ATARAX- hydroxyzine hydrochloride tablet
ATARAX- hydroxyzine hydrochloride syrup
Roerig

ATARAX®
hydroxyzine hydrochloride
TABLETS AND SYRUP

DESCRIPTION

Hydroxyzine hydrochloride is designated chemically as 1-(p-chlorobenzhydryl) 4-[2-(2-hydroxyethoxy)-ethyl] piperazine dihydrochloride.

Inert ingredients for the tablets are: acacia; carnauba wax; dibasic calcium phosphate; gelatin; lactose; magnesium stearate; precipitated calcium carbonate; shellac; sucrose; talc; white wax. The 10 mg tablets also contain: sodium hydroxide; starch; titanium dioxide; Yellow 6 Lake. The 25 mg tablets also contain: starch; velo dark green. The 50 mg tablets also contain: starch; velo yellow. The 100 mg tablets also contain: alginic acid; Blue 1; polyethylene glycol; Red 3.

The inert ingredients for the syrup are: alcohol; menthol; peppermint oil; sodium benzoate; spearmint oil; sucrose; water.

CLINICAL PHARMACOLOGY

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

Atarax 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 anti- histaminic 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 Atarax'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 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.

For Tablets Only

This product is manufactured with 1,1,1-trichloroethane, a substance which harms public health and the environment by destroying ozone in the upper atmosphere.

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 Atarax. 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 ATARAX 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 ATARAX 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 ATARAX and observed closely.

ADVERSE REACTIONS

Side effects reported with the administration of Atarax (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 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 Atarax 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 Levophed® (levarterenol), or Aramine® (metaraminol). Do not use epinephrine as Atarax counteracts its pressor action.

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, 50–100 mg q.i.d.; children under 6 years, 50 mg daily 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 daily 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.

SUPPLY

Atarax Tablets

10 mg–orange tablets: 100's (NDC 0049-5600-66)

25 mg–green tablets: 100's (NDC 0049-5610-66),
500's (NDC 0049-5610-73)

50 mg–yellow tablets: 100's (NDC 0049-5620-66)

Atarax 100 Tablets

100 mg–red tablets: 100's (NDC 0049-5630-66)

Atarax Syrup

10 mg per teaspoon (5 ml): 1 pint bottles (NDC 0049-5590-93)
Alcohol Content–Ethyl Alcohol–0.5% v/v

BIBLIOGRAPHY

Available on request.

Rx only

Distributed by

Roerig
Division of Pfizer Inc, NY, NY 10017

LAB-0122-2.0
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ATARAX

hydroxyzine hydrochloride tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0049-5600
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
hydroxyzine hydrochloride (UNII: 76755771U3) (hydroxyzine - UNII:30S50YM8OG)		10 mg

Inactive Ingredients	
Ingredient Name	**Strength**
acacia ()	
carnauba wax ()	
dibasic calcium phosphate ()	
gelatin ()	
lactose ()	
magnesium stearate (UNII: 70097M6I30)	
precipitated calcium carbonate ()	
shellac ()	
sucrose (UNII: C151H8M554)	
talc (UNII: 7SEV7J4R1U)	
white wax ()	
sodium hydroxide (UNII: 55X04QC32I)	
starch ()	
titanium dioxide (UNII: 15FIX9V2JP)	
Yellow 6 Lake ()	

Product Characteristics			
Color	ORANGE (ORANGE)	**Score**	no score

Shape	TRIANGLE (TRIANGLE)	**Size**	7mm
Flavor		**Imprint Code**	Atarax;10
Contains			
Coating	false	**Symbol**	false

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0049-5600-66	100 in 1 BOTTLE		

ATARAX

hydroxyzine hydrochloride tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0049-5610
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
hydroxyzine hydrochloride (UNII: 76755771U3) (hydroxyzine - UNII:30S50YM8OG)		25 mg

Inactive Ingredients

Ingredient Name	Strength
acacia ()	
carnauba wax ()	
dibasic calcium phosphate ()	
gelatin ()	
lactose ()	
magnesium stearate (UNII: 70097M6I30)	
precipitated calcium carbonate ()	
shellac ()	
sucrose (UNII: C151H8M554)	
talc (UNII: 7SEV7J4R1U)	
white wax ()	
starch ()	
velo dark green ()	

Product Characteristics

Color	GREEN (GREEN)	**Score**	no score
Shape	TRIANGLE (TRIANGLE)	**Size**	7mm
Flavor		**Imprint Code**	Atarax;25
Contains			
Coating	false	**Symbol**	false

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0049-5610-66	100 in 1 BOTTLE		
2	NDC:0049-5610-73	500 in 1 BOTTLE		

ATARAX

hydroxyzine hydrochloride tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0049-5620
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
hydroxyzine hydrochloride (UNII: 76755771U3) (hydroxyzine - UNII:30S50YM8OG)		50 mg

Inactive Ingredients	
Ingredient Name	Strength
acacia ()	
carnauba wax ()	
dibasic calcium phosphate ()	
gelatin ()	
lactose ()	
magnesium stearate (UNII: 70097M6I30)	
precipitated calcium carbonate ()	
shellac ()	
sucrose (UNII: C151H8M554)	
talc (UNII: 7SEV7J4R1U)	
white wax ()	
starch ()	
velo yellow ()	

Product Characteristics			
Color	YELLOW (YELLOW)	**Score**	no score
Shape	TRIANGLE (TRIANGLE)	**Size**	9mm
Flavor		**Imprint Code**	Atarax;50
Contains			
Coating	false	**Symbol**	false

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0049-5620-66	100 in 1 BOTTLE		

ATARAX

hydroxyzine hydrochloride tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0049-5630
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
hydroxyzine hydrochloride (UNII: 76755771U3) (hydroxyzine - UNII:30S50YM8OG)		100 mg

Inactive Ingredients	
Ingredient Name	Strength
acacia ()	
carnauba wax ()	
dibasic calcium phosphate ()	
gelatin ()	
lactose ()	
magnesium stearate (UNII: 70097M6I30)	
precipitated calcium carbonate ()	
shellac ()	
sucrose (UNII: C151H8M554)	
talc (UNII: 7SEV7J4R1U)	
white wax ()	
alginic acid ()	
Blue 1 ()	
polyethylene glycol ()	
Red 3 ()	

Product Characteristics			
Color	RED (RED)	Score	no score
Shape	TRIANGLE (TRIANGLE)	Size	12mm
Flavor		Imprint Code	Atarax;100
Contains			
Coating	false	Symbol	false

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0049-5630-66	100 in 1 BOTTLE		

ATARAX

hydroxyzine hydrochloride syrup

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0049-5590
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
hydroxyzine hydrochloride (UNII: 76755771U3) (hydroxyzine - UNII:30S50YM8OG)		10 mg in 5 mL

Inactive Ingredients	
Ingredient Name	**Strength**
alcohol (UNII: 3K9958V90M)	
menthol (UNII: 80R52064AQ)	
peppermint oil ()	
sodium benzoate (UNII: OJ245FE5EU)	
spearmint oil ()	
sucrose (UNII: C151H8M554)	
water (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0049-5590-93	473 mL in 1 BOTTLE		

Labeler - Roerig

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