MOTION SICKNESS- dimenhydrinate tablet
Strategic Sourcing Services, LLC (Sunmark)

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.

SunMark 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

- 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	

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 table 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 25ºC (77ºF); excursions permitted between 15º-30ºC (59º-86ºF)
- 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

sunmark®

*COMPARE TO DRAMAMINE®
ORIGINAL FORMULA ACTIVE INGREDIENT
NDC 70677-0022-1

motion sickness
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

*This product is not manufactured or distributed by Prestige Brands, Inc., owner of the registered trademark Dramamine® Original Formula.

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motion sickness
DIMENHYDRINATE 50 mg
Antiemetic
12 TABLETS
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Fast acting relief of motion sickness for children & adults
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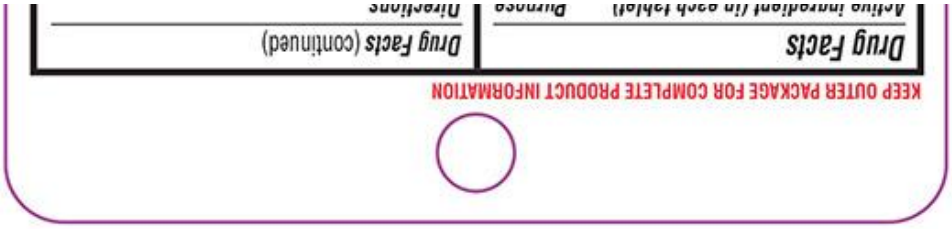
Warnings
Do not use for children under 2 years of age unless directed by a doctor.
Ask a doctor before use if you have
■ a breathing problem such as emphysema or chronic bronchitis ■ glaucoma
■ difficulty in urination due to enlargement of the prostate gland
Ask a doctor or pharmacist before use if you 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.
Uses for the prevention and treatment of nausea, vomiting, or dizziness associated with motion sickness
Active ingredient (in each tablet) Purpose
Dimenhydrinate 50 mg Antiemetic
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
■ 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
TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING
No Print/No Varnish Area
Lot & Exp. date
0 10939 84944 1



Sunmark 44-198

MOTION SICKNESS

dimenhydrinate tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:70677-0022
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: M28OL1HH48)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

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:70677-0022-1	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 - Strategic Sourcing Services, LLC (Sunmark) (116956644)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(70677-0022)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	MANUFACTURE(70677-0022)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	PACK(70677-0022)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	PACK(70677-0022)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	PACK(70677-0022)