# GRAVOL- dimenhydrinate capsule, liquid filled 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.

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## **Gravol™ Motion Sickness Relief - Liquid Gels**

#### Active ingredient (in each Liquid Gel)

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:

- take 1 to 2 liquid gels every 4-6 hours
- do not take more than 8 liquid gels in 24 hours, or as directed by a doctor
- give 1 liquid gel every 6-8 hours

children 6 to under 12 years: • do not give more than 3 liquid gels 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**

Gelatin, glycerin, mannitol, polyethylene glycol 400, povidone, purified water, Red 33, sorbitan, sorbitol

## 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

Ages 6+

Gravol™ LIQUID GELS

Gravol™

MOTION SICKNESS RELIEF

Dimenhydrinate 50 mg - Antiemetic

8

LIQUID GELS

(Liquid Filled

Capsules)

TASTE FREE

**EASY TO SWALLOW** 

Prevents and Treats:

## Nausea & Vomiting Dizziness\*

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

Ages 6+









If pregnant or breast-feeding, ask a doctor before use. Keep out of reach of children, in case of accidental Country for the present of the present of the present Country Country (Section 2)

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





CRFC-00163-02 72022777

#### **GRAVOL**

# **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:10237-940

**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
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
MANNITOL (UNII: 30WL53L36A)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
WATER (UNII: 059QF0KO0R)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
SORBITOL (UNII: 506T60A25R)	
SORBITAN (UNII: 6O92ICV9RU)	
POVIDONE (UNII: FZ 989GH94E)	

#### **Product Characteristics**

Color	pink	Score	score with uneven pieces
Shape	CAPSULE	Size	15mm
Flavor		Imprint Code	

Contains

#### **Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10237-940- 08	1 in 1 CARTON	03/02/2022	
1		8 in 1 BLISTER PACK; Type 0: Not a Combination Product		

# **Marketing Information**

Marketing	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	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(10237-940)	

Revised: 3/2022 Church & Dwight Co., Inc.