

MOTION SICKNESS RELIEF- dimenhydrinate tablet
Topco Associates, 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.

TopCare 44-198

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

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 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
- alcohol, sedatives, and tranquilizers may increase drowsiness
- use caution when driving a motor vehicle or operating machinery
- avoid alcoholic beverages

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	½ 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	½ tablet every 6-8 hours; do not exceed 1½ tablets in 24 hours, or as directed by a doctor

Other information

- **each tablet contains:** calcium 35 mg
- **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, dibasic calcium phosphate dihydrate, magnesium stearate, microcrystalline cellulose, silicon dioxide, stearic acid

Questions or comments?

1-888-423-0139

Principal display panel

**TopCare®
health™**

NDC 36800-930-12

**COMPARE TO DRAMAMINE® ORIGINAL
FORMULA ACTIVE INGREDIENT***

ORIGINAL FORMULA

Motion Sickness Relief

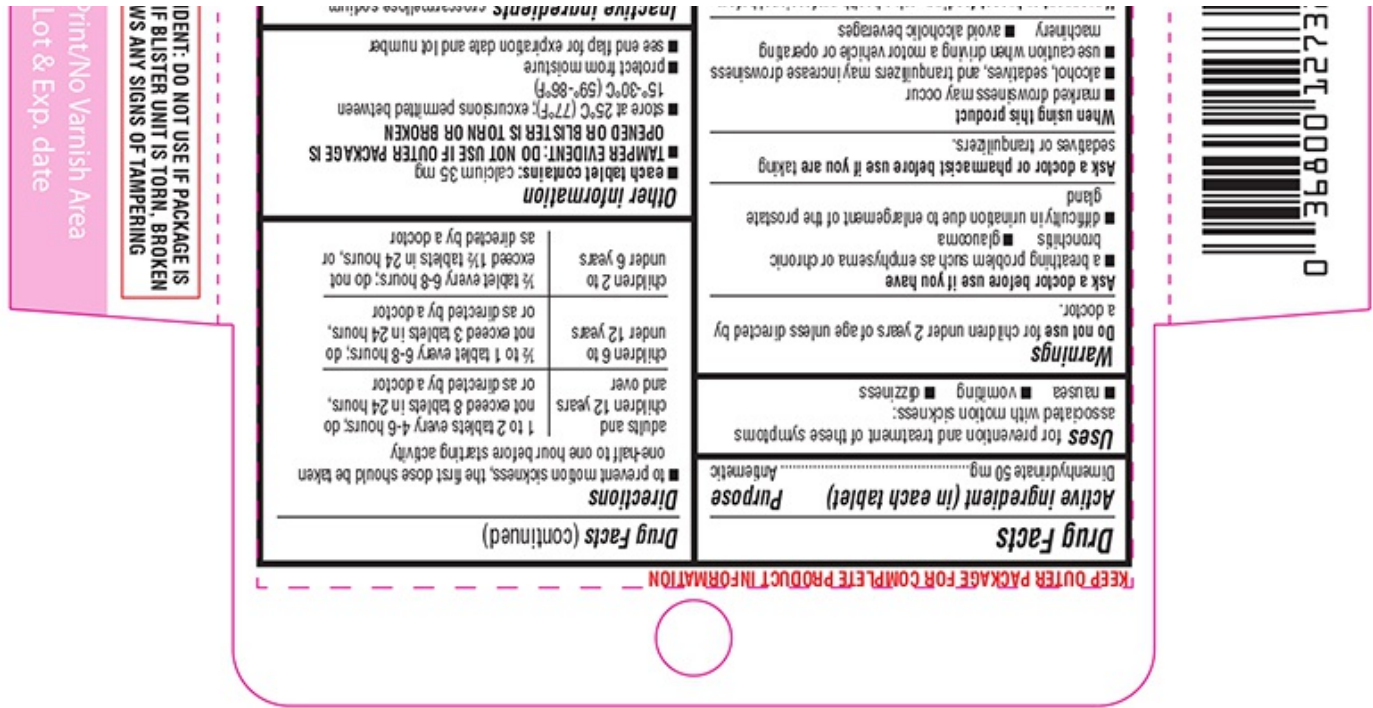
DIMENHYDRINATE, 50 mg - ANTIEMETIC

Prevents Nausea, Dizziness & Vomiting

12 TABLETS

For Children & Adults

actual size



Topcare 44-198

MOTION SICKNESS RELIEF

dimenhydrinate tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-930
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIMENHYDRINATE (UNII: JB937PER5C) (DIPHENHYDRAMINE - UNII:8GTS82S83M, CHLORTHEOPHYLLINE - UNII:GE2UA340 FM)	DIMENHYDRINATE	50 mg

Inactive Ingredients

Ingredient Name	Strength
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	

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:36800-930-12	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 - Topco Associates, LLC (006935977)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	MANUFACTURE(36800-930)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	PACK(36800-930)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(36800-930)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	PACK(36800-930)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	PACK(36800-930)