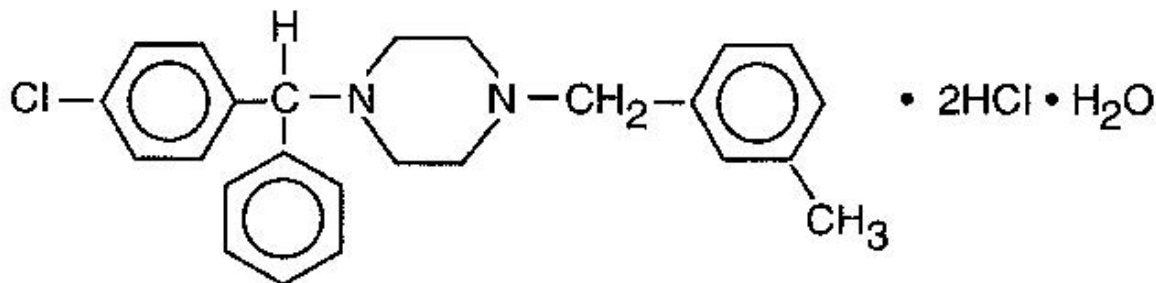


**MECLIZINE HYDROCHLORIDE- meclizine hydrochloride tablet**  
**Par Pharmaceutical, Inc.**

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**Rx Only**

**DESCRIPTION**

Meclizine hydrochloride, 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<sub>25</sub>H<sub>27</sub>ClN<sub>2</sub>•2HCl•H<sub>2</sub>O  
M.W. 481.89

The chemical name is 1-(*p*-chloro- $\alpha$ -phenylbenzyl)-4-(*m*-methyl-benzyl) - piperazine dihydrochloride monohydrate.

Meclizine Hydrochloride Tablets are available in 12.5 mg, and \*25 mg strengths for oral administration.

\*Contains FD&C Yellow #5 (see **PRECAUTIONS**).

Each tablet contains the following inactive ingredients: colloidal silicon dioxide, lactose, magnesium stearate, microcrystalline cellulose, sodium starch glycolate, starch, and stearic acid. In addition, the 12.5 mg tablet contains FD&C Blue #1; and the 25 mg tablet contains D&C Yellow #10 and FD&C Yellow #5.

**CLINICAL PHARMACOLOGY**

Meclizine hydrochloride 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.

***Pharmacokinetics***

The available pharmacokinetic information for meclizine following oral administration has been summarized from published literature.

**Absorption**

Meclizine is absorbed after oral administration with maximum plasma concentrations reaching at a median T<sub>max</sub> value of 3 hours post-dose (range: 1.5 to 6 hours) for the tablet dosage form.

**Distribution**

Drug distribution characteristics for meclizine in humans is unknown.

**Metabolism**

The metabolic fate of meclizine in humans is unknown. In an *in vitro* metabolic study using human hepatic microsome and recombinant CYP enzyme, CYP2D6 was found to be the dominant enzyme for

metabolism of meclizine.

The genetic polymorphism of CYP2D6 that results in extensive-, poor-, intermediate- and ultrarapid metabolizer phenotypes could contribute to large inter-individual variability in meclizine exposure.

### **Elimination**

Meclizine has a plasma elimination half-life of about 5 to 6 hours in humans.

## **INDICATIONS AND USAGE**

### **INDICATIONS**

Based on a review of this drug by the National Academy of Sciences – National Research Council and/or other information, FDA has classified the indications as follows:

Effective: Management of nausea and vomiting, and dizziness associated with motion sickness.

Possibly Effective: Management of vertigo associated with diseases affecting the vestibular system.

Final classification of the less than effective indications required further investigation.

### **CONTRAINDICATIONS**

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

### **WARNINGS**

Since drowsiness may, on occasion, occur with 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 the 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 Children***

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

#### ***Usage in Pregnancy***

Pregnancy Category B. Reproduction studies in rats have shown cleft palates at 25 to 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.

### **PRECAUTIONS**

The Meclizine Hydrochloride Tablets, 25 mg contain FD&C Yellow #5 (tartrazine) which may cause allergic-type reactions (including bronchial asthma) in certain susceptible individuals. Although the overall incidence of FD&C Yellow #5 (tartrazine) sensitivity in the general population is low, it is frequently seen in patients who also have aspirin hypersensitivity.

#### ***Nursing Mothers***

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when meclizine is administered to a nursing woman.

#### ***Hepatic Impairment***

The effect of hepatic impairment on the pharmacokinetic of meclizine has not been evaluated. As meclizine undergoes metabolism, hepatic impairment may result in increased systemic exposure of the drug. Treatment with meclizine should be administered with caution in patients with hepatic impairment.

#### ***Renal Impairment***

The effect of renal impairment on the pharmacokinetics of meclizine has not been evaluated. Due to a potential for drug/metabolite accumulation, meclizine should be administered with caution in patients with renal impairment and in the elderly as renal function generally declines with age.

### ***Drug Interactions***

There may be increased CNS depression when meclizine is administered concurrently with other CNS depressants, including alcohol, tranquilizers, and sedatives. (see **WARNINGS**).

Based on *in-vitro* evaluation, meclizine is metabolized by CYP2D6. Therefore there is a possibility for a drug interaction between meclizine and CYP2D6 inhibitors.

### **ADVERSE REACTIONS**

Anaphylactoid reaction, drowsiness, dry mouth, headache, fatigue, vomiting and, on rare occasions, blurred vision have been reported.

### **DOSAGE AND ADMINISTRATION**

#### ***Vertigo***

For the control of vertigo associated with diseases affecting the vestibular system, the recommended dose is 25 to 100mg daily, in divided dosage, depending upon clinical response.

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

### **HOW SUPPLIED**

Meclizine Hydrochloride Tablets, USP 12.5 mg - blue, oval tablets debossed with "034" on one side and "par" on the other side. Tablets may contain characteristic dye spots. They are supplied in bottles of 100 (NDC 49884-034-01) and 1000 (NDC 49884-034-10).

Meclizine Hydrochloride Tablets, USP 25 mg - yellow, oval tablets debossed with "035" on one side and "par" on the other side. They are supplied in bottles of 100 (NDC 49884-035-01) and 1000 (NDC 49884-035-10).

Dispense in tight, light-resistant containers as defined in the USP.

Store at controlled room temperature 15° to 30°C (59° to 86°F).

Manufactured by:

**PAR PHARMACEUTICAL COMPANIES, INC.**

Chestnut Ridge, NY 10977

Revised:

07/15

01-1-15

OS034-

**PRINCIPAL DISPLAY PANEL: 12.5 MG CONTAINER LABEL 100 TABLETS**

NDC 49884-034-01

**Meclizine Hydrochloride Tablets, USP**

**12.5 mg**

Rx only  
100 Tablets



**Each tablet contains:**  
Meclizine HCl, USP..... 12.5 mg

**USUAL DOSAGE:**  
Read Accompanying Literature.

**KEEP THIS AND ALL DRUGS OUT OF REACH OF CHILDREN.**

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

**Store at controlled room temperature 15° to 30°C (59° to 86°F).**

R07/15 LA034-01-1-15

Manufactured by:  
Par Pharmaceutical Companies, Inc.  
Chestnut Ridge, NY 10977



N 3 49884-034-01 6

**PRINCIPAL DISPLAY PANEL: 25 MG CONTAINER LABEL 100 TABLETS**

NDC 49884-035-01

**Meclizine Hydrochloride Tablets, USP**

**25 mg**

Rx only  
100 Tablets



**Each tablet contains:**  
Meclizine HCl, USP..... 25 mg

**USUAL DOSAGE:**  
Read Accompanying Literature.

**CAUTION:** This product contains FD&C Yellow No. 5 (tartrazine) which may cause allergic type reactions in certain susceptible individuals.

**KEEP THIS AND ALL DRUGS OUT OF REACH OF CHILDREN.**

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

**Store at controlled room temperature 15° to 30°C (59° to 86°F).**

R07/15 LA035-01-1-15

Manufactured by:  
Par Pharmaceutical Companies, Inc.  
Chestnut Ridge, NY 10977



N 3 49884-035-01 3


**PRINCIPAL DISPLAY PANEL: 12.5 MG CONTAINER LABEL 1000 TABLETS**

NDC 49884-034-10

**Meclizine Hydrochloride Tablets, USP**

**12.5 mg**

Rx only  
1000 Tablets



**Each tablet contains:**  
Meclizine HCl, USP..... 12.5 mg

**USUAL DOSAGE:**  
Read Accompanying Literature.


**KEEP THIS AND ALL DRUGS OUT OF REACH OF CHILDREN.**

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

**Store at controlled room temperature 15° to 30°C (59° to 86°F).**

R07/15 LA034-10-1-12

Manufactured by:  
Par Pharmaceutical Companies, Inc.  
Chestnut Ridge, NY 10977



N 3 49884-034-10 8

**PRINCIPAL DISPLAY PANEL: 25 MG CONTAINER LABEL 1000 COUNT**

NDC 49884-035-10

# Meclizine Hydrochloride Tablets, USP

## 25 mg

Rx only  
1000 Tablets



**Each tablet contains:**  
Meclizine HCl, USP ..... 25 mg

**USUAL DOSAGE:**  
Read Accompanying Literature.

**CAUTION:** This product contains FD&C Yellow No. 5 (tartrazine) which may cause allergic type reactions in certain susceptible individuals.

**KEEP THIS AND ALL DRUGS OUT OF REACH OF CHILDREN.**

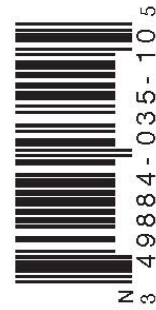
Dispense in a tight, light-resistant container as defined in the USP.

**Store at controlled room temperature 15° to 30°C (59° to 86°F).**

LA035-10-1-14

R07/15

Manufactured by:  
Par Pharmaceutical Companies, Inc.  
Chestnut Ridge, NY 10977



## MECLIZINE HYDROCHLORIDE

meclizine hydrochloride tablet

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:49884-035
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MECLIZINE HYDROCHLORIDE (UNII: HDP7W44CIO) (MECLIZINE - UNII:3L5TQ84570)	MECLIZINE HYDROCHLORIDE	25 mg

### Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
WATER (UNII: 059QF0K00R)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

### Product Characteristics

<b>Color</b>	YELLOW	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	6mm
<b>Flavor</b>		<b>Imprint Code</b>	Par;035
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:49884-035-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	06/03/1981	
2	NDC:49884-035-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	06/03/1981	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA087128	06/03/1981	

MECLIZINE HYDROCHLORIDE				
meclizine hydrochloride tablet				
Product Information				
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:49884-034	
Route of Administration	ORAL			
Active Ingredient/Active Moiety				
	Ingredient Name	Basis of Strength	Strength	
	MECLIZINE HYDROCHLORIDE (UNII: HDP7W44CIO) (MECLIZINE - UNII:3L5TQ84570)	MECLIZINE HYDROCHLORIDE	12.5 mg	
Inactive Ingredients				
	Ingredient Name	Strength		
	ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)			
	CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)			
	SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)			
	FD&C BLUE NO. 1 (UNII: H3R47K3TBD)			
	WATER (UNII: 059QF0KO0R)			
	ISOPROPYL ALCOHOL (UNII: ND2M416302)			
	STARCH, CORN (UNII: O8232NY3SJ)			
	STEARIC ACID (UNII: 4ELV7Z65AP)			
	MAGNESIUM STEARATE (UNII: 70097M6I30)			
	SILICON DIOXIDE (UNII: ETJ7Z6XBU4)			
Product Characteristics				
Color	BLUE	Score	no score	
Shape	OVAL	Size	5mm	
Flavor		Imprint Code	Par;034	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49884-034-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	06/03/1981	
2	NDC:49884-034-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	06/03/1981	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA087127	06/03/1981		

**Labeler** - Par Pharmaceutical, Inc. (092733690)

**Establishment**

Name	Address	ID/FEI	Business Operations
Par Pharmaceutical Inc.		092733690	ANALYSIS(49884-035, 49884-034) , MANUFACTURE(49884-035, 49884-034)

Revised: 8/2017

Par Pharmaceutical, Inc.