

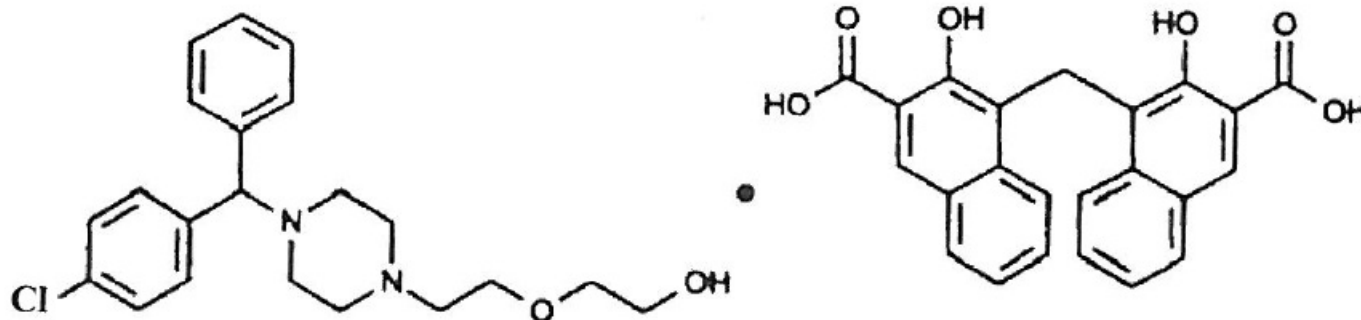
HYDROXYZINE PAMOATE- hydroxyzine pamoate capsule Cardinal Health

HYDROXYZINE PAMOATE CAPSULES USP

Rx only

DESCRIPTION

Hydroxyzine pamoate is designated chemically as 1-(p-chlorobenzhydryl) 4-[2-(2-hydroxyethoxy) ethyl] diethylenediamine salt of 1,1'-methylene bis (2 hydroxy-3-naphthalene carboxylic acid). It has the following structural formula:



$C_{21}H_{27}ClN_2O_2 \cdot C_{23}H_{16}O_6$ M.W. 763.27

Hydroxyzine Pamoate Capsules USP are administered in doses equivalent to 25 mg, 50 mg or 100 mg of hydroxyzine hydrochloride. In addition, each capsule contains the following inactive ingredients: croscarmellose sodium, magnesium stearate, and pregelatinized starch. The 25 mg also contains anhydrous lactose. The 50 mg and 100 mg also contain lactose monohydrate.

The capsule shell ingredients for the 25 mg capsule are D&C red no. 28, D&C yellow no. 10, FD&C blue no. 1, FD&C red no. 40, FD&C yellow no. 6, gelatin, and titanium dioxide. The 50 mg capsule shell contains D&C red no. 33, D&C yellow no. 10, FD&C yellow no. 6, gelatin, and titanium dioxide. The 100 mg capsule shell contains D&C red no. 28, D&C red no. 33, D&C yellow no. 10, FD&C blue no. 1, FD&C red no. 40, gelatin, and titanium dioxide.

The edible imprinting ink on the 25 mg, 50 mg and 100 mg capsules contains black iron oxide, D&C yellow no. 10 aluminum lake, FD&C blue no. 1 aluminum lake, FD&C blue no. 2 aluminum lake, FD&C red no. 40 aluminum lake, propylene glycol, and shellac glaze.

CLINICAL PHARMACOLOGY

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

Hydroxyzine pamoate 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 pamoate'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 premedication and following general anesthesia, **Hydroxyzine may potentiate meperidine (Demerol®) 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 pamoate is 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 the drug, patients should be warned of this possibility and cautioned against driving a car or operating dangerous machinery while taking hydroxyzine pamoate. Patients should be advised against the simultaneous use of other CNS depressant drugs, and cautioned that the effect of alcohol may be increased.

Geriatric Use

A determination has not been made whether controlled clinical studies of hydroxyzine pamoate 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 pamoate 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 pamoate and observed closely.

ADVERSE REACTIONS

Side effects reported with the administration of hydroxyzine pamoate 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.

In postmarketing experience, the following additional undesirable effects have been reported:

Body as a Whole:

allergic reaction.

Nervous System:

headache.

Psychiatric:

hallucination.

Skin and Appendages:

pruritus, rash, urticaria.

OVERDOSAGE

The most common manifestation of overdosage of hydroxyzine pamoate 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 vasopressors (**do not use epinephrine as hydroxyzine counteracts its pressor action**). Caffeine and Sodium Benzoate Injection, USP, may be used to counteract central nervous system depressant effects.

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: in adults, 50 to 100 mg q.i.d.; children under 6 years, 50 mg daily in divided doses; and 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: in adults, 25 mg t.i.d. or q.i.d.; children under 6 years, 50 mg daily in divided doses; and 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 in adults, and 0.6 mg/kg in children.

When treatment is initiated by the intramuscular route of administration, subsequent doses may be administered orally.

As with all medications, the dosage should be adjusted according to the patient's response to therapy.

HOW SUPPLIED:

Hydroxyzine Pamoate Capsules USP (hydroxyzine pamoate equivalent to hydroxyzine hydrochloride), 25 mg are available as light yellow opaque cap and pink opaque body filled with yellow powder, imprinted in black ink **barr** over "323" on one piece and 25 on the other piece. They are available as follows:

NDC 51079-077-20 – Unit dose blister packages of 100 (10 cards of 10 capsules each).

Hydroxyzine Pamoate Capsules USP (hydroxyzine pamoate equivalent to hydroxyzine hydrochloride), 50 mg are available as light yellow opaque cap and maroon opaque body filled with yellow powder, imprinted in black ink **barr** over "302" on one piece and 50 on the other piece. They are available as follows:

NDC 51079-078-20 – Unit dose blister packages of 100 (10 cards of 10 capsules each).

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

Manufactured by:

Teva Pharmaceuticals USA
Sellersville, PA 18960

Distributed by:

Mylan Institutional Inc.
Rockford, IL 61103 U.S.A.

S-9804 R5

2/13

Package/Label Display Panel

Hydroxyzine Pamoate Capsules, USP

50 mg

10 Capsules



NDC 55154-5092-0

Z84

**HydrOXYzine PAMOATE
CAPSULES, USP 50 mg**

10 CAPSULES

Each capsule contains hydroxyzine pamoate, USP equivalent to 50 mg of hydroxyzine hydrochloride.

Usual Dosage: See product insert for prescribing information, precautions and warnings.

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

RX ONLY

WARNING: This package is intended for institutional use only. Keep this and all drugs out of the reach of children. This unit dose package is not child resistant.

Manufactured by:
Teva Pharmaceuticals USA
Sellersville, PA 18960

Packaged and Distributed by:
Mylan Institutional Inc.
Rockford, IL 61103 U.S.A

Mylan.com

Mylan is a trademark owned by its respective owner.

Repackaged by Cardinal Health
Zanesville, OH 43701
L42652780714

LOT #: XXXX



EXP. DATE: 12/34



Package/Label Display Panel

Hydroxyine Pamoate Capsules, USP

25 mg

10 Capsules



V23

NDC 55154-5564-0

**HydroXYzine PAMOATE
CAPSULES, USP 25 mg**

10 CAPSULES

Each capsule contains hydroxyzine pamoate, USP equivalent to 25 mg of hydroxyzine hydrochloride.

Usual Dosage: See product insert for prescribing information, precautions and warnings.

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

RX ONLY

WARNING: This package is intended for institutional use only. Keep this and all drugs out of the reach of children. This unit dose package is not child resistant.

Manufactured by:
Teva Pharmaceuticals USA
Sellersville, PA 18960
Packaged and Distributed by:
Mylan Institutional Inc.
Rockford, IL 61103 U.S.A
Mylan.com

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Repackaged by Cardinal Health
Zanesville, OH 43701
L29069641213A

LOT #: XXXX



EXP. DATE: 12/34



HYDROXYZINE PAMOATE

hydroxyzine pamoate capsule

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG LABEL	Item Code (Source)	NDC:55154- 5092(NDC:51079-078)
Route of Administration	ORAL	DEA Schedule	

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
HYDROXYZINE PAMO ATE (HYDROXYZINE)	HYDROXYZINE HYDROCHLORIDE	50 mg

Inactive Ingredients	
Ingredient Name	Strength
CROSCARMELOSE SODIUM	
MAGNESIUM STEARATE	
STARCH, CORN	
LACTOSE MONOHYDRATE	
D&C RED NO. 33	
D&C YELLOW NO. 10	
FD&C YELLOW NO. 6	
GELATIN	
TITANIUM DIOXIDE	
FERROSO FERRIC OXIDE	
FD&C BLUE NO. 1	
FD&C BLUE NO. 2	
FD&C RED NO. 40	
ALUMINUM OXIDE	
PROPYLENE GLYCOL	
SHELLAC	

Product Characteristics			
Color	YELLOW (Light yellow) , RED (Maroon)	Score	no score
Shape	CAPSULE	Size	16mm
Flavor		Imprint Code	barr;302;50
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55154-5092-0	10 in 1 BAG		
1		1 in 1 BLISTER PACK; Combination Product Type = C112160		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

ANDA	ANDA088487	08/03/2011	
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HYDROXYZINE PAMOATE

hydroxyzine pamoate capsule

Product Information

Product Type	HUMAN PRESCRIPTION DRUG LABEL	Item Code (Source)	NDC:55154- 5564(NDC:51079-077)
Route of Administration	ORAL	DEA Schedule	

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
CROSCARMELOSE SODIUM	
MAGNESIUM STEARATE	
STARCH, CORN	
ANHYDROUS LACTOSE	
D&C RED NO. 28	
D&C YELLOW NO. 10	
FD&C BLUE NO. 1	
FD&C RED NO. 40	
FD&C YELLOW NO. 6	
GELATIN	
TITANIUM DIOXIDE	
FERROSO FERRIC OXIDE	
ALUMINUM OXIDE	
FD&C BLUE NO. 2	
PROPYLENE GLYCOL	
SHELLAC	

Product Characteristics

Color	YELLOW (Light yellow) , PINK	Score	no score
Shape	CAPSULE	Size	16mm
Flavor		Imprint Code	barr;323;25
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55154-5564- 0	10 in 1 BAG		

1	1 in 1 BLISTER PACK; Combination Product Type = C112160		
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Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA088496	09/25/2012	

Labeler - Cardinal Health (188557102)

Registrant - UDL Laboratories, Inc. (039615992)

Establishment

Name	Address	ID/FEI	Business Operations
Cardinal Health		188557102	REPACK(55154-5092, 55154-5564)