

HYDROXYZINE PAMOATE- hydroxyzine pamoate capsule
TYA Pharmaceuticals

HYDROXYZINE PAMOATE CAPSULES USP

0323

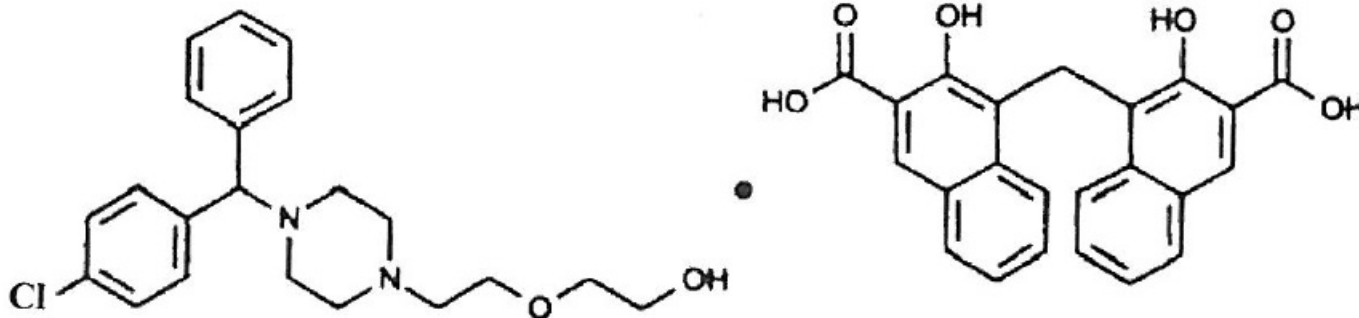
0302

0324

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:



C₂₇H₃₁ClN₂O₅ • C₂₀H₁₄O₆ M.W. 763.27 21272223166

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 corn 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, 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. **Hydroxyzine may potentiate meperidine (Demerol) and barbiturates**®

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.

Skin and Appendages:

Oral hydroxyzine hydrochloride is associated with fixed drug eruptions in postmarketing reports.

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

HYDROXYZINE PAMOATE 25MG CAPS(100CTBTL)

RX ONLY

0555-0323-02

LOT: XXXX

EXP: XX-XX-XX

MFR: TEVA

REPACKAGED BY: T.Y.A. PHARMACEUTICALS

2930 CRESCENT DR.

TALLAHASSEE, FL 32301

(850) 385-0228



DOSE: SEE PACKAGE INSERT

HYDROXYZINE PAMOATE

hydroxyzine pamoate capsule

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:64725-0302(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 HYDROCHLORIDE	50 mg

Inactive Ingredients

Ingredient Name	Strength
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
STARCH, CORN (UNII: O8232NY3SJ)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	

ALUMINUM OXIDE (UNII: LM26O6933)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
INDIGOTINDISULFONATE SODIUM (UNII: D3741U8K7L)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	

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:64725-0302-1	100 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA088487	07/01/1984	

HYDROXYZINE PAMOATE

hydroxyzine pamoate capsule

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:64725-0323(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 HYDROCHLORIDE	25 mg

Inactive Ingredients

Ingredient Name	Strength
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
STARCH, CORN (UNII: O8232NY3SJ)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
D&C RED NO. 28 (UNII: 767IP0Y5NH)	

D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
ALUMINUM OXIDE (UNII: LM26O6933)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
INDIGOTINDISULFONATE SODIUM (UNII: D3741U8K7L)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	

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:64725-0323-1	100 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA088496	07/01/1984	

Labeler - TYA Pharmaceuticals (938389038)

Registrant - TYA Pharmaceuticals (938389038)

Establishment

Name	Address	ID/FEI	Business Operations
TYA Pharmaceuticals		938389038	RELABEL(64725-0302, 64725-0323) , REPACK(64725-0302)