

MECLIZINE HCL- meclizine hcl tablet
Aidarex Pharmaceuticals LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Meclizine HCl Caplets USP

Active Ingredient

(in each caplet)

Meclizine HCl 12.5 mg USP

Purpose

Antiemetic

Uses

prevents and treats nausea, vomiting, or dizziness due to motion sickness

WARNINGS

Ask a doctor before use if you have

- glaucoma
- a breathing problem such as emphysema or chronic bronchitis
- trouble urinating due to an enlarged prostate gland

Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers

When using this product

- you may get drowsy
- avoid alcoholic drinks
- alcohol, sedatives & tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating a machinery

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- **adults and children 12 years and over:** 2-4 caplets once daily
- **children under 12 years:** ask a doctor

Other Information

- each caplet contains: calcium 51 mg
- store at room temperature 15°-30°C (59°-86°F)

Inactive Ingredients

croscarmellose sodium, dicalcium phosphate, magnesium stearate, microcrystalline cellulose, silicon

dioxide, stearic acid

Questions or Comments

Call 1-800-645-2158, 9 am – 5 pm ET, Monday - Friday

TAMPER EVIDENT: DO NOT USE IF CARTON IS OPENED OR BLISTER UNIT IS BROKEN OR DAMAGED

Rugby® Duluth, Georgia 30097

Repackaged By :
Aidarex Pharmaceuticals LLC,
Corona, CA 92880

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 33261-0748-30

Meclizine HCl 12.5 mg Caplets USP
Antiemetic

30 caplets

CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION. SEE PACKAGE INSERT, KEEP OUT OF REACH OF CHILDREN. STORE AT CONTROLLED ROOM TEMP. 15-30°C (59-86°F)

Packaged and Distributed by: **AIDAREX PHARMACEUTICALS LLC.**

MECLIZINE

12.5mg

30 TABS

EACH TABLET CONTAINS THE FOLLOWING ACTIVE INGREDIENTS:
MECLIZINE..... 12.5 mg
HYDROCHLORIDE

WHITE OBLONG TABLET W/ LOGOP 117 ON ONE SIDE & SCORE ON REVERSE

GENERIC FOR: BONINE
NDC: 33261-0748-30

TAKE _____ EVERY _____ HOURS _____ TIMES A DAY
TOME _____ CADA _____ HORAS _____ VECES AL DIA

MFG: FOR: RUGBY LABORATORIES, INC. DULUTH, GEORGIA, 30097

RX QLS0000

MECLIZINE 12.5mg
NDC: 33261-0748-30
RX QLS0000 30

MECLIZINE 12.5mg
NDC: 33261-0748-30
RX QLS0000 30

MECLIZINE 12.5mg
NDC: 33261-0748-30
RX QLS0000 30

PEEL HERE
PATIENT LOG CHART
BILL PEEL HERE

MECLIZINE HCL

meclizine hcl tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:33261-748(NDC:0536-3985)
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
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: L11K75P92J)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Product Characteristics

Color	WHITE	Score	2 pieces
Shape	CAPSULE	Size	13mm
Flavor		Imprint Code	AP;117
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:33261-748-30	30 in 1 BOTTLE, PLASTIC		
2	NDC:33261-748-60	60 in 1 BOTTLE, PLASTIC		
3	NDC:33261-748-90	90 in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part336	07/14/2006	

Labeler - Aidarex Pharmaceuticals LLC (801503249)

Revised: 1/2014

Aidarex Pharmaceuticals LLC