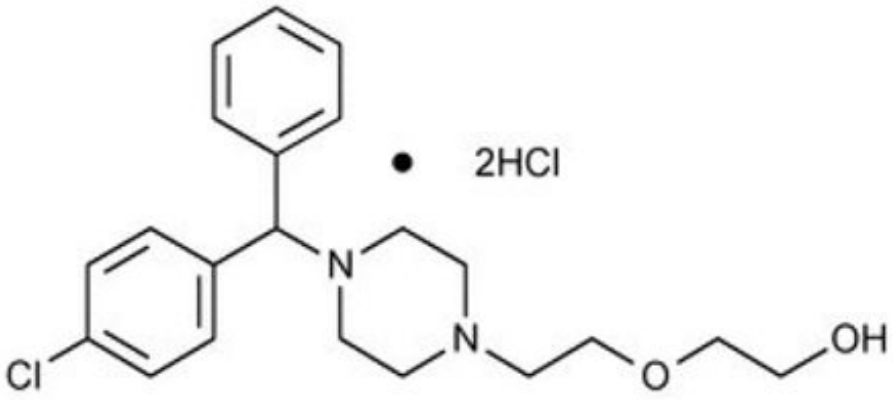
HYDROXYZINE HYDROCHLORIDE- hydroxyzine hydrochloride tablet, film coated
Denton Pharma, Inc. DBA Northwind Pharmaceuticals

Hydroxyzine Hydrochloride Tablets USP, Film-Coated

Rx Only

DESCRIPTION

Hydroxyzine hydrochloride, USP has the chemical name of 2-[2-[4-(*p*-Chloro-α-phenylbenzyl)-1-piperazinyl]ethoxy]ethanol dihydrochloride.



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

M.W. 447.83

Hydroxyzine hydrochloride, USP occurs as a white, odorless powder which is very soluble in water.

Each tablet for oral administration contains 10 mg, 25 mg or 50 mg hydroxyzine hydrochloride, USP. Inactive ingredients include carnauba wax, colloidal silicon dioxide, crospovidone, lactose monohydrate, magnesium stearate, microcrystalline cellulose, D&C Yellow #10 Aluminum Lake (25 mg and 50 mg), FD&C Blue #2 Aluminum Lake (25 mg), FD&C Red #40 Aluminum Lake (50 mg), FD&C Yellow #6 Aluminum Lake (10 mg and 50 mg), hypromellose, polyethylene glycol 3350, polyvinyl alcohol, talc, titanium dioxide, triacetin and yellow iron oxide (10 mg).

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 hydroxyzine’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 a 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 is contraindicated in patients with a prolonged QT interval.

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 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.

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).

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 also be advised against the simultaneous use of other CNS depressant drugs, and cautioned that the effects 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 over sedation in the elderly; elderly patients generally should be started on low doses of hydroxyzine and observed closely.

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.

ADVERSE REACTIONS

Side effects reported with the administration of hydroxyzine hydrochloride 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 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.

Cardiac System: QT prolongation, Torsade de Pointes.

In postmarketing experience, the following additional undesirable effects have been reported:

Body as a Whole: Allergic reaction.

Nervous System: Headache.

Psychiatric: Hallucination.

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

Pruritus, rash, urticaria.

OVERDOSAGE

The most common manifestation of hydroxyzine overdosage 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 levarterenol or metaraminol. Do not use epinephrine as hydroxyzine counteracts its pressor action.

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 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: adults, 50 to 100 mg q.i.d.; children under 6 years, 50 mg daily in divided doses; children 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: adults, 25 mg t.i.d. or q.i.d.; children under 6 years, 50 mg daily in divided doses; children 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 for adults and 0.6 mg/kg of body weight in children.

When treatment is initiated by the intramuscular route of administration, subsequent doses may be administered orally.

As with all potent medication, the dosage should be adjusted according to the patient's response to therapy.

HOW SUPPLIED

Hydroxyzine Hydrochloride Tablets USP, 10 mg are available as 9/32", Orange round biconvex film-coated tablets, debossed **“Є”** above **“159”** on one side and plain on the other side, packaged in bottles of 100’s, 500’s and 1000’s.

Hydroxyzine Hydrochloride Tablets USP, 25 mg are available as 10/32", Green round biconvex film-coated tablets debossed **“Є”** above **“160”** on one side and plain on the other side, packaged in bottles of 100’s, 500’s and 1000’s.

Hydroxyzine Hydrochloride Tablets USP, 50 mg are available as 11/32", Yellow round biconvex film-coated tablets, debossed **“Є”** above **“161”** on one side and plain on the other side, packaged in bottles of 100’s, 500’s and 1000’s.

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

required.

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

KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.

Manufactured by:

Epic Pharma, LLC

Laurelton, NY 11413

Manufactured in USA

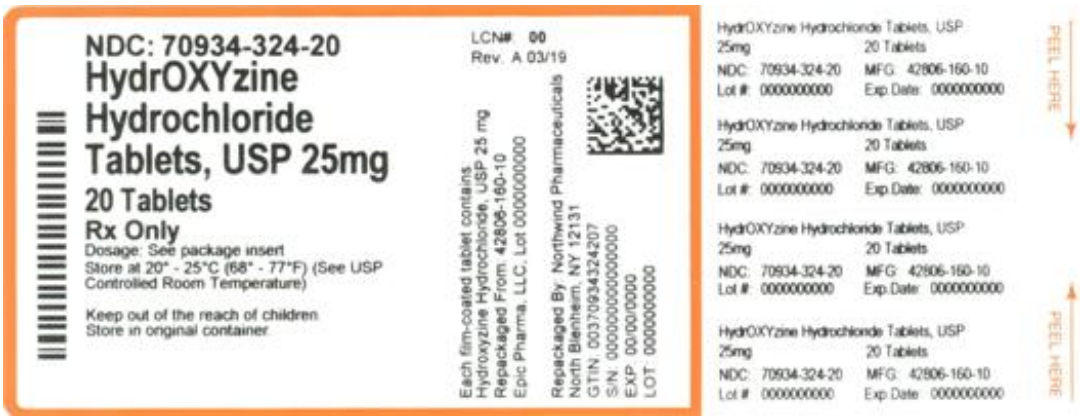
Revised October 2016

MF159REV10/16

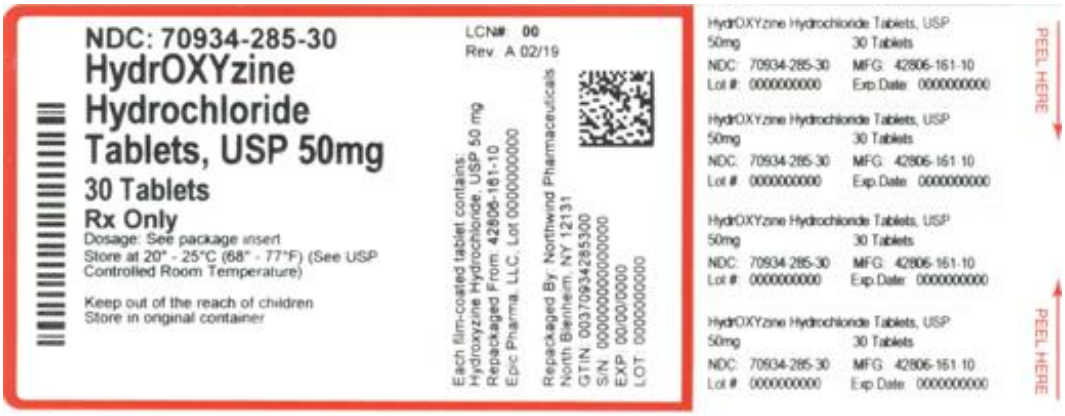
OE1518

Principal Display Panel

NDC: 70934-324-20



NDC: 70934-285-30



HYDROXYZINE HYDROCHLORIDE

hydroxyzine hydrochloride tablet, film coated

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70934-324(NDC:42806-160)
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
HYDROXYZINE HYDROCHLORIDE (UNII: 76755771U3) (HYDROXYZINE - UNII:30S50YM8OG)	HYDROXYZINE HYDROCHLORIDE	25 mg

Inactive Ingredients	
Ingredient Name	**Strength**
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSPOVIDONE (UNII: 2S7830E561)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
POLYVINYL ALCOHOL (UNII: 532B59J990)	
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)	
TALC (UNII: 7SEV7J4R1U)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
TRIACETIN (UNII: XHX3C3X673)	

Product Characteristics			
Color	green	**Score**	no score
Shape	ROUND (biconvex)	**Size**	8mm
Flavor		**Imprint Code**	E160
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:70934-324-20	20 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/21/2019	
2	NDC:70934-324-30	30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/08/2019	
3	NDC:70934-324-60	60 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/12/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA040602	03/21/2019	

HYDROXYZINE HYDROCHLORIDE

hydroxyzine hydrochloride tablet, film coated

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70934-285(NDC:42806-161)
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
HYDROXYZINE HYDROCHLORIDE (UNII: 76755771U3) (HYDROXYZINE - UNII:30S50YM8OG)	HYDROXYZINE HYDROCHLORIDE	50 mg

Inactive Ingredients	
Ingredient Name	**Strength**
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSPOVIDONE (UNII: 2S7830E561)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
POLYVINYL ALCOHOL (UNII: 532B59J990)	
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)	
TALC (UNII: 7SEV7J4R1U)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
TRIACETIN (UNII: XHX3C3X673)	

Product Characteristics			
Color	yellow	**Score**	no score
Shape	ROUND (biconvex)	**Size**	9mm
Flavor		**Imprint Code**	E161
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:70934-285-30	30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/15/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

ANDA	ANDA040604	02/15/2019	

Labeler - Denton Pharma, Inc. DBA Northwind Pharmaceuticals (080355546)

Registrant - Denton Pharma, Inc. DBA Northwind Pharmaceuticals (080355546)

Establishment

Name	Address	ID/FEI	Business Operations
Denton Pharma, Inc. DBA Northwind Pharmaceuticals		080355546	repack(70934-285, 70934-324)

Revised: 3/2020 Denton Pharma, Inc. DBA Northwind Pharmaceuticals