DIMENHYDRINATE- dimenhydrinate tablet
Qualitest 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.

DIMENHYDRINATE TABLETS, USP
50 mg

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
- alcohol, sedatives and tranquilizers may increase drowsiness
- avoid alcoholic drinks
- be careful 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. (1-800-222-1222).

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, use the following dosing

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

Other information

store at 15° to 30°C (59° to 86°F)

You may report serious side effects to: *130 Vintage Drive, Huntsville, AL 35811*.

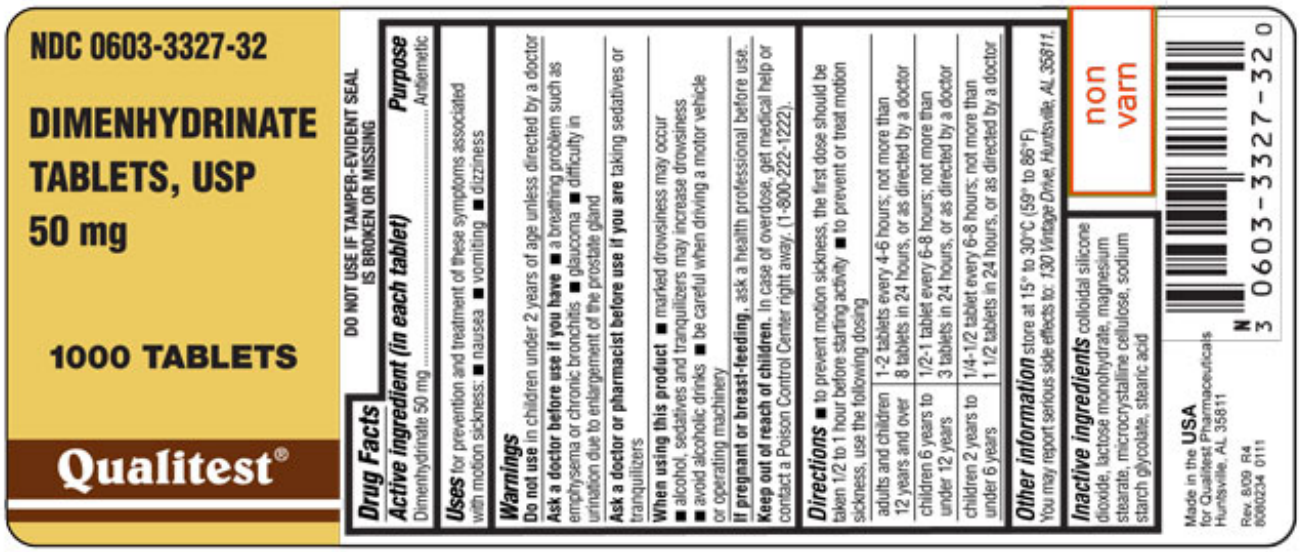
Inactive ingredients

colloidal silicone dioxide, lactose monohydrate, magnesium stearate, microcrystalline cellulose, sodium starch glycolate, stearic acid

Made in the **USA**
for Qualitest Pharmaceuticals
Huntsville, AL 35811

Rev. 8/09 R4
8080234 0111

PRINCIPAL DISPLAY PANEL



DIMENHYDRINATE

dimenhydrinate tablet

Product Information			
Product Type	HUMAN OTC DRUG LABEL	**Item Code (Source)**	NDC:0603-3327

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
SILICON DIOXIDE	
LACTOSE MONOHYDRATE	
MAGNESIUM STEARATE	
CELLULOSE, MICROCRYSTALLINE	
SODIUM STARCH GLYCOLATE TYPE A POTATO	
STEARIC ACID	

Product Characteristics

Color	WHITE	**Score**	2 pieces
Shape	ROUND	**Size**	9mm
Flavor		**Imprint Code**	0111;V
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0603-3327-21	100 in 1 BOTTLE, PLASTIC		
2	NDC:0603-3327-32	1000 in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part336	03/01/2004	

Labeler - Qualitest Pharmaceuticals (011103059)

Establishment

Name	Address	ID/FEI	Business Operations
Vintage Pharmaceuticals-Huntsville		825839835	MANUFACTURE(0603-3327)