# DRAMAMINE FOR KIDS- dimenhydrinate tablet, chewable 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.

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#### **Dramamine for Kids**

#### **Drug Facts**

### Active ingredient

(in each tablet)

Dimenhydrinate 25 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 the child has

- a breathing problem such as emphysema or chronic bronchitis
- glaucoma

### Ask a doctor or pharmacist before use if the child is

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

### 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:

Children 2 to under 6 years	<ul> <li>give ½ to 1 chewable tablet every 6-8 hours</li> <li>do not give more than 3 chewable tablets in 24 hours, or as directed by a doctor</li> </ul>
Children 6 to under 12 years	<ul> <li>give 1 to 2 chewable tablets every 6-8 hours</li> <li>do not give more than 6 chewable tablets in 24 hours, or as directed by a doctor</li> </ul>

### Other information

- Phenylketonurics: contains phenylalanine 0.84 mg per tablet
- store at room temperature 68° 77°F (20° 25°C)
- do not use if blister is broken or torn

### **Inactive ingredients**

aspartame, citric acid, flavor, magnesium stearate, methacrylic acid copolymer, sorbitol

### Questions?

1-800-382-7219 Dramamine.com

### PRINCIPAL DISPLAY PANEL

#1Pharmacist Recommended Brand
Ages 2 – 12
Safe, Precise Dose
Children's Chewable Formula
Dramamine MOTION SICKNESS RELIEF for Kids
8 Chewable Tablets
Dye Free Grape Flavor





ate 25 mg.

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  a breathing problem such as emphysema or chronic bronchitis
- glaucoma
- Ask a doctor or pharmacist before use if the child is 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 If pregnant or breast-feeding, ask a doctor

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.

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- 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:

Children 2	■ give 1/2 to 1 chewable tablet every 6-8 hours
to under 6	■ do not give more than 3 chewable tablets
years	in 24 hours, or as directed by a doctor

Children 6 update 1 to 2 chewable tablets every 6-8 hours to under 12 do not give more than 6 chewable tablets in 24 hours, or as directed by a doctor

#### Other information

- Phenylketonurics: contains phenylalanine 0.84 mg per tablet
- store at room temperature 68°-77°F (20°-25°C)
   do not use if blister is broken or torn

Inactive ingredients aspartame, citric acid, flavor, magnesium stearate, methacrylic acid copolymer, sorbitol

### Questions? 1-800-382-7219

Dramamine.com



#### DRAMAMINE FOR KIDS

dimenhydrinate tablet, chewable

#### **Product Information**

HUMAN OTC DRUG NDC:63029-904 Product Type Item Code (Source)

**Route of Administration** ORAL

#### **Active Ingredient/Active Moiety**

**Basis of Strength** Ingredient Name Strength DIMENHYDRINATE (UNII: JB937PER5C) (DIPHENHYDRAMINE - UNII:8GTS82S83M) DIMENHYDRINATE 25 mg

**Inactive Ingredients** 

### **Ingredient Name** Strength ASPARTAME (UNII: Z0H242BBR1) CITRIC ACID MONOHYDRATE (UNII: 2968 PHW8 QP) MAGNESIUM STEARATE (UNII: 70097M6I30) SORBITOL (UNII: 506T60A25R)

### **Product Characteristics**

WHITE Color Score 2 pieces

Shape	ROUND	Size	10 mm
Flavor	GRAPE	Imprint Code	DRA
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63029-904-01	1 in 1 BLISTER PACK		
1		8 in 1 CASE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part336	0 2/15/20 12	

## Labeler - Medtech Products Inc. (122715688)

Establishment				
Name	Address	ID/FEI	Business Operations	
Contract Pharmacal Corporation		057795122	MANUFACTURE(63029-904)	

Revised: 4/2012 Medtech Products Inc.