

Bottle of 12, NDC 53217-0007-12

Bottle of 20, NDC 53217-0007-20

Bottle of 30, NDC 53217-0007-30

Bottle of 60, NDC 53217-0007-60

Bottle of 90, NDC 53217-0007-90

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

Store at 20° to 25°C with excursions permitted between 15° to 30°C (59° to 86°F) [See USP Controlled Room Temperature].

Manufactured by:

KVK-TECH, INC.

110 Terry Dr. Suite 200

Newtown, PA 18940

Item ID # 6015/02 06/10

Manufacturer's Code: 10702

Repackaged By :
Aidarex Pharmaceuticals LLC,
Corona, CA 92880

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL – 50 mg Bottle Label

NDC 53217-0007-30

HYDROXYZINE

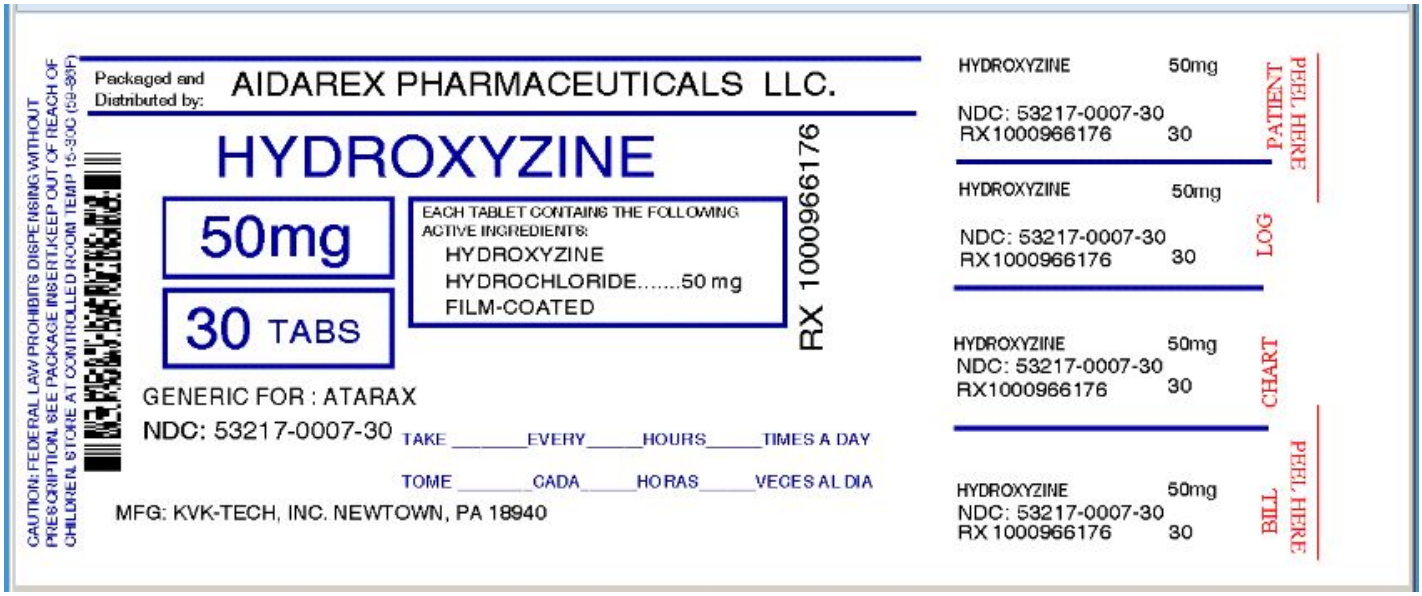
HYDROCHLORIDE

TABLETS, USP

50 mg

30 TABLETS

Rx Only



HYDROXYZINE HYDROCHLORIDE

hydroxyzine hydrochloride tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:53217-007(NDC:10702-012)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROXYZINE HYDROCHLORIDE (UNII: 76755771U3) (HYDROXYZINE - UNII:30S50YM8OG)	HYDROXYZINE HYDROCHLORIDE	50 mg

Inactive Ingredients

Ingredient Name	Strength
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSPOVIDONE (UNII: 68401960MK)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYVINYL ALCOHOL (UNII: 532B59J990)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	WHITE	**Score**	no score

Shape	ROUND	**Size**	9mm
Flavor		**Imprint Code**	K;12
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53217-007-12	12 in 1 BOTTLE, PLASTIC		
2	NDC:53217-007-20	20 in 1 BOTTLE, PLASTIC		
3	NDC:53217-007-30	30 in 1 BOTTLE, PLASTIC		
4	NDC:53217-007-60	60 in 1 BOTTLE, PLASTIC		
5	NDC:53217-007-90	90 in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA040788	07/24/2012	

Labeler - Aidarex Pharmaceuticals LLC (801503249)

Revised: 10/2013 Aidarex Pharmaceuticals LLC