DIMENHYDRINATE- dimenhydrinate tablet
Major Pharmaceuticals

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.

1006-Major

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

Do not give to children under 2 years of age unless directed by a doctor

Ask a doctor before use if you have

■ glaucoma

■ a breathing problem such as emphysema or chronic bronchitis

■ 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 drowsiness

■ use caution when driving a motor vehicle or operating machinery

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

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Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Directions

■ to prevent motion sickness, the rst dose should be taken one-half to one hour before starting activity

■ **adults and children 12 years of age 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 of age**: 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 of age**: 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 29 mg

■ store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)

■ protect from moisture

■ see end -ap for expiration date and lot number

■ TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN

croscarmellose sodium, dicalcium phosphate, magnesium stearate, microcrystalline cellulose

Questions or comments?

1-800-616-2471

KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

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

Distributed by: **MAJOR® PHARMACEUTICALS**

17177 N Laurel Park Drive, Suite 233

Livonia, MI 48152 USA

MAJOR ®

NDC 0904-6772-12

Compare to the Active Ingredient in DRAMAMINE ® Original Formula*

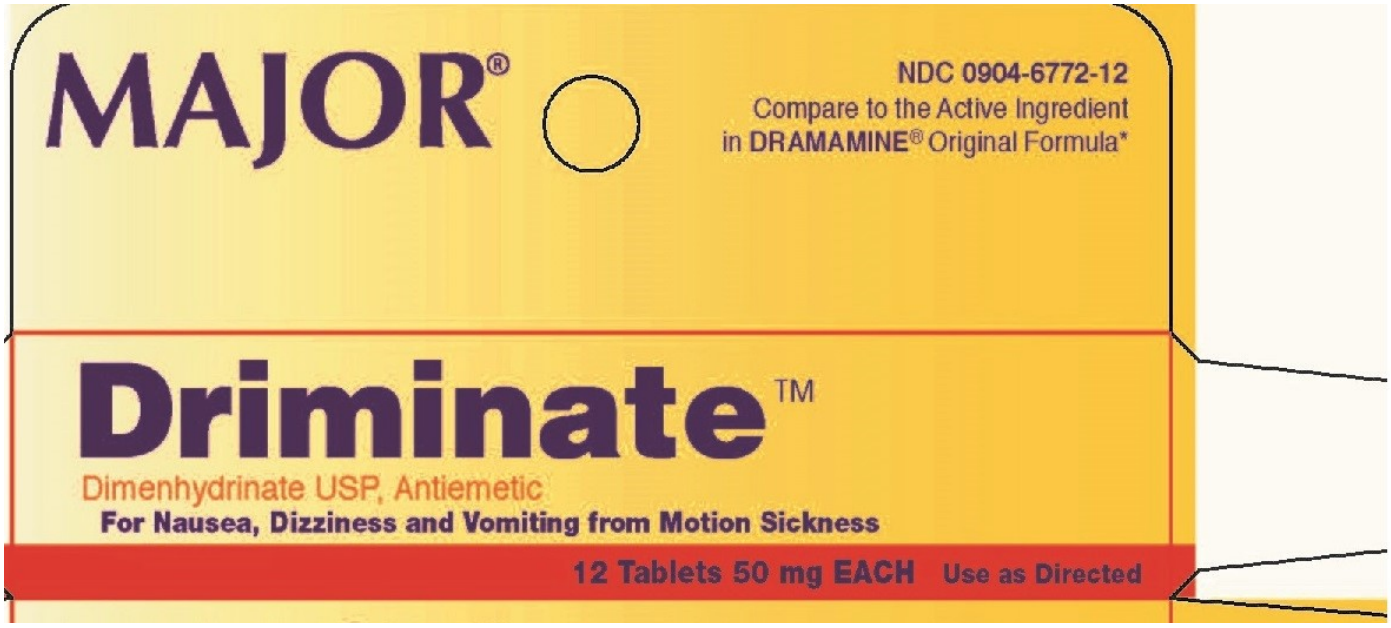
Driminate ™

Dimenhydrinate USP, Antiemetic

For Nausea, Dizziness and Vomiting from Motion Sickness

12 Tablets 50mg Each

Use as Directed



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Drug Facts

Active ingredient (in each tablet) **Purpose**
Dimenhydrinate 50 mg ..... Antiemetic

Uses for the prevention and treatment of nausea, vomiting, or dizziness associated with motion sickness

Warnings

Do not give to children under 2 years of age unless directed by a doctor

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- glaucoma
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Drug Facts (continued)

If pregnant or breast-feeding, ask a health professional before use.
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Drug Facts (continued)

Inactive ingredients croscarmellose sodium, dicalcium phosphate, magnesium stearate, microcrystalline cellulose

Questions or comments?

1-800-616-2471

MAJOR®
Compare to the Active Ingredient in DRAMAMINE® Original Formula*
NDC 0904-6772-12
Dramamine™
Dimenhydrinate USP, Antiemetic
For Nausea, Dizziness and Vomiting from Motion Sickness
12 Tablets
50 mg EACH
Use as Directed

Distributed by: MAJOR® PHARMACEUTICALS
17177 N Laurel Park Drive, Suite 233
Livonia, MI 48152 USA
Re-Order No. 700992
Rev. 09/18
M-29

DIMENHYDRINATE

dimenhydrinate tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0904-6772
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**
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	

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

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0904-6772-12	1 in 1 CARTON	02/14/2019	
1		12 in 1 BLISTER PACK; 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	02/14/2019	

Labeler - Major Pharmaceuticals (191427277)

Revised: 11/2020 Major Pharmaceuticals