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, AHNYDROUS 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

irections:

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:

nauseavomitingdizziness

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.

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)	
CROSCARMELLOSE 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 monograph 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)