VISTARIL- hydroxyzine pamoate capsule
Pfizer Laboratories Div Pfizer Inc

VISTARIL®
(hydroxyzine pamoate)
Capsules and
Oral Suspension

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).

Inert ingredients for the capsule formulations are: hard gelatin capsules (which may contain Yellow 10, Green 3, Yellow 6, Red 33, and other inert ingredients); magnesium stearate; sodium lauryl sulfate; starch; sucrose.

Inert ingredients for the oral suspension formulation are: carboxymethylcellulose sodium; lemon flavor; propylene glycol; sorbic acid; sorbitol solution; water.

CLINICAL PHARMACOLOGY

Vistaril® (hydroxyzine pamoate) is unrelated chemically to the phenothiazines, reserpine, meprobamate, or the benzodiazepines.

Vistaril 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 Vistaril's 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 is contraindicated in patients with a prolonged QT interval.

Hydroxyzine pamoate is contraindicated for patients who have shown a previous hypersensitivity to any component of this medication.

Hydroxyzine is contraindicated in patients with known hypersensitivity to hydroxyzine products, and in patients with known hypersensitivity to cetirizine hydrochloride or levocetirizine hydrochloride.

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 Vistaril (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.

QT Prolongation/Torsade de Pointes (TdP)

Cases of QT prolongation and Torsade de Pointes have been reported during post-marketing use of hydroxyzine. The majority of reports occurred in patients with other risk factors for QT prolongation/TdP (pre-existing heart disease, electrolyte imbalances or concomitant arrhythmogenic drug use). Therefore, hydroxyzine should be used with caution in patients with risk factors for QT prolongation, congenital long QT syndrome, a family history of long QT syndrome, other conditions that predispose to QT prolongation

and ventricular arrhythmia, as well as recent myocardial infarction, uncompensated heart failure, and bradyarrhythmias.

Caution is recommended during the concomitant use of drugs known to prolong the QT interval. These include Class 1A (e.g., quinidine, procainamide) or Class III (e.g., amiodarone, sotalol) antiarrhythmics, certain antipsychotics (e.g., ziprasidone, iloperidone, clozapine, quetiapine, chlorpromazine), certain antidepressants (e.g., citalopram, fluoxetine), certain antibiotics (e.g., azithromycin, erythromycin, clarithromycin, gatifloxacin, moxifloxacin); and others (e.g., pentamidine, methadone, ondansetron, droperidol).

Acute Generalized Exanthematous Pustulosis (AGEP)

Hydroxyzine may rarely cause acute generalized exanthematous pustulosis (AGEP), a serious skin reaction characterized by fever and numerous small, superficial, non-follicular, sterile pustules, arising within large areas of edematous erythema. Inform patients about the signs of AGEP, and discontinue hydroxyzine at the first appearance of a skin rash, worsening of pre-existing skin reactions which hydroxyzine may be used to treat, or any other sign of hypersensitivity. If signs or symptoms suggest AGEP, use of hydroxyzine should not be resumed and alternative therapy should be considered. Avoid cetirizine or levocetirizine in patients who have experienced AGEP or other hypersensitivity reactions with hydroxyzine, due to the risk of cross-sensitivity.

Geriatric Use

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

ADVERSE REACTIONS

Side effects reported with the administration of Vistaril are usually mild and transitory in nature.

Skin and Appendages: Oral hydroxyzine hydrochloride is associated with Acute Generalized Exanthematous Pustulosis (AGEP) and fixed drug eruptions in post-marketing 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.

Cardiac System: QT prolongation, Torsade de Pointes.

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 Vistaril 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.

Hydroxyzine overdose may cause QT prolongation and Torsade de Pointes. ECG monitoring is recommended in cases of hydroxyzine overdose.

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

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 4 times daily; 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 3 times daily or 4 times daily; 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

Vistaril Capsules (hydroxyzine pamoate equivalent to hydroxyzine hydrochloride)

25 mg:	100's (NDC 0069-5410-66), two-tone green capsules
50 mg:	100's (NDC 0069-5420-66), green and white capsules

Store Vistaril® Capsules below 30°C (86°F). Dispense in tight, light-resistant containers (USP).

Vistaril Oral Suspension (hydroxyzine pamoate equivalent to 25 mg hydroxyzine hydrochloride per teaspoonful-5 mL): 1 pint (473 mL) bottles (NDC 0069-5440-93) and 4 ounce (120 mL) bottles (NDC 0069-5440-97) in packages of 4.

Store Vistaril® Oral Suspension at 20°C to 25°C (68°F to 77°F) [see USP Controlled Room Temperature]. Shake vigorously until product is completely resuspended.

This product's label may have been updated. For full prescribing information, please visit www.pfizer.com.

Pfizer

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Pfizer Labs
Division of Pfizer Inc.
New York, NY 10001

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PRINCIPAL DISPLAY PANEL - 25 mg Capsule Bottle Label

Pfizer

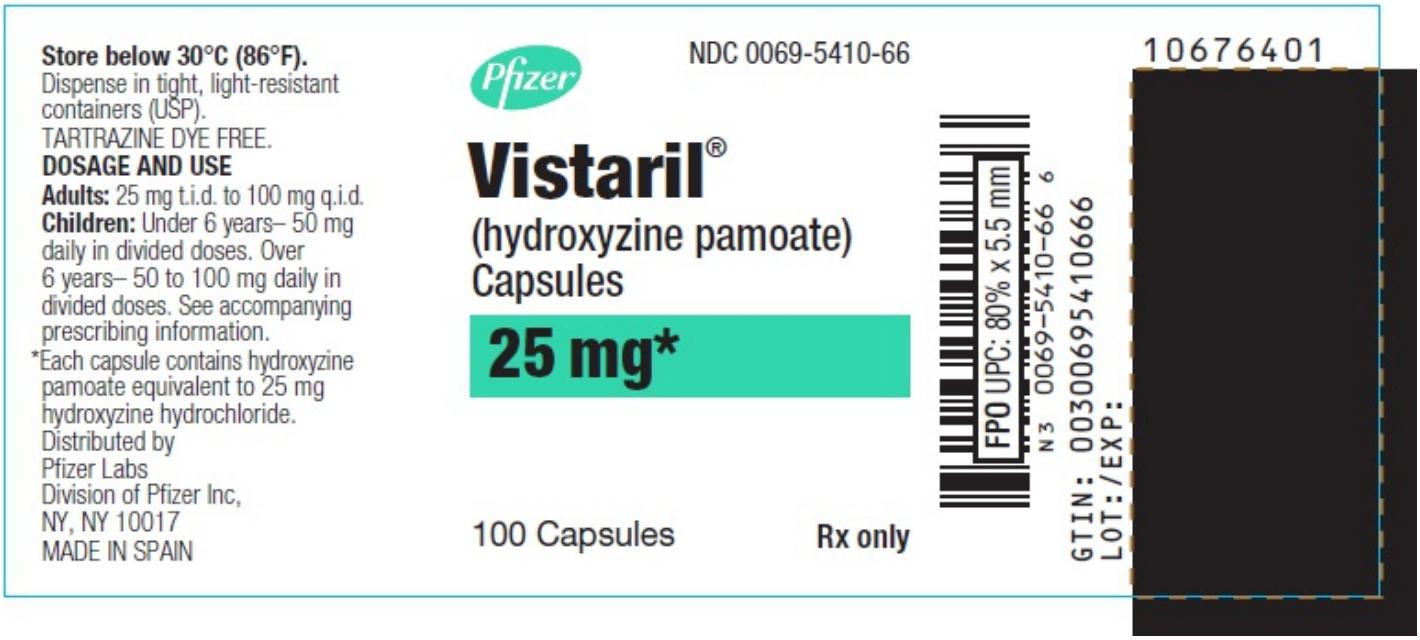
NDC 0069-5410-66

Vistaril®
(hydroxyzine pamoate)
Capsules

25 mg*

100 Capsules

Rx only



PRINCIPAL DISPLAY PANEL - 50 mg Capsule Bottle Label

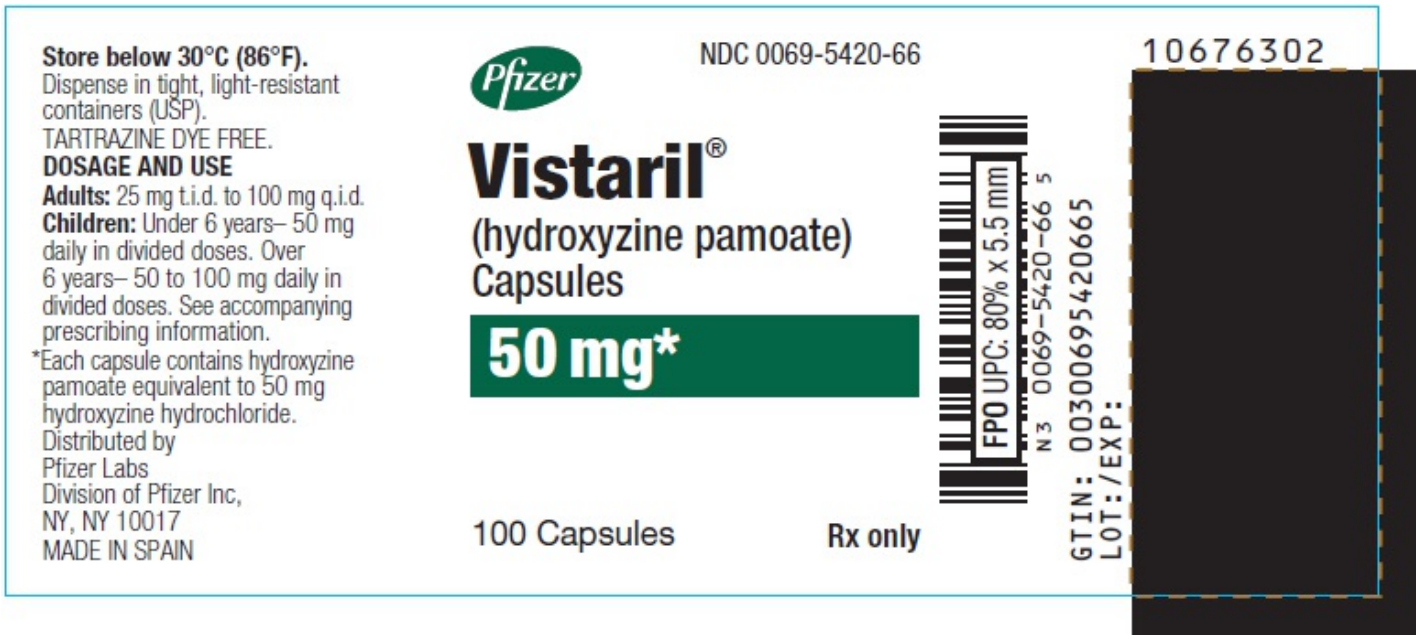
Pfizer

NDC 0069-5420-66

Vistaril®
(hydroxyzine pamoate)
Capsules

50 mg*

100 Capsules
Rx only



VISTARIL

hydroxyzine pamoate capsule

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0069-5410
Route of Administration	ORAL		

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

Inactive Ingredients	
Ingredient Name	**Strength**
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SUCROSE (UNII: C151H8M554)	

Product Characteristics			
Color	GREEN (two-tone green)	**Score**	no score
Shape	CAPSULE	**Size**	14mm
Flavor		**Imprint Code**	Vistaril;Pfizer;541
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0069-5410-66	100 in 1 BOTTLE; Type 0: Not a Combination Product	11/28/1994	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA011459	11/28/1994	

VISTARIL

hydroxyzine pamoate capsule

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0069-5420
Route of Administration	ORAL		

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

Inactive Ingredients	
Ingredient Name	**Strength**
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SUCROSE (UNII: C151H8M554)	

Product Characteristics			
Color	GREEN, WHITE	**Score**	no score
Shape	CAPSULE	**Size**	14mm
Flavor		**Imprint Code**	Vistaril;Pfizer;542
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0069-5420-66	100 in 1 BOTTLE; Type 0: Not a Combination Product	11/15/1968	12/31/2023

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA011459	11/15/1968	12/31/2023

Labeler - Pfizer Laboratories Div Pfizer Inc (134489525)

Revised: 4/2024

Pfizer Laboratories Div Pfizer Inc