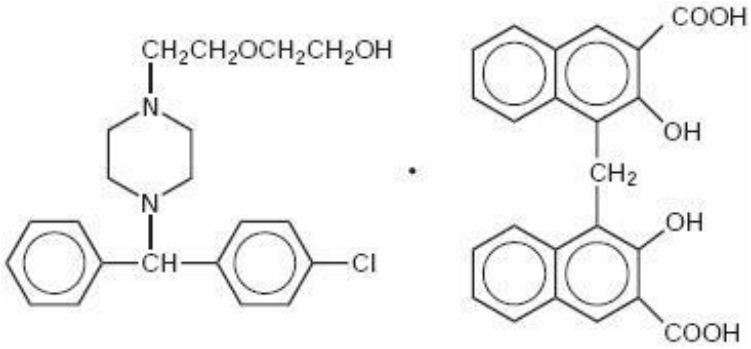
HYDROXYZINE PAMOATE- hydroxyzine pamoate capsule
Contract Pharmacy Services-PA

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 1-(p-chlorobenzhydryl) 4-[2-(2-hydroxyethoxy) ethyl] diethylenediamine salt of 1,1'-methylene bis (2 hydroxy-3-naphthalene carboxylic acid) and can be structurally represented as follows:



Chemical Formula:

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

Molecular Weight: 763.29

Each capsule, for oral administration, contains hydroxyzine pamoate equivalent to 25 mg or 50 mg of hydroxyzine hydrochloride. In addition, each capsule contains the following inactive ingredients: colloidal silicon dioxide, D&C yellow #10, D&C yellow #10 Aluminum Lake, FD&C Blue #1 Aluminum Lake, FD&C Blue #2 Aluminum Lake, FD&C Green #3, FD&C Red #40 Aluminum Lake, FD&C Yellow #6, gelatin, hydroxypropyl cellulose, lactose monohydrate, magnesium sterate, sodium lauryl sulfate, sodium starch glycolate and titanium dioxide.

CLINICAL PHARMACOLOGY

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

Hydroxyzine pamoate is not a cortical depressant, although 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 and barbiturates,** therefore use of these agents 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 anti-anxiety 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 BARBlTURATES. 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 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 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 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 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 (hydroxyzine pamoate equivalent to hydroxyzine hydrochloride) are supplied as follows:

25 mg capsules: Light green/dark green capsules imprinted "E 613".

50 mg capsules: Dark green/white capsules imprinted "E 615".

Storage

Store below 30° C (86° F) [see USP].

Dispense in a tight, light-resistant container as defined in USP/NF.

BIBLIOGRAPHY

Available on request.

Sandoz Inc.

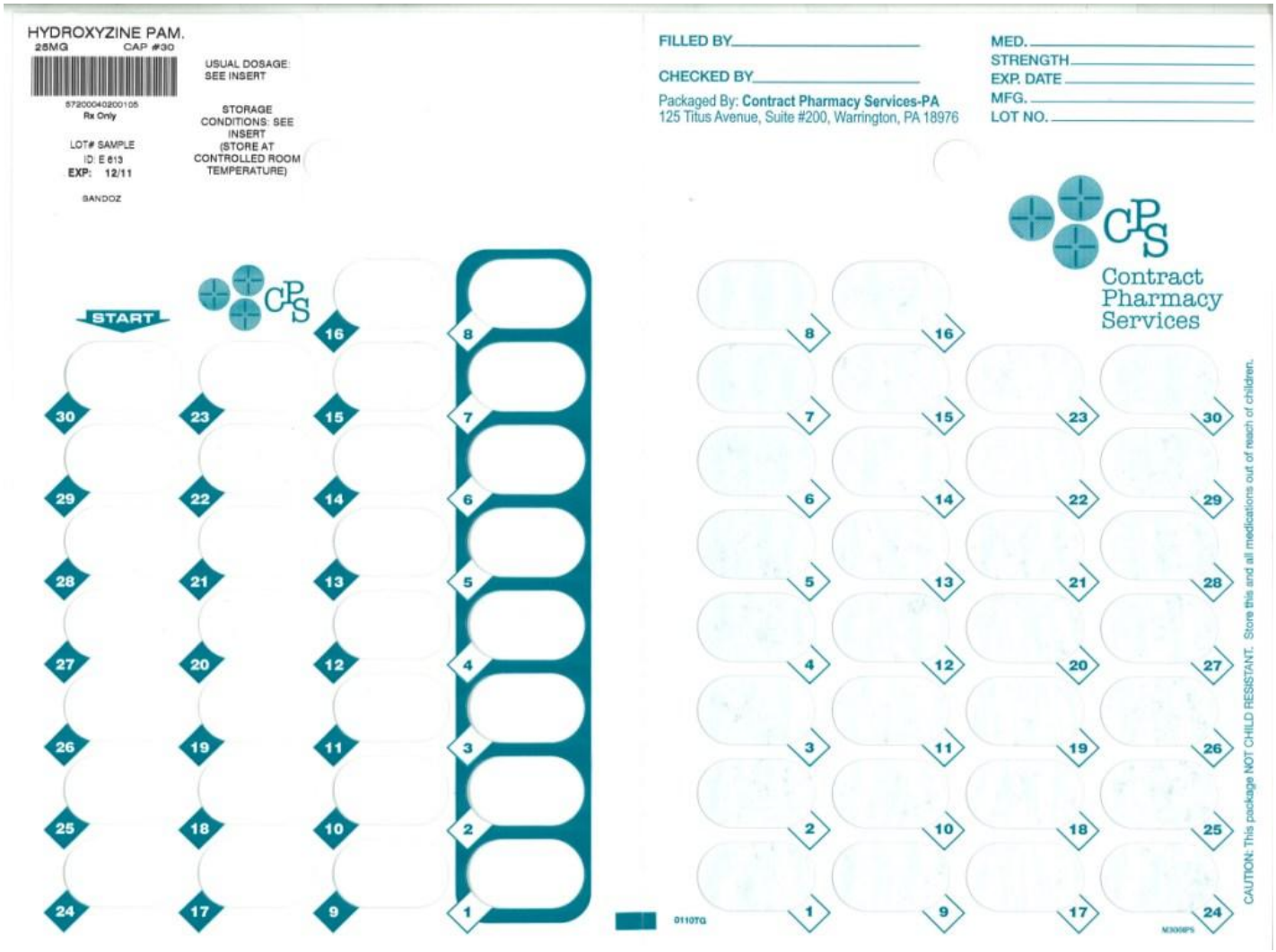
Princeton, NJ 08540

Repackaged by:

Contract Pharmacy Services-PA
125 Titus Ave Suite 200
Warrington, PA 18976 USA

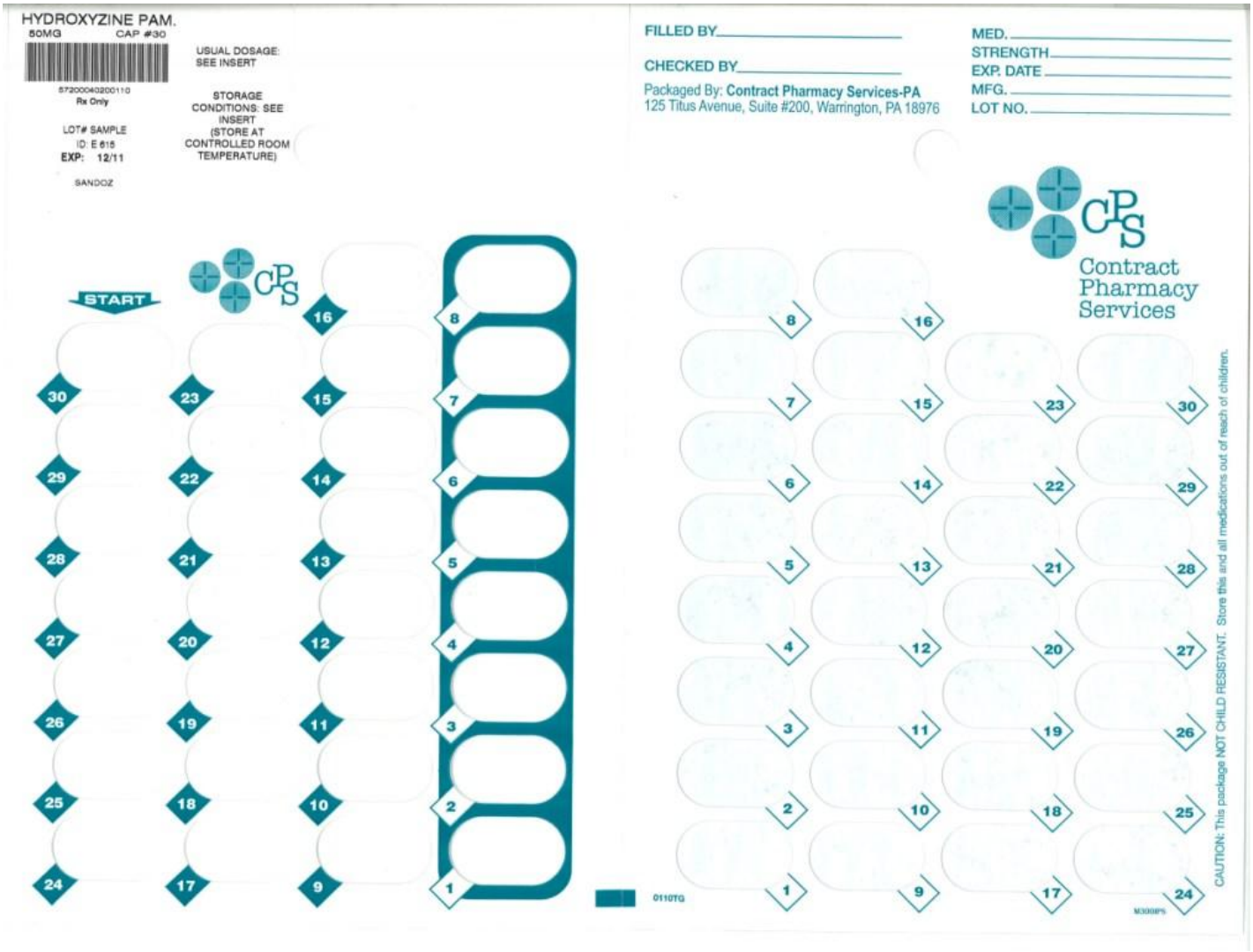
Original--08/2010--NJW

PRINCIPAL DISPLAY PANEL



25 mg Capsules

PRINCIPAL DISPLAY PANEL



50 mg Capsules

HYDROXYZINE PAMOATE

hydroxyzine pamoate capsule

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:67046-281(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 BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
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**	16mm
Flavor		**Imprint Code**	E;613
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67046-281-30	30 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA087479	08/16/2010	

HYDROXYZINE PAMOATE

hydroxyzine pamoate capsule

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:67046-282(NDC:0185-0615)
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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	GREEN (dark green/white)	**Score**	no score
Shape	CAPSULE	**Size**	19mm
Flavor		**Imprint Code**	E;615
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67046-282-30	30 in 1 BLISTER PACK		
2	NDC:67046-282-60	60 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA086183	08/16/2010	

Labeler - Contract Pharmacy Services-PA (945429777)

Revised: 8/2010 Contract Pharmacy Services-PA