

**MOTION SICKNESS RELIEF- dimenhydrinate tablet**  
**Cardinal Health**

*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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**Leader 44-198**

***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**

- glaucoma
- a breathing problem such as emphysema or chronic bronchitis
- difficulty in urination due to enlargement of the prostate gland

**Ask a doctor or pharmacist before use if you are**

taking sedatives or tranquilizers.

**When using this product**

- avoid alcoholic beverages
- marked drowsiness may occur
- 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 and over	1 to 2 tablets every 4-6 hours; do not exceed 8 tablets in 24 hours, or as directed by a doctor
children 6 to under 12 years	1/2 to 1 tablet every 6-8 hours; do not exceed 3 tablets in 24 hours, or as directed by a doctor
children 2 to under 6 years	1/2 tablet every 6-8 hours; do not exceed 1 1/2 tablets in 24 hours, or as directed by a doctor

***Other information***

- **TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN**
- 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?***

**1-800-426-9391**

**Principal Display Panel**

NDC 70000-0250-1

**Motion Sickness Relief**

Dimenhydrinate, 50 mg | Antiemetic

Fast acting

Relief of Motion Sickness

for Children & Adults

**12 TABLETS**

**TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING**

All LEADER™ Brand Products Have A

**100% Money Back Guarantee**

Return to place of purchase if not satisfied.

\*This product is not manufactured or distributed by Medtech Products Inc., owner of the registered trademark Dramamine®.

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DUBLIN, OHIO 43017

www.myleader.com 1-800-200-6313

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Leader 44-198

## MOTION SICKNESS RELIEF

dimenhydrinate tablet

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70000-0250
<b>Route of Administration</b>	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
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	

**Product Characteristics**

Color	WHITE	Score	2 pieces
Shape	ROUND	Size	9mm
Flavor		Imprint Code	44;198
Contains			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0250-1	2 in 1 CARTON	12/01/1992	
1		6 in 1 BLISTER 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	12/01/1992	

**Labeler** - Cardinal Health (097537435)**Establishment**

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(70000-0250)

**Establishment**

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	MANUFACTURE(70000-0250)

**Establishment**

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	PACK(70000-0250)

## Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	PACK(70000-0250)

## Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	PACK(70000-0250)

Revised: 2/2020

Cardinal Health