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.

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

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



Dimenhydrinate 50 mg/Antiemetic

Motion Sickne
Dimenhydrinate 50 mg/Antiemetic

freds



Actual Size

Motion Sickness

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



NDC 55315-630-12

Compare to the active ingredient in

Dramamine**

Lot No.: Exp. Date:

TAMPER EVIDENT: DO NOT USE IF CARTON IS UNIT IS TORN, BROKEN OR SHOWS ANY SII

12 Tablets 50 mg Each

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

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

PLD-D FC001841 freds Promise Not Happy With This Product? Just Bring It Back For a Refund!



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161			Drug Facts

Fred's Motion Sickness Tablets

dimenhydrinate tablet

Product Information			
Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:55315-630
Route of Administration	ORAL	DEA Schedule	

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
DIMENHYDRINATE (DIPHENHYDRAMINE)	DIMENHYDRINATE	50 mg	

Inactive Ingredients		
Ingredient Name	Strength	
CROSCARMELLOSE SODIUM		
CALCIUM PHO SPHATE, DIBASIC, ANHYDRO US		
MAGNESIUM STEARATE		
CELLULO SE, MICRO CRYSTALLINE		

Product Characteristics			
Color	WHITE	Score	2 pieces
Shape	ROUND	Size	9 mm
Flavor		Imprint Code	1006;1006
Contains			

Pack	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC	:55315-630-12	1 in 1 CARTON		
1		12 in 1 BLISTER PACK		

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

Labeler - Freds Inc (005866116)

$\pmb{Registrant - } \ \ P \ \ and \ \ L \ \ Development \ of \ New \ \ York \ \ Corporation \ (800014821)$

Revised: 4/2014 Freds Inc