DIMENHYDRINATE- dimenhydrinate tablet
Carilion Materials Management

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

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

- nausea
- vomiting
- dizziness

Warnings

in children under 2 years of age unless directed by a doctor **Do not use**

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

taking sedatives or tranquilizers **Ask a doctor or pharmacist before use if you are**

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

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

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*

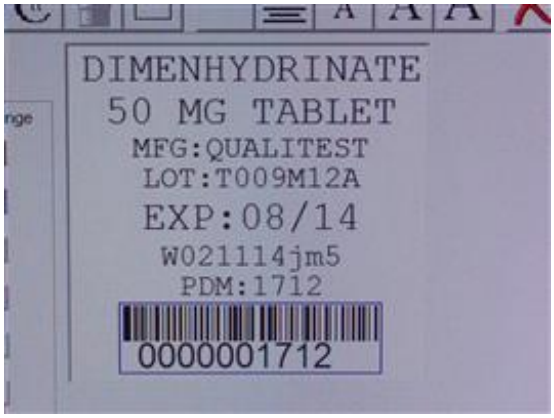
Inactive ingredients

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

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

Rev. 8/09 R4 8080234 0111

Dimenhydrinate



DIMENHYDRINATE

dimenhydrinate tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68151-1712(NDC:0603-3327)
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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

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:68151-1712-2	1 in 1 PACKAGE		

Marketing Information

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

Labeler - Carilion Materials Management (079239644)

Registrant - Carilion Materials Management (079239644)

Establishment

Name	Address	ID/FEI	Business Operations
Carilion Materials Management		079239644	REPACK(68151-1712)

Revised: 12/2012 Carilion Materials Management