

DIMENHYDRINATE - dimenhydrinate tablet, film coated

Time Cap Labs, Inc

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.

EACH TABLET CONTAINS DIMENHYDRINATE 50 MG

COLLOIDAL SILICON DIOXIDE, CROSCARMELLOSE SODIUM, HYPROMELLOSE,
ANHYDROUS LACTOSE, MAGNESIUM STEARATE, CELLULOSE, MICROCRYSTALLINE,
MINEROL

Antiemetic

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

Directions:

To prevent motion sickness, the first dose should be taken one-half to one hour before starting activity.

Adults and children 12 years of age and over - 1 to 2 tablets every 4 to 6 hours, not to exceed 8 tablets in 24 hours, or as directed by a doctor

Children 6 to under 12 years of age 1/2 to 1 tablet every 6 to 8 hours, not to exceed 3 tablets in 24 hours, or as directed by a doctor

Children 2 to under 6 years of age - 1/4 to 1/2 tablet every 6 to 8 hours, not to exceed 1 1/2 tablets in 24 hours, or as directed by a doctor

Warnings

Do not use for children under 2 years of age unless directed by a doctor

Use

for prevention and treatment of these symptoms associated with motion sickness:

nausea vomiting dizziness

Ask a doctor before use if you have glaucoma; a breathing problem such as emphysema or chronic bronchitis; difficulty in urination due to an enlargement of the prostate gland.

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

When using this product: do not exceed recommended dosage; marked drowsiness may occur; avoid alcoholic drinks; alcohol, sedatives, and tranquilizers may increase drowsiness. Be careful when driving a motor vehicle or operating machinery.

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

Drug Facts
 Active ingredient (in each tablet) Dimenhydrinate 50 mg
 Purpose Antiemetic
 Uses for the prevention and treatment of these symptoms associated with motion sickness, nausea, vomiting, dizziness
 Drug Facts (continued)

Time-Cap Labs, Inc. NDC 49483-352-36
 *Compare to the active ingredient in Dramamine®

Travel-Time

Dimenhydrinate Tablets/Antiemetic

Fast Acting Relief of Motion Sickness for Children and Adults

36 TABLETS (50 mg EACH)

This product is not manufactured or distributed by McNeil Consumer Healthcare, owner of the registered trademark Dramamine® Tablets.
 Manufactured by: Time-Cap Labs, Inc. 7 Michael Avenue Farmingdale, NY 11735
 LOT #: EXP. DATE:

TAMPER EVIDENT: EACH TABLET IS SAFELY SEALED. DO NOT USE IF BLISTER OR FOIL IS BROKEN OR MISSING
 49483-352-36

Drug Facts (continued)
 Other information SODIUM FREE
 store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
 use by expiration date on package
 Inactive ingredients colloidal silicon dioxide, croscarmellose sodium, hypromellose, lactose anhydrous, magnesium stearate, microcrystalline cellulose, mineral oil
 Drug Facts (continued)

Drug Facts (continued)
 Warnings Do not use for children under 2 years of age unless directed by a doctor
 Ask a doctor before use if you have a breathing problem such as emphysema or chronic bronchitis, difficulty in urination due to an enlargement of the prostate gland
 Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers
 When using this product Do not exceed recommended dosage, marked drowsiness may occur, alcohol, sedatives, and tranquilizers may increase drowsiness
 If pregnant or breast-feeding, ask a health professional before use.
 Directions To prevent motion sickness, the first dose should be taken one-half to one hour before starting activity
 adults and children 12 years of age and over 1 to 2 tablets every 4 to 6 hours, not to exceed 8 tablets in 24 hours, or as directed by a doctor
 children 6 to under 12 years of age 1/2 to 1 tablet every 6 to 8 hours, not to exceed 3 tablets in 24 hours, or as directed by a doctor
 children 2 to under 6 years of age 1/2 tablet every 6 to 8 hours, not to exceed 1 1/2 tablets in 24 hours, or as directed by a doctor
 Drug Facts (continued)
 Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

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DIMENHYDRINATE
 dimenhydrinate tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49483-352
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIMENHYDRINATE (UNII: JB937PER5C) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIMENHYDRINATE	50 mg

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
MINERAL OIL (UNII: T5L8T28FGP)	

Product Characteristics

Color	white	Score	2 pieces
Shape	ROUND	Size	8mm
Flavor		Imprint Code	TCL;352
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49483-352-36	36 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC mono graph final	part336	01/28/2011	

Labeler - Time Cap Labs, Inc (037052099)**Establishment**

Name	Address	ID/FEI	Business Operations
Time Cap Labs, Inc.		037052099	manufacture(49483-352)