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:
\[ \text{C}_{21}\text{H}_{27}\text{ClN}_2\text{O}_2 \quad \text{C}_{23}\text{H}_{16}\text{O}_6 \]
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, FD&C blue #1, gelatin, magnesium stearate, pregelatinized starch, sodium lauryl sulfate, and titanium dioxide. The imprinting ink on the capsules contains synthetic black iron oxide.

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 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 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: Dark green opaque cap/light green opaque body filled with yellow powder. Imprinted in black ink WATSON over
800 on the cap and 25 mg on the body, in bottles of 100 and 500.
50 mg capsules: Dark green opaque cap/white opaque body filled with yellow powder. Imprinted in black ink WATSON over 801 on
the cap and 50 mg on the body, in bottles of 100 and 500.
They are supplied by State of Florida DOH Central Pharmacy as follows:
<table>
<thead>
<tr>
<th>NDC</th>
<th>Strength</th>
<th>Quantity/Form</th>
<th>Color</th>
<th>Source Prod. Code</th>
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<tbody>
<tr>
<td>53808-0426-1</td>
<td>25 mg</td>
<td>30 Capsules in a Blister Pack</td>
<td>dark green opaque/light green opaque</td>
<td>0591-0800</td>
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<tr>
<td>53808-0429-1</td>
<td>50 mg</td>
<td>30 Capsules in a Blister Pack</td>
<td>opaque white</td>
<td>0591-0801</td>
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</tbody>
</table>

**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.
Manufactured by:
Patheon Pharmaceuticals Inc.
Cincinnati, OH 45215 USA
For:
**Watson Laboratories, Inc.**
Corona, CA 92880
This Product was Repackaged By:
**State of Florida DOH Central Pharmacy**
104-2 Hamilton Park Drive
Tallahassee, FL 32304
United States

**25MG LABEL**

```
HYDROXYZINE PAMOATE
25 MG CAPS
RX Only
QTY: 30
WATSON LOT: 3071528
DCS LOT: 121420089
EXP: 063010 INT/PH: MM/JWW
PKG BY DCH Central Pharmacy
Tallahassee, FL 32304

UPC# 305910800017
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HYDROXYZINE PAM
50MG CAPS       RX Only
QTY: 30
WATSON          LOT: 3075075
DCH LOT #12092003A
EXP:063010      INT/RPH:TWIJJWW
PKG BY DOH Central Pharmacy
Tallahassee, FL 32304

UPC# 305910801052