

GRAVOL- dimenhydrinate syrup
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.

kids Gravol™ Motion Sickness Relief

Active ingredient (in each 5 mL)

Dimenhydrinate 15 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:

children 2 to 6 years	<ul style="list-style-type: none">• take 1 teaspoon (5 mL) every 4-6 hours• do not take more than 5 teaspoons (25 mL) in 24 hours, or as directed by a doctor
children 6 to under 12 years	<ul style="list-style-type: none">• give 2 teaspoons (10 mL) every 6-8 hours• do not give more than 10 teaspoons (50 mL) 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

Citric acid, flavor, polysorbate 80, propylene glycol, sodium benzoate, sorbitol, sucrose, water

Questions or comments?

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

PRINCIPAL DISPLAY PANEL

OVER 70 YEARS OF
QUALITY & TRUST†

Children 2+

Prevents and Treats:

Nausea & Vomiting

Dizziness*

kids Gravol™

MOTION SICKNESS RELIEF

Dimenhydrinate 15 mg Syrup - Antiemetic

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

MIXED FRUIT

FLAVOR

DYE FREE ALCOHOL FREE

2.5 FL OZ (75 mL)

Church & Dwight Co., Inc.,

Ewing, NJ 08628

Gravol is a trademark of

Church & Dwight Canada Corp.

Made in Canada

GRFC-00164-01 72022778



Drug Facts	
Active ingredient (in each 5 mL)	Purpose
Dimenhydrinate 15 mg	Antiemetic
Use	
For the 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 drowsiness •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:	
•children 2 to 6 years •take 1 teaspoon (5 mL) every 4-6 hours	
•do not take more than 5 teaspoons (25 mL) in 24 hours, or as directed by a doctor	
•children 6 to under 12 years •give 2 teaspoons (10 mL) every 6-8 hours	
•do not give more than 10 teaspoons (50 mL) 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	
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Children 2+

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**Nausea & Vomiting
Dizziness***




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Dimenhydrinate 15 mg Syrup – Antiemetic




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

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DYE FREE | ALCOHOL FREE

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2.5 FL OZ (75 mL)



GRAVOL

dimenhydrinate syrup

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10237-942
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIMENHYDRINATE (UNII: JB937PER5C) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIMENHYDRINATE	15 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
SUCROSE (UNII: C151H8M554)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0K00R)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL (UNII: 506T60A25R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10237-942-25	1 in 1 CARTON	03/02/2022	
1		75 mL in 1 BOTTLE; 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(10237-942)

Revised: 3/2022

Church & Dwight Co., Inc.