

GRAVOL- dimenhydrinate tablet, coated
Church & Dwight Co., 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.

Gravol™ Motion Sickness Relief - Coated Tablets

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 dizziness
- be careful when driving a motor vehicle or operating machinery or any activity that requires alertness

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 $\frac{1}{2}$ to 1 hour before starting activity
- to prevent or treat motion sickness, see below:

adults and children 12 years and over:	<ul style="list-style-type: none">• take 1 to 2 tablets every 4-6 hours• do not take more than 8 tablets in 24 hours, or as directed by a doctor
children 6 to under 12 years:	<ul style="list-style-type: none">• give $\frac{1}{2}$ to 1 tablet every 6-8 hours• do not give more than 3 tablets in 24 hours, or as directed by a doctor
children 2 to under 6 years:	<ul style="list-style-type: none">• give $\frac{1}{4}$ to $\frac{1}{2}$ tablet every 6-8 hours• do not give more than 1-$\frac{1}{2}$ tablets in 24 hours, or as directed by a doctor

Other information

- store at room temperature 59°-77°F (15°-25°C)
- **do not use if packet is torn**

Inactive ingredients

Corn starch, croscarmellose sodium, FD&C yellow 6 aluminum lake, iron oxide yellow, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, silicon dioxide, talc, titanium dioxide

Questions or comments?

1-800-952-5080 M-F 9am to 5pm ET

PRINCIPAL DISPLAY PANEL

OVER 70 YEARS OF

QUALITY & TRUST†

Prevents and Treats:

Nausea & Vomiting

Dizziness*

*Prevention and treatment of nausea,
vomiting and dizziness due to motion sickness

Gravol™ COATED TABLETS

Gravol™

MOTION SICKNESS RELIEF

Dimenhydrinate 50 mg Tablets - Antiemetic

10

COATED TABLETS

TASTE FREE

EASY TO SWALLOW

Prevents and Treats:

Nausea & Vomiting
Dizziness*

*Prevention and treatment of nausea, vomiting and dizziness due to motion sickness



Gravol™ COATED TABLETS



Gravol™ COATED TABLETS

Drug Facts	
Active Ingredient (in each tablet) Dimenhydrinate 50 mg. Antiemetic	Purpose To prevent or treat motion sickness, sea sickness, and dizziness.
Use For the prevention and treatment of those symptoms associated with motion sickness: seasickness, 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 (asthma) or 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, impaired dizziness may occur. Avoid alcoholic drinks, alcohol, sedatives, and tranquilizers. *Hold alcoholic drinks, alcohol, sedatives, and tranquilizers may increase dizziness. *Be careful when driving a motor vehicle or operating machinery or any activity that requires alertness. 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.	
Questions? Call us at 1-800-952-5000. M-F 9am to 5pm ET.	

GRAFC00162/01 7/2022/7/6

Gravol™

Chubb & Dwyer Co., Inc., Exton, PA 19341
Gravol is a trademark of Chubb & Dwyer Canada Corp.
Made in Canada



GRAVOL

dimenhydrinate tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10237-941
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
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
MAGNESIUM STEARATE (UNII: 70097M6130)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TALC (UNII: 7SEV7J4R1U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CROSCARMELOSE (UNII: 029TFK992N)	
STARCH, CORN (UNII: O8232NY3SJ)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	

Product Characteristics

Color	orange	Score	4 pieces
Shape	ROUND	Size	8mm
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10237-941-10	1 in 1 CARTON	03/02/2022	
1		10 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	03/02/2022	

Labeler - Church & Dwight Co., Inc. (001211952)**Establishment**

Name	Address	ID/FEI	Business Operations
Church & Dwight Canada Corp.		253933600	manufacture(10237-941)

Revised: 3/2022

Church & Dwight Co., Inc.