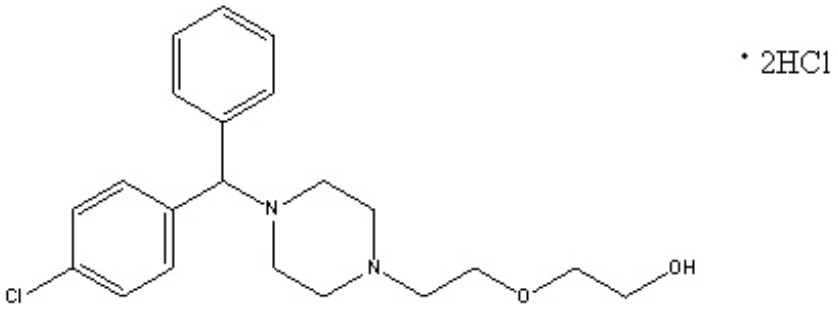
HYDROXYZINE HYDROCHLORIDE- hydroxyzine hydrochloride tablet, film coated
Mylan Pharmaceuticals Inc.

DESCRIPTION

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



$C_{21}H_{27}ClN_2O_2$ • 2HCl M.W. 447.83

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

Each tablet for oral administration contains 10 mg, 25 mg or 50 mg hydroxyzine hydrochloride. Inactive ingredients include: anhydrous lactose, colloidal silicon dioxide, crospovidone, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, sodium lauryl sulfate, talc and titanium dioxide.

In addition, the 10 mg tablet contains FD&C Blue No. 1 Aluminum Lake and the 25 mg and 50 mg tablets contain FD&C Blue No. 2 Aluminum Lake.

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 hydrochloride tablets 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 hydrochloride tablets are 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 hydrochloride tablets 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

Oral hydroxyzine hydrochloride is contraindicated in patients with known hypersensitivity to hydroxyzine hydrochloride products, and in patients with known hypersensitivity to cetirizine hydrochloride or levocetirizine hydrochloride.

Hydroxyzine hydrochloride tablets, 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 hydrochloride tablets are contraindicated in early pregnancy.

Hydroxyzine hydrochloride tablets are contraindicated for patients who have shown a previous hypersensitivity to any component of this medication.

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.

In post-marketing experience, the following additional undesirable effects have been reported:

Body as a Whole: allergic reaction

Nervous System: headache

Psychiatric: hallucination

Skin and Appendages: Oral hydroxyzine hydrochloride is associated with fixed drug eruptions in post-marketing reports.

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

As a sedative when used as a premedication and following general anesthesia: 50 mg to 100 mg in 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 containing 10 mg, 25 mg or 50 mg of hydroxyzine hydrochloride, USP.

The 10 mg tablets are light blue film-coated, round, unscored tablets debossed with **M** on one side of the tablet and **H10** on the other side. They are available as follows:

NDC 0378-2586-01
bottles of 100 tablets

NDC 0378-2586-10
bottles of 1000 tablets

The 25 mg tablets are blue film-coated, round, unscored tablets debossed with **M** on one side of the tablet and **H25** on the other side. They are available as follows:

NDC 0378-2587-01
bottles of 100 tablets

NDC 0378-2587-10
bottles of 1000 tablets

The 50 mg tablets are blue film-coated, round, unscored tablets debossed with **M** on one side of the tablet and **H50** on the other side. They are available as follows:

NDC 0378-2588-01
bottles of 100 tablets

NDC 0378-2588-10
bottles of 1000 tablets

Store at 20º to 25ºC (68º to 77ºF). [See USP Controlled Room Temperature.]

Dispense in a tight, light-resistant container using a child-resistant closure.

Mylan Pharmaceuticals Inc.
Morgantown, WV 26505 U.S.A.

REVISED JUNE 2014
HYDZ:R4

PRINCIPAL DISPLAY PANEL - 10 mg

NDC 0378-2586-01

HydrOXYzine
Hydrochloride
Tablets, USP
10 mg

Rx only 100 Tablets

Each film-coated tablet
contains: Hydroxyzine
hydrochloride, USP 10 mg

Dispense in a tight, light-resistant

container as defined in the USP using a child-resistant closure.

Keep container tightly closed.

Keep this and all medication out of the reach of children.

Store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature.]

Usual Dosage: See accompanying prescribing information.

Mylan Pharmaceuticals Inc.
Morgantown, WV 26505 U.S.A.

Mylan.com

RM2586A2

PRINCIPAL DISPLAY PANEL - 25 mg

NDC 0378-2587-01

HydrOXYzine
Hydrochloride
Tablets, USP
25 mg

Rx only 100 Tablets

Each film-coated tablet contains: Hydroxyzine hydrochloride, USP 25 mg

Dispense in a tight, light-resistant container as defined in the USP using a child-resistant closure.

Keep container tightly closed.

Keep this and all medication

out of the reach of children.

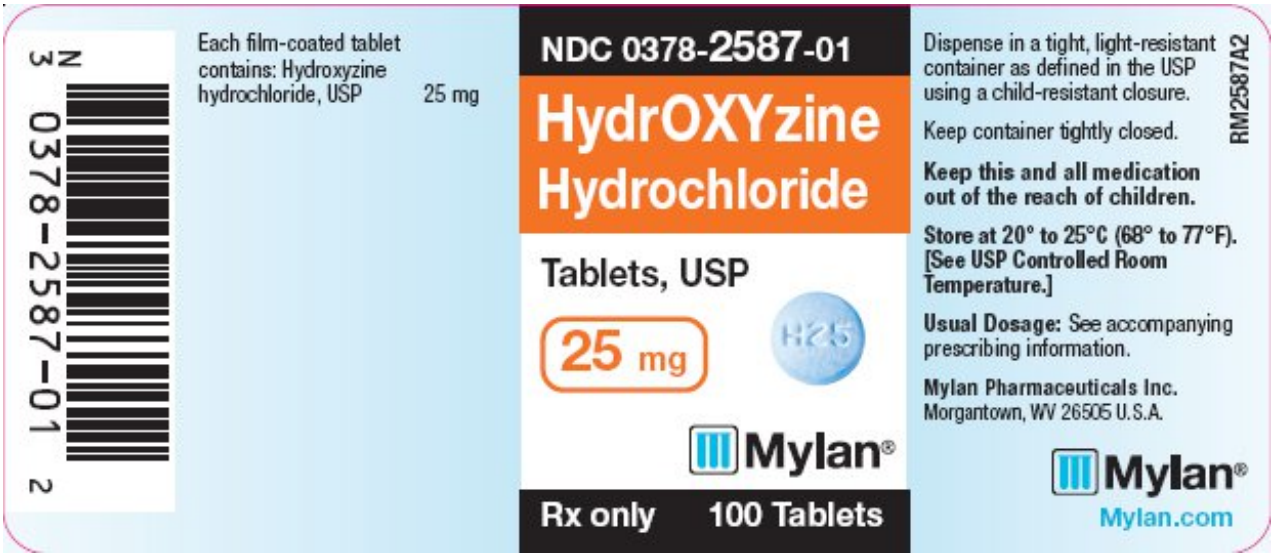
Store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature.]

Usual Dosage: See accompanying prescribing information.

Mylan Pharmaceuticals Inc.
Morgantown, WV 26505 U.S.A.

Mylan.com

RM2587A2



PRINCIPAL DISPLAY PANEL - 50 mg

NDC 0378-2588-01

HydrOXYzine Hydrochloride Tablets, USP 50 mg

Rx only 100 Tablets

Each film-coated tablet contains: Hydroxyzine hydrochloride, USP 50 mg

Dispense in a tight, light-resistant container as defined in the USP using a child-resistant closure.

Keep container tightly closed.

Keep this and all medication out of the reach of children.

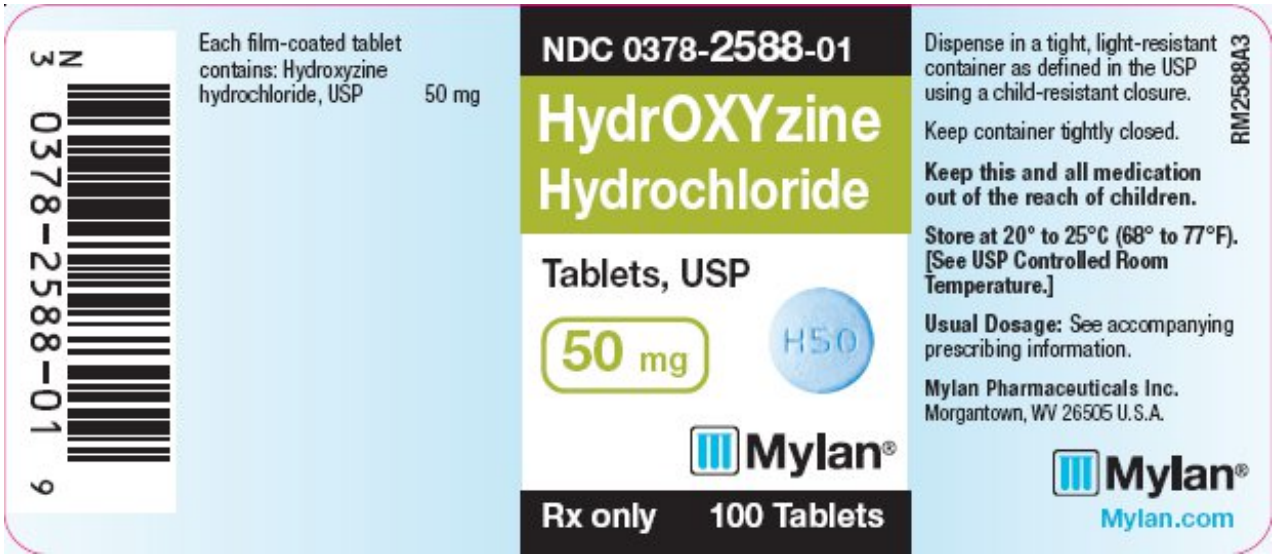
Store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature.]

Usual Dosage: See accompanying prescribing information.

Mylan Pharmaceuticals Inc.
Morgantown, WV 26505 U.S.A.

Mylan.com

RM2588A3



HYDROXYZINE HYDROCHLORIDE

hydroxyzine hydrochloride tablet, film coated

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG LABEL	**Item Code (Source)**	NDC:0378-2586
Route of Administration	ORAL	**DEA Schedule**	

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
HYDROXYZINE HYDROCHLORIDE (HYDROXYZINE)	HYDROXYZINE HYDROCHLORIDE	10 mg

Inactive Ingredients	
Ingredient Name	**Strength**
ANHYDROUS LACTOSE	
SILICON DIOXIDE	
CROSPOVIDONE	
MAGNESIUM STEARATE	
CELLULOSE, MICROCRYSTALLINE	
POLYETHYLENE GLYCOLS	
POLYVINYL ALCOHOL	
SODIUM LAURYL SULFATE	

TALC	
TITANIUM DIOXIDE	
FD&C BLUE NO. 1	

Product Characteristics			
Color	BLUE (light blue)	**Score**	no score
Shape	ROUND	**Size**	6mm
Flavor		**Imprint Code**	M;H10
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0378-2586-01	100 in 1 BOTTLE, PLASTIC		
2	NDC:0378-2586-10	1000 in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091176	07/23/2010	

HYDROXYZINE HYDROCHLORIDE

hydroxyzine hydrochloride tablet, film coated

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG LABEL	**Item Code (Source)**	NDC:0378-2587
Route of Administration	ORAL	**DEA Schedule**	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROXYZINE HYDROCHLORIDE (HYDROXYZINE)	HYDROXYZINE HYDROCHLORIDE	25 mg

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS LACTOSE	
SILICON DIOXIDE	
CROSPOVIDONE	
MAGNESIUM STEARATE	
CELLULOSE, MICROCRYSTALLINE	
POLYETHYLENE GLYCOLS	
POLYVINYL ALCOHOL	
SODIUM LAURYL SULFATE	

TALC	
TITANIUM DIOXIDE	
FD&C BLUE NO. 2	

Product Characteristics			
Color	BLUE	**Score**	no score
Shape	ROUND	**Size**	6mm
Flavor		**Imprint Code**	M;H25
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0378-2587-01	100 in 1 BOTTLE, PLASTIC		
2	NDC:0378-2587-10	1000 in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091176	07/23/2010	

HYDROXYZINE HYDROCHLORIDE

hydroxyzine hydrochloride tablet, film coated

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG LABEL	**Item Code (Source)**	NDC:0378-2588
Route of Administration	ORAL	**DEA Schedule**	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROXYZINE HYDROCHLORIDE (HYDROXYZINE)	HYDROXYZINE HYDROCHLORIDE	50 mg

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS LACTOSE	
SILICON DIOXIDE	
CROSPOVIDONE	
MAGNESIUM STEARATE	
CELLULOSE, MICROCRYSTALLINE	
POLYETHYLENE GLYCOLS	
POLYVINYL ALCOHOL	
SODIUM LAURYL SULFATE	

TALC	
TITANIUM DIOXIDE	
FD&C BLUE NO. 2	

Product Characteristics			
Color	BLUE	**Score**	no score
Shape	ROUND	**Size**	8mm
Flavor		**Imprint Code**	M;H50
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0378-2588-01	100 in 1 BOTTLE, PLASTIC		
2	NDC:0378-2588-10	1000 in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091176	07/23/2010	

Labeler - Mylan Pharmaceuticals Inc. (059295980)

Revised: 6/2014 Mylan Pharmaceuticals Inc.