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	 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	 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	 give ½ tablet every 6-8 hours do not give more than 1½ 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)

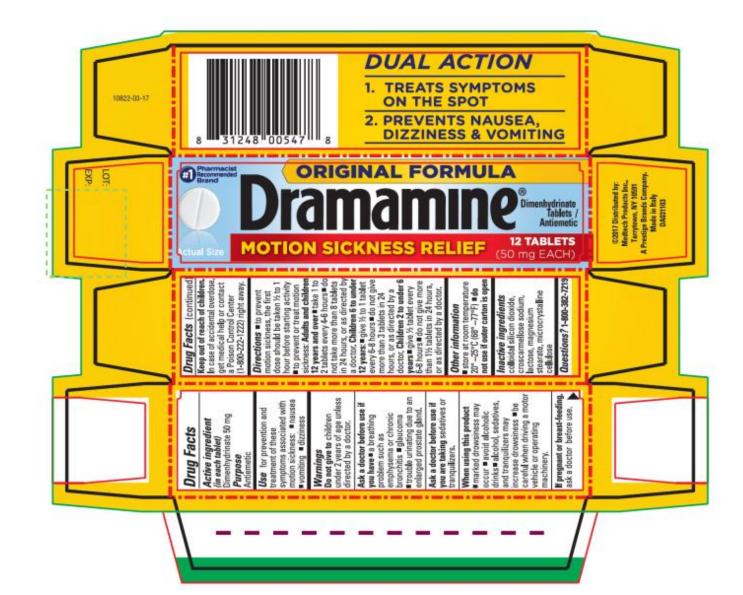
ORIGINAL FORMULA

Dramamine[®]

Dimenhydrinate Tablets/Antiemetic

MOTION SICKNESS RELIEF

36 Tablets (50 mg EACH)







DRAMAMINE ORIGINAL FORMULA

dimenhydrinate tablet

Product 1	Information
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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 DIO XIDE (UNII: ETJ7Z6 XBU4)			

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CROSCARMELLOSE SODIUM (UNII: M28 OL1HH48)	
LACTOSE, UNSPECIFIED FORM (UNII: J2B2A4N98G)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICRO CRYSTALLINE (UNII: OP1R32D61U)	

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

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63029-901-01	3 in 1 BOX	0 1/15/20 12	
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:63029-901-02	1 in 1 BOX	0 1/15/20 12	
2		12 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:63029-901-03	1 in 1 CARTON	0 1/15/20 12	
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	0 1/15/20 12	

Labeler - Medtech Products Inc. (122715688)

Revised: 5/2020 Medtech Products Inc.