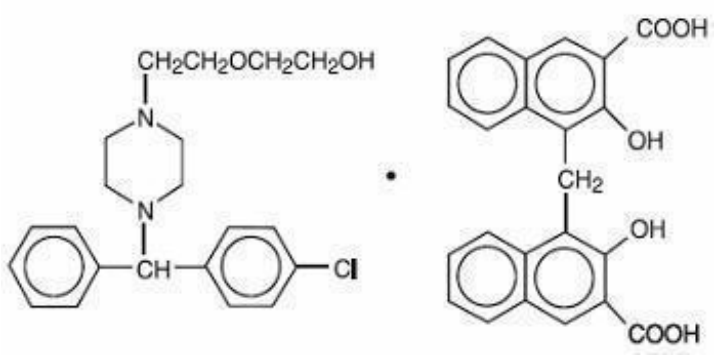
HYDROXYZINE PAMOATE - hydroxyzine pamoate capsule
STAT Rx USA LLC

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) [10246-75-0] and can be structurally represented as follows:



$C_{21}H_{27}ClN_2O_2 \cdot C_{23}H_{16}O_6$

M.W. 763.27

Each capsule, for oral administration, contains hydroxyzine pamoate equivalent to hydroxyzine hydrochloride 25 mg or 50 mg. In addition, each capsule contains the following inactive ingredients: colloidal silicon dioxide, D&C yellow No. 10, FD&C green No. 3, FD&C yellow No. 6, gelatin, hydroxypropyl cellulose, lactose monohydrate, magnesium stearate, propylene glycol, sodium lauryl sulfate, sodium starch glycolate and titanium dioxide.

CLINICAL PHARMACOLOGY

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

Hydroxyzine pamoate capsules are not a cortical depressant, but their 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 capsules clinical effects are usually noted within 15 to 30 minutes after oral administration.

INDICATIONS

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 capsules. 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 capsules 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 capsules 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 capsules and observed closely.

ADVERSE REACTIONS

Side effects reported with the administration of hydroxyzine pamoate capsules 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 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: pruritus, rash, urticaria

OVERDOSAGE

The most common manifestation of overdosage of hydroxyzine pamoate capsules 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 mg to 100 mg q.i.d.; children under 6 years, 50 mg daily in divided doses; and 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: 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 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 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 for oral administration are available as:

25 mg: (equivalent to 25 mg hydroxyzine hydrochloride) are light green/dark green capsules imprinted "*E* 613" and supplied as:

Bottles of 12 - NDC # 16590-357-12

Bottles of 30 - NDC # 16590-357-30

Bottles of 60 - NDC # 16590-357-60

Bottles of 120 - NDC # 16590-357-72

Storage

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Protect from moisture. Dispense in a tight, light-resistant container as defined in the USP, with a child-resistant closure, as required.

To report SUSPECTED ADVERSE REACTIONS, contact Sandoz Inc. at 1-800-525-8747 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Manufactured for

Sandoz Inc.

Princeton, NJ 08540

Manufactured by

Epic Pharma, LLC

Laurelton, NY 11413

Rev. 09/09

MF0613REV09/09

OS7127

Sandoz Inc.

Princeton, NJ 08540

OS8905

Rev. 09/09

Relabeling and Repackaging by:
STAT Rx USA LLC
Gainesville, GA 30501

PACKAGE LABEL - HYDROXYZINE PAMOATE 25 MG CAPSULES

HYDROXYZINE PAMOATE

hydroxyzine pamoate capsule

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:16590-357(NDC:0185-0613)
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**
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
HYDROXYPROPYL CELLULOSE (UNII: RFW2ET671P)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	GREEN (light green/dark green)	**Score**	no score
Shape	CAPSULE	**Size**	19mm
Flavor		**Imprint Code**	E613
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:16590-357-12	12 in 1 BOTTLE		
2	NDC:16590-357-30	30 in 1 BOTTLE		
3	NDC:16590-357-60	60 in 1 BOTTLE		
4	NDC:16590-357-72	120 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA087479	12/14/1981	

Labeler - STAT Rx USA LLC (786036330)

Registrant - PSS World Medical Inc. (101822682)

Establishment

Name	Address	ID/FEI	Business Operations
STAT Rx USA LLC		786036330	relabel(16590-357) , repack(16590-357)

Revised: 10/2012 STAT Rx USA LLC