DRAMAMINE- dimenhydrinate tablet
Navajo Manufacturing Company 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.

Dramamine

Drug Facts

Active ingredient (in each tablet)

Dimenhydrinate 50 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 you have

• a breathing problem such as emphysema or chronic bronchitis
• glaucoma
• 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
• 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 1/2 to 1 hour before starting activity
to prevent or treat motion sickness:

adults and children 12 years and over	• take 1 to 2 chewable tablets every 4-6 hours • do not take more than 8 chewable tablets in 24 hours, or as directed by a doctor
children 6 to under 12 years	• give 1/2 to 1 chewable tablet every 6-8 hours • do not give more than 3 chewable tablets in 24 hours, or as directed by a doctor
children 2 to under 6 years	• give 1/2 chewable tablet every 6-8 hours • do not give more than 1-1/2 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 20º-25ºC (68º- 77ºF)
- do not use if pouch is opened
- see pouch for lot number and expiration date

Inactive ingredients

anhydrous citric acid, aspartame, FD&C yellow 6 aluminum lake, flavors, magnesium stearate, maltodextrin, methacrylic acid copolymer, modified starch, sorbitol

Questions or comments?

call 1-800-382-7219

Package Labeling:

DRAMAMINE

dimenhydrinate tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:67751-170(NDC:63029-901)
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DIMENHYDRINATE (UNII: JB937PER5C) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIMENHYDRINATE	50 mg

Inactive Ingredients	
Ingredient Name	**Strength**
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
ASPARTAME (UNII: Z0H242BBR1)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics			
Color	orange	**Score**	2 pieces
Shape	ROUND	**Size**	8mm
Flavor	ORANGE	**Imprint Code**	
Contains			

Packaging				
			Marketing Start	**Marketing End**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67751-170-01	1 in 1 CARTON	09/23/2016	
1		2 in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:67751-170-02	1 in 1 CARTON	09/23/2016	
2		4 in 1 POUCH; 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	09/23/2016	

Labeler - Navajo Manufacturing Company Inc. (091917799)

Establishment

Name	Address	ID/FEI	Business Operations
Navajo Manufacturing Company Inc.		136941411	relabel(67751-170) , repack(67751-170)

Revised: 3/2023 Navajo Manufacturing Company Inc.