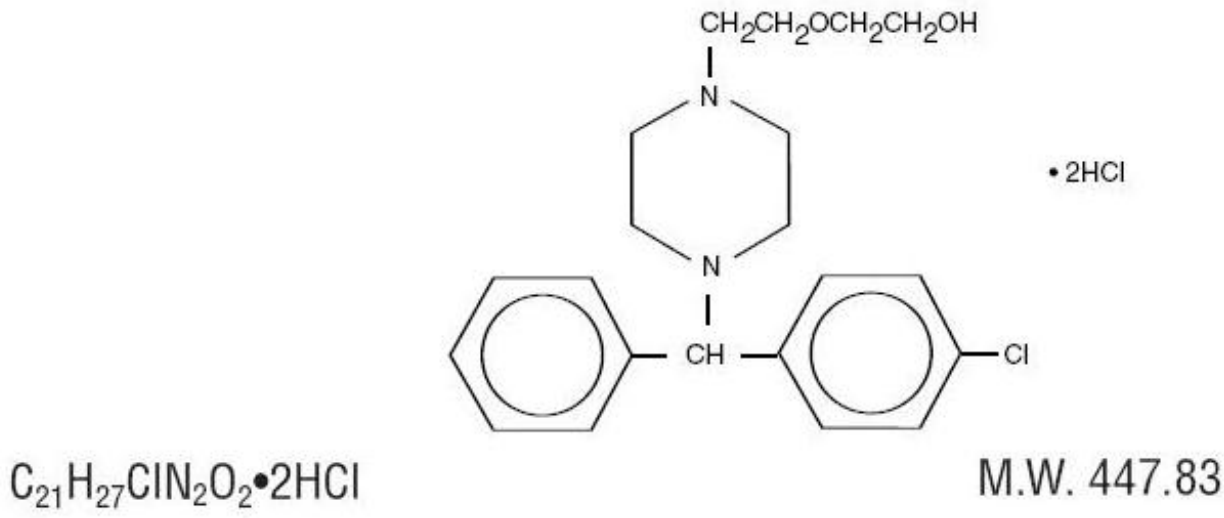
HYDROXYZINE HYDROCHLORIDE - hydroxyzine hydrochloride tablet
Caraco Pharmaceutical Laboratories, Ltd.

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 film-coated tablet for oral administration contains 10 mg, 25 mg, or 50 mg hydrOXYzine hydrochloride, USP. Inactive ingredients include anhydrous lactose, colloidal silicon dioxide, crospovidone, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, sodium starch glycolate, 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 urticaria 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 preanesthetic 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 urticaria 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 contains 10 mg, 25 mg, or 50 mg of hydrOXYzine hydrochloride, USP and are supplied as follows:

10 mg: White to off-white, round, biconvex, bevel edge, film-coated tablets debossed with ‘112’ on one side and plain on the other side.

NDC 57664-112-83	Bottles of 30	CRC
NDC 57664-112-88	Bottles of 100	CRC
NDC 57664-112-08	Bottles of 100	NCRC

NDC 57664-112-13 Bottles of 500 NCRC
NDC 57664-112-18 Bottles of 1000 NCRC

25 mg: White to off-white, round, biconvex, bevel edge, film-coated tablets debossed with‘113’ on one side and plain on the other side.

NDC 57664-113-83 Bottles of 30 CRC
NDC 57664-113-88 Bottles of 100 CRC
NDC 57664-113-08 Bottles of 100 NCRC
NDC 57664-113-13 Bottles of 500 NCRC
NDC 57664-113-18 Bottles of 1000 NCRC

50 mg: White to off-white, round, biconvex, bevel edge, film-coated tablets debossed with ‘114’ on one side and plain on the other.

NDC 57664-114-83 Bottles of 30 CRC
NDC 57664-114-88 Bottles of 100 CRC
NDC 57664-114-08 Bottles of 100 NCRC
NDC 57664-114-13 Bottles of 500 NCRC
NDC 57664-114-18 Bottles of 1000 NCRC

Dispense in a tight container as defined in the USP.
Store at 20 - 25°C (68 - 77°F). (See USP Controlled Room Temperature).

Distributed by: **Caraco Pharmaceutical Laboratories, Ltd.**
Detroit, MI 48202

Manufactured by: **Sun Pharmaceutical Industries, Inc.**
Cranbury, New Jersey 08512

Issued: November 2008

Stock No. 6033T01

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL- 10 mg 100 count

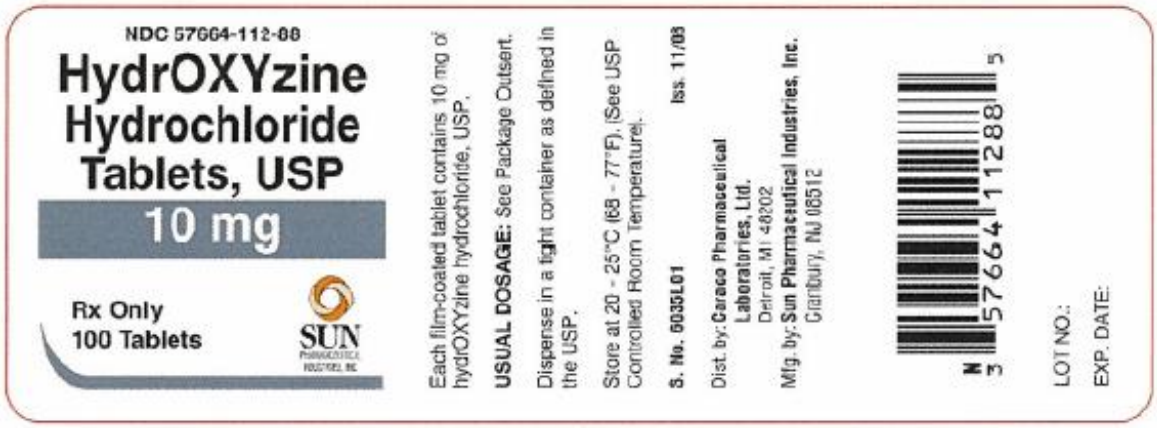
NDC 57664-112-88

HydrOXYzine Hydrochloride Tablets, USP

10 mg

Rx Only

100 Tablets



PACKAGE LABEL.PRINCIPAL DISPLAY PANEL- 25 mg 100 count

NDC 57664-113-88

HydrOXYzine Hydrochloride Tablets, USP

25 mg

Rx Only

100 Tablets

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL- 50 mg 100 count

NDC 57664-114-88

HydrOXYzine Hydrochloride Tablets, USP

50 mg

Rx Only

100 Tablets

HYDROXYZINE HYDROCHLORIDE

hydroxyzine hydrochloride tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:57664-112

Route of Administration	ORAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
HYDROXYZINE HYDROCHLORIDE (UNII: 76755771U3) (HYDROXYZINE - UNII:30S50YM8OG)	HYDROXYZINE HYDROCHLORIDE	10 mg

Inactive Ingredients	
Ingredient Name	**Strength**
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSPOVIDONE (UNII: 68401960MK)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL (UNII: 532B59J990)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	WHITE (White to off-white)	**Score**	no score
Shape	ROUND (biconvex)	**Size**	7mm
Flavor		**Imprint Code**	112
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:57664-112-83	30 in 1 BOTTLE		
2	NDC:57664-112-88	100 in 1 BOTTLE		
3	NDC:57664-112-08	100 in 1 BOTTLE		
4	NDC:57664-112-13	500 in 1 BOTTLE		
5	NDC:57664-112-18	1000 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA040899	03/31/2009	

HYDROXYZINE HYDROCHLORIDE

hydroxyzine hydrochloride tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:57664-113
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
HYDROXYZINE HYDROCHLORIDE (UNII: 76755771U3) (HYDROXYZINE - UNII:30S50YM8OG)	HYDROXYZINE HYDROCHLORIDE	25 mg

Inactive Ingredients	
Ingredient Name	**Strength**
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSPOVIDONE (UNII: 68401960MK)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL (UNII: 532B59J990)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	WHITE (White to off-white)	**Score**	no score
Shape	ROUND (biconvex)	**Size**	7mm
Flavor		**Imprint Code**	113
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:57664-113-83	30 in 1 BOTTLE		
2	NDC:57664-113-88	100 in 1 BOTTLE		
3	NDC:57664-113-08	100 in 1 BOTTLE		
4	NDC:57664-113-13	500 in 1 BOTTLE		
5	NDC:57664-113-18	1000 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA040899	03/31/2009	

HYDROXYZINE HYDROCHLORIDE

hydroxyzine hydrochloride tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:57664-114
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
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSPOVIDONE (UNII: 68401960MK)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL (UNII: 532B59J990)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	WHITE (White to off-white)	**Score**	no score
Shape	ROUND (biconvex)	**Size**	10mm
Flavor		**Imprint Code**	114
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57664-114-83	30 in 1 BOTTLE		
2	NDC:57664-114-88	100 in 1 BOTTLE		
3	NDC:57664-114-08	100 in 1 BOTTLE		
4	NDC:57664-114-13	500 in 1 BOTTLE		
5	NDC:57664-114-18	1000 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA040899	03/31/2009	

Labeler - Caraco Pharmaceutical Laboratories, Ltd. (146974886)

Registrant - Sun Pharmaceutical Industries, Inc. (621633481)

Establishment

Name	Address	ID/FEI	Business Operations
Sun Pharmaceutical Industries, Inc.		621633481	Manufacture, Analysis

Revised: 2/2010 Caraco Pharmaceutical Laboratories, Ltd.