

## **MOTION SICKNESS- dimenhydrinate tablet**

**Freds 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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### **Drug Facts**

#### **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 an 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
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- use caution when driving a motor vehicle or operating machinery

##### **If pregnant or breast-feeding,**

ask a health care professional before use.

##### **Keep out of reach of children.**

In case of overdose, get medical help or contact a Poison Control Center right away.

#### **Directions**

- to prevent motion sickness, the first dose should be taken ½ to 1 hour before starting activity

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a dults and children 12 | 1 to 2 tablets every 4-6 hours; not to exceed 8 tablets in 24 hours, or as

years and over	directed by a doctor
children 6 to under 12 years	1/2 to 1 tablet every 6-8 hours; not to exceed 3 tablets in 24 hours, or as directed by a doctor
children 2 to under 6 years	1/4 to 1/2 tablet every 6-8 hours; not to exceed 1-1/2 tablets in 24 hours, or as directed by a doctor

**Other information**

- each tablet contains: **calcium 30 mg**
- store at room temperature 20°-25°C (68°-77°F)

**Inactive ingredients**

croscarmellose sodium, dicalcium phosphate, magnesium stearate, microcrystalline cellulose

**Questions or comments?**

Call **1-877-753-3935 Monday-Friday 9AM-5PM EST**

**PRINCIPAL DISPLAY PANEL**

Motion Sickness

Dimenhydrinate 50 mg/Antiemetic

Fast Acting Motion Sickness Relief

For Children and Adults

Tablets 50 mg Each

Compare to the active ingredient in Dramamine®\*

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

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

**KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION**

**Product Label**

**fred's**  
Motion Sickness  
Dimenhydrinate 50 mg/Antiemetic

NDC 55315-630-12

**fred's**  
Motion Sickness  
Dimenhydrinate 50 mg/Antiemetic

Actual Size

**Motion Sickness**  
Dimenhydrinate 50 mg/Antiemetic  
Fast Acting Motion Sickness Relief  
For Children and Adults

**fred's**  
LAB TESTED  
Lab Tested for Quality,  
Fred Tested for Satisfaction

Compare to the active ingredient in Dramamine\*\*

**12 Tablets 50 mg Each**

TAMPER EVIDENT: DO NOT USE IF CARTON IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING.  
KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

Lot No.:  
Exp. Date:

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DISTRIBUTED BY: fred's, Inc.  
4300 NEW GETWELL RD, MEMPHIS, TN 38118  
www.fredsinc.com

PLD-D  
FC001841

**fred's** Promise  
Not Happy With This Product?  
Just Bring It Back For a Refund!



<b>Drug Facts</b>	<b>Active ingredient (in each tablet)</b> Dimenhydrinate 50 mg.....Antiemetic
<b>Uses</b>	for the prevention and treatment of nausea, vomiting, or dizziness associated with motion sickness.
<b>Warnings</b>	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 an 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 ■ avoid alcoholic drinks ■ alcohol, sedatives, and tranquilizers may increase drowsiness ■ use caution when driving a motor vehicle or operating machinery 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 right away.
<b>Directions</b>	■ to prevent motion sickness, the first dose should be taken 1/2 to 1 hour before starting activity adults and children 12 years and over 1 to 2 tablets every 4-6 hours; not to 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; not to exceed 3 tablets in 24 hours, or as directed by a doctor children 2 to under 6 years 1/4 to 1/2 tablet every 6-8 hours; not to exceed 1-1/2 tablets in 24 hours, or as directed by a doctor
<b>Other information</b>	■ each tablet contains: calcium 30 mg ■ store at room temperature 20°-25°C (68°-77°F)
<b>Inactive ingredients</b>	croscarmellose sodium, dicalcium phosphate, magnesium stearate, microcrystalline cellulose
<b>Questions or comments?</b>	Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

Fred's Motion Sickness Tablets

MOTION SICKNESS

dimenhydrinate tablet

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:55315-630
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
DIMENHYDRINATE (UNII: JB937PER5C) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIMENHYDRINATE	50 mg

### Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: L11K75P92J)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	

### Product Characteristics

<b>Color</b>	WHITE	<b>Score</b>	2 pieces
<b>Shape</b>	ROUND	<b>Size</b>	9mm
<b>Flavor</b>		<b>Imprint Code</b>	1006;1006
<b>Contains</b>			

### Packaging

#	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:55315-630-12	1 in 1 CARTON		
1		12 in 1 BLISTER PACK		

### Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC MONOGRAPH FINAL	part336	07/08/2010	

**Labeler** - Freds Inc (005866116)

**Registrant** - P and L Development of New York Corporation (800014821)