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	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	$\frac{1}{2}$ tablet every 6-8 hours; do not exceed $\frac{1}{2}$ 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

*This product is not manufactured or distributed by Medtech Product Inc., owner of the registered trademark Dramamine® Original Formula. 50844 REV0518A19802

DISTRIBUTED BY TOPCO ASSOCIATES LLC, ELK GROVE VILLAGE, IL 60007 ©TOPCO LNKA1018 QUESTIONS? 1-888-423-0139 topcare@topco.com www.topcarebrand.com

This TopCare® product is laboratory tested to guarantee its highest quality. Your total satisfaction is guaranteed

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



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IDENT: DO NOT USE IF PACKAGE IS IF BLISTER UNIT IS TORN, BROKEN WS ANY SIGNS OF TAMPERING Print/No Varnish Area Lot & Exp. date		 Protect from mo Store at 25°C (79%) 	When using this product Tranked drowsiness may occur alcohol, sedatives, and tranquilizers may increase drowsiness alcohol, sedatives, and tranquilizers may increase drowsiness use caution when driving a motor vehicle or operating machinery a social alcoholic beverages machinery a social alcoholic beverages	122
USE IF I IT IS TOP OF TAM	Mains: calcium 35 mg NT: DO NOT USE IF OUTER PACKAGE IS	■ TAMPER EVIDE	Ask a doctor or pharmacist before use if you are taking sedatives or tranquiliters.	
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	½ to 1 tablet every 6-8 hours; do not exceed 3 tablets in 24 hours, or as directed by a doctor	children 6 to under 12 years	Warnings Do not use for children under 2 years of age unless directed by a doctor.	
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Topcare 44-198

MOTION SICKNESS	S RELIEF					
dimenhydrinate tablet						
Product Information						
Product Type	HUMAN OTC DRU	JG	Item Code (Source)		NDC:36800-9	30
Route of Administration	ORAL					
Active Ingredient/Active	Moiety					
	Ingredient Nan	ne			Basis of Strength	Strength
DIMENHYDRINATE (UNII: JB937PER5C) (DIPHENHYDRAMINE - UNII:8GTS82S83M, CHLORTHEOPHYLLINE - UNII:GE2UA340FM) DIMENHYDRINATE 50 m					50 mg	
Inactive Ingredients						
	Ingredien	t Name			Sti	rength
MAGNESIUM STEARATE (UNII	:70097M6I30)					
CROSCARMELLOSE SODIUM	(UNII: M28OL1HH48)					
MICRO CRYSTALLINE CELLU	LOSE (UNII: OP1R32D61U	J)				
SILICON DIO XIDE (UNII: ETJ72	Z6 XBU4)					
STEARIC ACID (UNII: 4ELV7Z6						
DIBASIC CALCIUM PHO SPHA	TE DIHYDRATE (UNII: 07	TSZ97GEP)				
Product Characteristics						
Color	WHITE	Score			2 pieces	
Shape	ROUND	Size			9 m m	

Flavor			Imprint Code		44;198
Contains					
Packaging					
# Item Code		Package Descrip	otion	Marketing Start Date	Marketing End Date
1 NDC:36800-930-12	2 in 1 CA	ARTON		12/01/1992	
1	6 in 1 BL	1 BLISTER PACK; Type 0: Not a Combination Product			
Marketing Inf	ormat	ion			
Marketing Catego		oplication Number or M	onograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FIN		-		12/01/1992	Lind Dute
	purt purt				

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)

Revised: 1/2020

Topco Associates, LLC