# DRIMINATE- dimenhydrinate tablet Avera McKennan Hospital

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.

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# Active ingredient (in each tablet)

Dimenhydrinate 50 mg

## **Purpose**

Antiemetic

#### Uses

for the prevention and treatment of nausea, vomiting, or dizziness associated with motion sickness

# **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
- glaucoma
- 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

- marked drowsiness may occur
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- use caution when driving a motor vehicle or operating 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 (1-800-222-1222) 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 4-6 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 6-8 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 6-8 hours; not to exceed 1 1/2 tablets in 24 hours, or as directed by a doctor

# Other information

- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- protect from moisture
- see end flap for expiration date and lot number

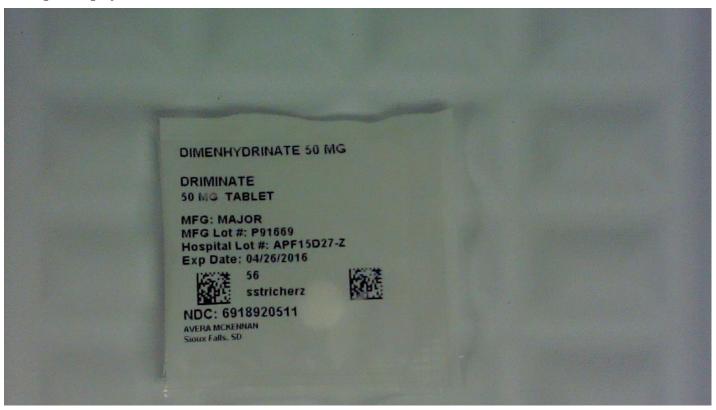
# **Inactive ingredients**

croscarmellose sodium, dicalcium phosphate, magnesium stearate, microcrystalline cellulose, silica gel, stearic acid

#### Questions or comments?

(800) 616-2471

# **Principal Display Panel**



# DRIMINATE dimenhydrinate tablet Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:69189-2051(NDC:0904-2051) 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
CROSCARMELLOSE SODIUM (UNII: M28 OL1HH48)	
CALCIUM PHO SPHATE, DIBASIC, ANHYDRO US (UNII: L11K75P92J)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULO SE, MICRO CRYSTALLINE (UNII: OP1R32D61U)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics				
Color	WHITE	Score	2 pieces	
Shape	ROUND	Size	11mm	
Flavor		Imprint Code	44;198	
Contains				

	Packaging			
:	# Item Code Package Description		<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1 NDC:69189-2051-1 1 in 1 DOSE PACK; Type 0: Not a Combination Product				

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC MONOGRAPH FINAL	part336	04/27/2015		

# Labeler - Avera McKennan Hospital (068647668)

Establishment			
Name	Address	ID/FEI	Business Operations
Avera McKennan Hospital		068647668	relabel(69189-2051), repack(69189-2051)

Revised: 1/2016 Avera McKennan Hospital