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.

Dimenhydrinate 50 mg tablets

Drug Facts

Active Ingredient (in each tablet)

Dimenhydrinate 50 mg

Purpose

Antiemetic

Uses

for prevention and treatment of these symptoms associated with motion sickness:

- nausea
- vomiting
- dizziness

Warnings

Do not use

in 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 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 $\frac{1}{2}$ to 1 hour before starting activity
- do not exceed recommended dosage. Not for frequent or prolonged use except on the advice of a
 doctor

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

Other information

- each tablet contains: calcium 30 mg
- store below 86° F (30° C)
- protect from heat and humidity
- *This product is not manufactured or distributed by Prestige Brands, Inc., owner of the registered trademark Dramamine®

Inactive ingredients

Croscarmellose Sodium, Dicalcium Phosphate, Magnesium Stearate and Microcrystalline Cellulose.

Questions or comments?

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

PRINCIPAL DISPLAY PANEL

Compare to Active Ingredient in Dramamine®*

Motion Sickness

Dimenhydrinate Tablets/ Antiemetic

Fast acting motion sickness relief

For children and Adults

THIS PRODUCT IS PACKAGED IN A CHILD RESISTANT AND TAMPER EVIDENT PACKAGE. USE ONLY IF BLISTERS ARE INTACT.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

Product Label



Motion Sickness

Dimenhydrinate Tablets/Antiemetic



NDC 55315-630-12



Actual Size

Motion Sickness

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



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THIS

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

Lot No.: Exp. Date:

12 Tablets 50 mg Each

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

fred's Promise

Not Happy With This Product? Just Bring It Back For a Refund!

PI D-C F63FR12



Questions or comments? Call toll free 1-877-753-3935 Monday-Friday 9AM-5PM EST

Drug Facts (continued)

Inactive ingredients croscarmellose sodium, dicalcium obosphate, magnesium stearate and microcrystalline cellulose.

Other information assa tablet contains:
calcium 30 mg astore below 86°F (30°C)
calcium 30 mg astore below 86°F (30°C)
product is not distributed by Prestige Brands,
1NC., owner of the registered trademark
Incommend of the registered trademark

ацества ву а аостог tablets in 24 hours or as 6 years of age take ¼ to ½ tablet every 6 to 8 hours; not to exceed 1-½ children 2 to under ділества бу з достог tablets in 24 hours or as 12 years of age 8 hours; not to exceed 3 take 1/2 to 1 tablet every 6 to children 6 to under

take 1 to 2 tablets every 4 to 6 hours; not to exceed 8 tablets in 24 hours or as directed by a doctor 12 years of age and adults and children

To prevent motion sickness, the first dose should be taken ½ to 1 hour before starting activity a do not exceed recommended dosage. Not for frequent or prolonged use except on the advice of a doctor. Directions

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. **Drug Facts** (continued)

If pregnant or breast-feeding, ask a health care professional before use.

oberating machinery ■ use caution when driving a motor vehicle or

increase drowsiness ■ alcohol, sedatives, and tranquilizers may

avoid alcoholic drinks
 avoid slooholic drinks

When using this product

sedatives or tranquilizers.

Ask a doctor or pharmacist before use if you are taking the prostate gland

■ difficulty in urination due to an enlargement of dlaucoma
 pronchitis

■ s preathing problem such as emphysema or

Ask a doctor before use if you have directed by a doctor. Do not use in children under 2 years of age, unless

ssociated with motion sickness:

■ nausea ■ vomiting ■ dizziness

USES for prevention and treatment of these symptoms Dimenhydrinate 50 mg.

(in each tablet) Active ingredient Purpose

Drug Facts

Warnings



MOTION SICKNESS

dimenhydrinate tablet

Product In	nformation
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Product TypeHUMAN OTC DRUG LABELItem Code (Source)NDC:55315-630Route of AdministrationORALDEA Schedule

Active Ingredient/Active Moiety

CELLULO SE, MICRO CRYSTALLINE

Ingredient Name Basis of Strength Strength

DIMENHYDRINATE (DIPHENHYDRAMINE) DIMENHYDRINATE 50 mg

Inactive Ingredients Ingredient Name Strength CROSCARMELLOSE SODIUM CALCIUM PHO SPHATE, DIBASIC, ANHYDROUS MAGNESIUM STEARATE

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

]	Packaging						
7	# 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 Inform	Tarketing Information			
ı	Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ı	OTC MONOGRAPH FINAL	part336	07/08/2010		
П					

Labeler - Freds Inc (005866116)

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

Revised: 1/2013 Freds Inc