

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

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 ½ 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 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 1/4 to 1/2 tablet every 6-8 hours• do not give more than 1-1/2 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

<p>Drug Facts</p> <p>Active ingredient (in each tablet): Dimenhydrinate 50 mg. Antiemetic</p> <p>Purpose To prevent or treat motion sickness, sea sickness, and dizziness.</p> <p>Use For the prevention and treatment of those symptoms associated with motion sickness: seasickness, vomiting, dizziness.</p> <p>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.</p>	
<p>Directions • To prevent motion sickness, the first dose should be taken 30 to 60 minutes before starting activity. • To prevent or treat motion sickness, see below. • Adults and children 12 years and over: Take 1 to 2 tablets every 4 to 6 hours. • Do not take more than 6 tablets in 24 hours. • Children 6 to 12 years: Give 1 to 2 tablets every 6 to 8 hours. • Do not give more than 3 tablets in 24 hours. • Children 2 to 6 years: Give 1/2 to 1 tablet every 6 to 8 hours. • Do not give more than 1 1/2 tablets in 24 hours. • Children 6 months to 2 years: Give 1/2 to 1 tablet every 6 to 8 hours. • Do not give more than 1 1/2 tablets in 24 hours. • Children 6 months and under: Give 1/2 to 1 tablet every 6 to 8 hours. • Do not give more than 1 1/2 tablets in 24 hours. • Children 6 months and under: Give 1/2 to 1 tablet every 6 to 8 hours. • Do not give more than 1 1/2 tablets in 24 hours. • Children 6 months and under: Give 1/2 to 1 tablet every 6 to 8 hours. • Do not give more than 1 1/2 tablets in 24 hours.</p>	<p>Other information • Store at room temperature or as directed by a doctor.</p> <p>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.</p> <p>Questions? Call us at 1-800-952-5000. M-F 9am to 5pm ET.</p>

Gravol is a trademark of Church & Dwight Canada Corp.
Church & Dwight Co., Inc., Ewing, NJ 08628
Made in Canada



Gravol™

GRAFC00162-01 73022776

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		
2	NDC:10237-941-30	3 in 1 CARTON	05/15/2024	
2		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 DRUG	M009	03/02/2022	

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

Establishment

Name	Address	ID/FEI	Business Operations
Church & Dwight Canada Corp		253933600	MANUFACTURE(10237-941) , PACK(10237-941)

Revised: 3/2022

Church & Dwight Co., Inc.