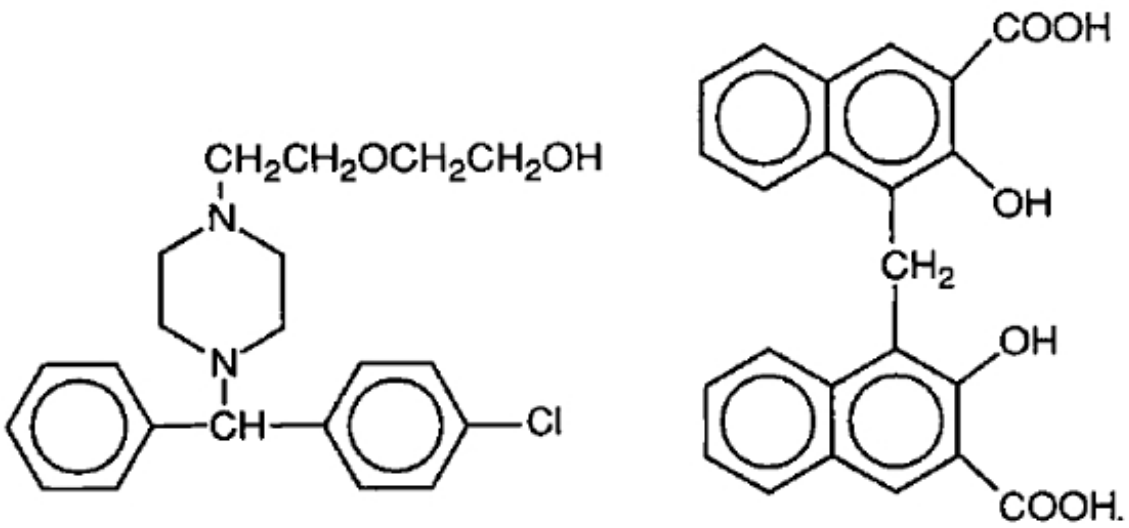
HYDROXYZINE PAMOATE - hydroxyzine pamoate capsule
State of Florida DOH Central Pharmacy

HYDROXYZINE PAMOATE CAPSULES, USP

Rx only

DESCRIPTION:

Hydroxyzine Pamoate is a light yellow, practically odorless powder, practically insoluble in water and methanol and freely soluble in dimethylformamide. It is chemically designated as 2-[2-[4-(*p*-chloro-α-phenylbenzyl)-1-piperazinyl]-ethoxy]ethanol 4,4'- methylenebis[3-hydroxy-2-naphthoate] (1:1) and can be structurally represented as follows:



$C_{21}H_{27}ClN_2O_2 \cdot C_{23}H_{16}O_6$ Molecular Weight: 763.29

Hydroxyzine Pamoate Capsules produce an ataraxic effect and they are administered in doses equivalent to 25 mg, 50 mg or 100 mg of hydroxyzine HCl.

Inactive Ingredients:

Croscarmellose sodium, ethyl alcohol, 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 are D&C red no. 28, D&C yellow no. 10, gelatin, sodium lauryl sulfate, and titanium dioxide. The 25 mg capsule shell also contains benzyl alcohol, butylparaben, EDTA calcium disodium, FD&C blue no. 1, FD&C red no. 40, methylparaben, propylparaben, and sodium propionate. The 50 mg capsule shell also contains benzyl alcohol, butylparaben, D&C red no. 33, EDTA calcium disodium, methylparaben, propylparaben, and sodium propionate. The 100 mg capsule shell also contains FD&C blue no. 1, FD&C red no. 40, and silicon dioxide.

The imprinting ink contains pharmaceutical glaze, propylene glycol, SDA-3A alcohol, and synthetic black iron oxide. The imprinting ink on the 25 mg and 50 mg capsules also contain ammonium hydroxide, dimethylpolysiloxane, ethylene glycol monoethyl ether, and lecithin. The imprinting ink on the 100 mg capsule also contains n-butyl alcohol, D&C yellow no. 10 aluminum lake, FD&C blue no. 1 aluminum lake, FD&C blue no. 2 aluminum lake, and FD&C red no. 40 aluminum lake.

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 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 maypotentiate 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 pamoate 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 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.

Overdosage:

The most common manifestation of overdosage of hydroxyzine pamoate 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 pamoate 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, 50-100 mg q.i.d.; children under 6 years, 50 mg daily in divided doses and over 6 years, 50-100 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, 50-100 mg daily in divided doses.

As a sedative when used as a premedication and following general anesthesia: 50-100 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 is equivalent to hydroxyzine hydrochloride.

25 mg:	Light yellow opaque cap/pink opaque body filled with yellow powder. Imprinted in black ink stylized **barr** over 323/25.
50 mg:	Light yellow opaque cap/maroon opaque body filled with yellow powder. Imprinted in black ink stylized **barr** over 302 /50.
100 mg:	Light yellow opaque cap/pink opaque body filled with yellow powder. Imprinted in black ink stylized **barr** over 324/100.

They are supplied by **State of Florida DOH Central Pharmacy** as follows:

NDC	Strength	Quantity/Form	Color	Source Prod. Code
53808-0373-1	25 mg	30 Capsules in a Blister Pack	PINK	0555-0323
53808-0374-1	50 mg	30 Capsules in a Blister Pack	MAROON	0555-0302
00555-0324-1	100 mg	30 Capsules in a Blister Pack	PINK	0555-0324

Dispense with a child-resistant closure in a well-closed container as defined in the USP/NF.

Store at controlled room temperature 15°-30°C (59°-86°F) [see USP].

MANUFACTURED BY

BARR LABORATORIES, INC.

POMONA, NY 10970

This Product was Repackaged By:

State of Florida DOH Central Pharmacy
104-2 Hamilton Park Drive
Tallahassee, FL 32304
United States

25mg Label

50mg Label

100mg Label

HYDROXYZINE PAMOATE

hydroxyzine pamoate capsule

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:53808-0373(NDC:0555-0323)
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
HYDROXYZINE PAMOATE (UNII: M20215MUFR) (HYDROXYZINE - UNII:30S50YM8OG)	HYDROXYZINE PAMOATE	25 mg

Inactive Ingredients	
Ingredient Name	**Strength**
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
ALCOHOL (UNII: 3K9958V90M)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics			
Color	PINK (PINK)	**Score**	no score
Shape	CAPSULE (CAPSULE)	**Size**	14mm
Flavor		**Imprint Code**	barr;323;25
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:53808-0373-1	30 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA088496	07/01/2009	

HYDROXYZINE PAMOATE

hydroxyzine pamoate capsule

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:53808-0374(NDC:0555-0302)
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
HYDROXYZINE PAMOATE (UNII: M20215MUFR) (HYDROXYZINE - UNII:30S50YM8OG)	HYDROXYZINE PAMOATE	50 mg

Inactive Ingredients	
Ingredient Name	**Strength**
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
ALCOHOL (UNII: 3K9958V90M)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics			
Color	RED (MAROON)	**Score**	no score
Shape	CAPSULE (CAPSULE)	**Size**	14mm
Flavor		**Imprint Code**	barr;302;50
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:53808-0374-1	30 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA088487	07/01/2009	

HYDROXYZINE PAMOATE

hydroxyzine pamoate capsule

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:53808-0431(NDC:0555-0324)
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
HYDROXYZINE PAMOATE (UNII: M20215MUFR) (HYDROXYZINE - UNII:30S50YM8OG)	HYDROXYZINE PAMOATE	100 mg

Inactive Ingredients

Ingredient Name	Strength
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
ALCOHOL (UNII: 3K9958V90M)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	PINK (PINK)	**Score**	no score
Shape	CAPSULE (CAPSULE)	**Size**	18mm
Flavor		**Imprint Code**	barr;324;100
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53808-0431-1	30 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA088488	07/01/2009	

Labeler - State of Florida DOH Central Pharmacy (829348114)

Establishment

Name	Address	ID/FEI	Business Operations
State of Florida DOH Central Pharmacy		829348114	repack

Revised: 5/2010 State of Florida DOH Central Pharmacy