

DRAMAMINE ORIGINAL FORMULA- dimenhydrinate tablet
Medtech Products Inc.

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.

Dramamine Original Formula

Drug Facts

Active ingredient

(in each tablet)

Dimenhydrinate 50 mg

Purpose

Antiemetic

Use

for 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
- trouble urinating due to an enlarged 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 dizziness
- be careful when driving a motor vehicle or operating machinery

If pregnant or breast-feeding,

ask a doctor before use.

Keep out of reach of children.

In case of accidental 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 ½ to 1 hour before starting activity
- to prevent or treat motion sickness, see below:

Adults and children 12 years and over	<ul style="list-style-type: none">• take 1 to 2 tables every 4-6 hours• do not take more than 8 tablets in 24 hours, or as directed by a doctor
Children 6 to under 12 years	<ul style="list-style-type: none">• give ½ to 1 tablet every 6-8 hours• do not give more than 3 tablets in 24 hours, or as directed by a doctor
Children 2 to under 6 years	<ul style="list-style-type: none">• give ½ tablet every 6-8 hours• do not give more than 1 ½ tablets in 24 hours, or as directed by a doctor

Other information

- store at room temperature 68-77°F (20-25°C)
- **do not use if carton is open or if blister unit is broken or torn**

Inactive ingredients

colloidal silicon dioxide, croscarmellose sodium, lactose, magnesium stearate, microcrystalline cellulose

Questions or comments?

Call 1-800-382-7219

PRINCIPAL DISPLAY PANEL

ORIGINAL FORMULA

Dramamine®
Dimenhydrinate Tablets/Antiemetic

MOTION SICKNESS RELIEF

12 Tablets (50 mg EACH)

ORIGINAL FORMULA

Dramamine®
Dimenhydrinate Tablets/Antiemetic

MOTION SICKNESS RELIEF

36 Tablets (50 mg EACH)

10822-03-17



DUAL ACTION

1. TREATS SYMPTOMS ON THE SPOT
2. PREVENTS NAUSEA, DIZZINESS & VOMITING

LOT:
EXP:



ORIGINAL FORMULA

Dramamine®

Dimenhydrinate Tablets / Antiemetic

MOTION SICKNESS RELIEF 12 TABLETS (50 mg EACH)

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0A631103

Drug Facts (continued)

Keep out of reach of children. In case of accidental 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 1/2 to 1 hour before starting activity ■ To prevent or treat motion sickness: **Adults and children 12 years and over** ■ take 1 to 2 tablets every 4-6 hours ■ do not take more than 8 tablets in 24 hours, or as directed by a doctor. **Children 6 to under 12 years:** ■ give 1/2 to 1 tablet every 6-8 hours ■ do not give more than 3 tablets in 24 hours, or as directed by a doctor. **Children 2 to under 6 years:** ■ give 1/4 tablet every 6-8 hours ■ do not give more than 1 1/2 tablets in 24 hours, or as directed by a doctor.

Other information ■ store at room temperature 20° - 25° C (68° - 77° F) ■ do not use if outer carton is open

Inactive ingredients calcium silicate dihydrate, croscarmellose sodium, lactose, magnesium stearate, microcrystalline cellulose

Questions? 1-800-382-7219

Drug Facts

Active ingredient (in each tablet)
Dimenhydrinate 50 mg

Purpose
Antiemetic

Use for prevention and treatment of these symptoms associated with motion sickness: ■ nausea ■ vomiting ■ dizziness

Warnings
Do not give to 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 ■ trouble urinating due to an enlarged prostate gland.

Ask a doctor 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 ■ be careful when driving a motor vehicle or operating machinery.

■ pregnant or breast-feeding, ask a doctor before use.

8138-01-17

#1 Pharmacist Recommended Brand

ORIGINAL FORMULA

Dramamine®

MOTION SICKNESS RELIEF

Dramamine®

MOTION SICKNESS RELIEF

EASY-TO-OPEN, NON-CHILD RESISTANT BLISTER. THIS PACKAGE FOR HOUSEHOLDS WITHOUT YOUNG CHILDREN.

LOT:
EXP:

TREATS SYMPTOMS ON THE SPOT

Dimenhydrinate Tablets/Antiemetic

PREVENTS NAUSEA

mine®
SS RELIEF



DRAMAMINE ORIGINAL FORMULA

dimenhydrinate tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63029-901
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIMENHYDRINATE (UNII: JB937PER5C) (CHLORTHEOPHYLLINE - UNII:GE2UA340FM)	DIMENHYDRINATE	50 mg

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
LACTOSE, UNSPECIFIED FORM (UNII: J2B2A4N98G)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	

Product Characteristics

Color	ORANGE	Score	2 pieces
Shape	ROUND	Size	8mm
Flavor	ORANGE	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63029-901-01	3 in 1 BOX	01/15/2012	
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:63029-901-02	1 in 1 BOX	01/15/2012	
2		12 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:63029-901-03	1 in 1 CARTON	01/15/2012	
3		2 in 1 POUCH; 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	01/15/2012	

Labeler - Medtech Products Inc. (122715688)