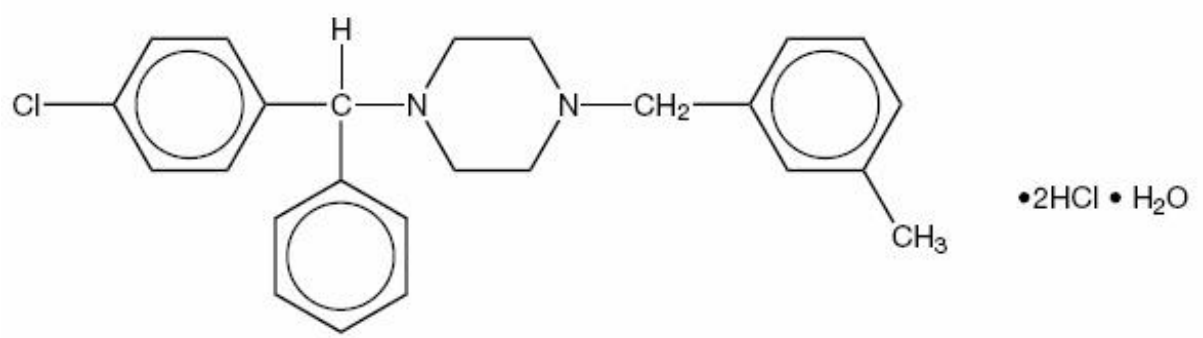
MECLIZINE HYDROCHLORIDE- meclizine hydrochloride tablet
Watson Laboratories, Inc.

70010599
Meclizine HCl
Tablets USP
Rx only

DESCRIPTION

Meclizine HCl, an oral antiemetic, is a white, slightly yellowish, crystalline powder which has a slight odor and is tasteless. It has the following structural formula:



$C_{25}H_{27}ClN_2.2HCl.H_2O$ 481.89

The chemical name is 1-(*p*-chloro-α-phenylbenzyl)-4-(*m*-methylbenzyl) piperazine dihydrochloride monohydrate.

Each tablet, for oral administration, contains 12.5 mg or 25 mg of Meclizine HCl. In addition, each tablet contains the following inactive ingredients: colloidal silicon dioxide, corn starch, D&C yellow # 10 lake (25 mg only), FD&C blue # 1 lake (12.5 mg only), lactose monohydrate, microcrystalline cellulose, povidone (12.5 mg only), sodium starch glycolate, and stearic acid.

ACTIONS

Meclizine HCl is an antihistamine which shows marked protective activity against nebulized histamine and lethal doses of intravenously injected histamine in guinea pigs. It has a marked effect in blocking the vasodepressor response to histamine, but only a slight blocking action against acetylcholine. Its activity is relatively weak in inhibiting the spasmogenic action of histamine on isolated guinea pig ileum. It has a slower onset and longer duration of action (24 hours) than most other antihistamines used for motion sickness.

Antihistamines have been observed to have both stimulant and depressant effects on the CNS, but no clear explanation exists in regard to their diverse central actions. The site and mode of their central action is unknown.

INDICATIONS:

Prophylactic treatment and management of nausea and vomiting, and dizziness associated with motion sickness.

CONTRAINDICATIONS

Meclizine HCl is contraindicated in individuals who have shown a previous hypersensitivity to it.

WARNINGS

Some drowsiness may, on occasion, occur with the use of this drug, patients should be warned of this possibility and cautioned against driving a car or operating dangerous machinery.

Patients should avoid alcoholic beverages while taking this drug. Due to its potential anticholinergic action, this drug should be used with caution in patients with asthma, glaucoma, or enlargement of the prostate gland.

USAGE IN PEDIATRIC PATIENTS

Clinical studies establishing safety and effectiveness in pediatric patients have not been done; therefore, usage is not recommended in pediatric patients under 12 years of age.

USAGE IN PREGNANCY

Pregnancy Category B. Reproduction studies in rats have shown cleft palates at 25-50 times the human dose. Epidemiological studies in pregnant women, however, do not indicate that meclizine increases the risk of abnormalities when administered during pregnancy. Despite the animal findings, it would appear that the possibility of fetal harm is remote. Nevertheless, meclizine, or any other medication, should be used during pregnancy only if clearly necessary.

ADVERSE REACTIONS

Drowsiness, dry mouth, and on rare occasions, blurred vision have been reported.

DOSAGE AND ADMINISTRATION

Motion Sickness: The initial dose of 25 to 50 mg of meclizine, should be taken prior to travel for protection against motion sickness. Thereafter, the dose may be repeated every 24 hours for the duration of the journey.

HOW SUPPLIED

Meclizine HCl Tablets USP are supplied as follows:

12.5 mg: Blue/white, oval, bi-layer tablet debossed **WATSON** and **802** on one side and a partial bisect on the other side, in bottles of 100.

25 mg: Yellow/white, oval, bi-layer tablet debossed **WATSON** and **803** on one side and a partial bisect on the other side, in bottles of 100 and 1000.

Store at controlled room temperature 15°-30°C (59°- 86°F). Dispense in a well-closed container as defined in USP/NF.

Manufactured For:
Watson Laboratories, Inc.
Corona, CA 92880 USA

Manufactured by:
Patheon Pharmaceuticals Inc.
Cincinnati, OH 45215 USA

Rev. 10/03
70010599

MECLIZINE HYDROCHLORIDE

meclizine hydrochloride tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0591-0803
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Meclizine Hydrochloride (UNII: HDP7W44CIO) (Meclizine - UNII:3L5TQ84570)		25 mg

Inactive Ingredients	
Ingredient Name	**Strength**
collidiol silicon dioxide ()	
corn starch ()	
D & C Yellow #10 lake ()	
lactose monohydrate ()	
microcrystalline cellulose ()	
sodium starch glycolate ()	
stearic acid (UNII: 4ELV7Z65AP)	

Product Characteristics			
Color	WHITE (white) , YELLOW (yellow)	**Score**	no score
Shape	OVAL	**Size**	13mm
Flavor		**Imprint Code**	WATSON;803
Contains			
Coating	false	**Symbol**	false

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0591-0803-01	100 in 1 BOTTLE		
2	NDC:0591-0803-10	1000 in 1 BOTTLE		

MECLIZINE HYDROCHLORIDE

meclizine hydrochloride tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0591-0802

Route of Administration	ORAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Meclizine Hydrochloride (UNII: HDP7W44CIO) (Meclizine - UNII:3L5TQ84570)		12.5 mg

Inactive Ingredients	
Ingredient Name	**Strength**
collidiol silicon dioxide ()	
corn starch ()	
FD & C Blue #1 lake ()	
lactose monohydrate ()	
microcrystalline cellulose ()	
povidone ()	
sodium starch glycolate ()	
stearic acid (UNII: 4ELV7Z65AP)	

Product Characteristics			
Color	BLUE (Blue) , WHITE (white)	**Score**	no score
Shape	OVAL	**Size**	13mm
Flavor		**Imprint Code**	WATSON;802
Contains			
Coating	false	**Symbol**	false

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0591-0802-01	100 in 1 BOTTLE		

Labeler - Watson Laboratories, Inc.

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