

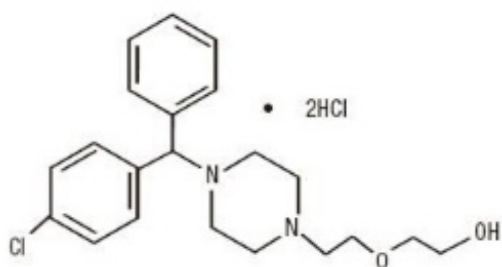
HYDROXYZINE HYDROCHLORIDE- hydroxyzine hydrochloride syrup Proficient Rx LP

HYDROXYZINE HYDROCHLORIDE ORAL SOLUTION, USP (SYRUP) 10 mg/5 mL

Rx only

DESCRIPTION

Hydroxyzine hydrochloride is designated chemically as (\pm)-2-[2-[4-(*p*-Chloro- α -phenylbenzyl)-1-piperaziny]ethoxy]ethanol dihydrochloride. Its structural formula is as follows:



$C_{21}H_{27}ClN_2O_2 \cdot 2HCl$

M.W. 447.83

Inactive Ingredients for Hydroxyzine Hydrochloride Oral Solution, USP (Syrup) are: alcohol 0.5%; liquid sugar; methylparaben; peppermint oil; propylene glycol; propylparaben; purified water and spearmint oil. **It may also contain** citric acid anhydrous or sodium citrate dihydrate for pH adjustment. The pH range is between 2.0 and 4.3.

CLINICAL PHARMACOLOGY

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

Hydroxyzine 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 its 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**, 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

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

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 for patients who have shown a previous hypersensitivity to it.

WARNINGS

Keep out of the reach of children.

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 this drug, patients should be warned of this possibility and cautioned against driving a car or operating dangerous machinery while

taking hydroxyzine. 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 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 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 oversedation 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 hydrochloride are usually mild and transitory in nature.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or www.fda.gov/medwatch. You may also report side effects to Wockhardt USA, LLC at 1-800-445-4290.

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 have 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 hydroxyzine overdosage 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 the 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 counteracts its pressor action.

There is no specific antidote. It is doubtful that hemodialysis would be of any value in the

treatment of overdose 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 to 100 mg q.i.d.; 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 t.i.d. or q.i.d.; 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

Hydroxyzine Hydrochloride Oral Solution, USP (Syrup) 10 mg per 5 mL (teaspoonful) is a colorless, peppermint-flavored syrup, supplied in 4 fl oz (118 mL) bottles.

NDC 63187-494-04

RECOMMENDED STORAGE

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

PROTECT FROM FREEZING

PROTECT FROM LIGHT

Dispense in a tight, light-resistant container as defined in the USP, with child-resistant closure.

Rx Only

Product No.: 8150

Manufactured For:
Wockhardt USA, LLC
Parsippany, NJ 07054

Manufactured By:
Morton Grove Pharmaceuticals, Inc.
Morton Grove, IL 60053

**Relabeled by:
Proficient Rx LP
Thousand Oaks, CA 91320**

A50-8150-16
REV. 06-14

PRINCIPAL DISPLAY PANEL - 118 mL Bottle Label

MGP

NDC 63187-494-04




**HydroXYzine
Hydrochloride
Oral Solution, USP
(Syrup)
10 mg/5 mL
Alcohol 0.5% (v/v)**

DO NOT USE IF INNER FOIL SEAL PRINTED "SEALED
FOR YOUR PROTECTION" IS BROKEN OR MISSING.

**This container not
intended for household use.**

Rx Only

NET: 4oz (118 mL)

		Scan Here 	NDC 63187-494-04	Relabeled By: Proficient Rx LP Thousand Oaks, CA 91320
			RX Only	
 3 6318749404 9	Hydroxyzine HCl 10mg/ 5mL		Hydroxyzine HCl 10mg/ 5mL 4 fl oz (118 mL) Oral Solution Lot #:00000 SN# MASTER NDC 63187-494-04 Exp:00/00/00	
	4 fl oz (118 mL) Oral Solution		Hydroxyzine HCl 10mg/ 5mL 4 fl oz (118 mL) Oral Solution Lot #:00000 SN# MASTER NDC 63187-494-04 Exp:00/00/00	
	Each 5ml (1tsp) contains: Hydroxyzine Hydrochloride, USP 10mg / Alcohol 0.5% (v/v)		Hydroxyzine HCl 10mg/ 5mL 4 fl oz (118 mL) Oral Solution Lot #:00000 SN# MASTER NDC 63187-494-04 Exp:00/00/00	
	See package insert.		 GTIN: 00363187494049 SN# MASTER Exp. 00/00/00 Lot #:00000	
Product ID: RH049404				
Mfr. By: Morton Grove Pharmaceuticals, Inc. Morton Grove, IL 60053				
Store at 20°-25°C (68°-77°F)		Keep medication out of the reach of children		

HYDROXYZINE HYDROCHLORIDE

hydroxyzine hydrochloride syrup

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:63187-494(NDC:60432-150)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROXYZINE DIHYDROCHLORIDE (UNII: 76755771U3) (Hydroxyzine - UNII:30S50YM8OG)	HYDROXYZINE DIHYDROCHLORIDE	10 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
water (UNII: 059QF0KO0R)	
alcohol (UNII: 3K9958V90M)	
peppermint oil (UNII: AV092KU4JH)	
spearmint oil (UNII: C3M81465G5)	
propylene glycol (UNII: 6DC9Q167V3)	
methylparaben (UNII: A2I8C7HI9T)	
propylparaben (UNII: Z8IX2SC1OH)	
Anhydrous Citric Acid (UNII: XF417D3PSL)	
Trisodium Citrate Dihydrate (UNII: B22547B95K)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	PEPPERMINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63187-494-04	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/02/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA087294	03/09/1995	

Labeler - Proficient Rx LP (079196022)

Establishment

Name	Address	ID/FEI	Business Operations
Proficient Rx LP		079196022	RELABEL(63187-494)

Revised: 10/2022

Proficient Rx LP