

PEPTO-BISMOL- bismuth subsalicylate suspension
The Procter & Gamble Manufacturing Company

Pepto Bismol®

Drug Facts

Active ingredient (in each 30 mL dose)

Bismuth subsalicylate 525 mg

Purpose

Upset stomach reliever and antidiarrheal

Uses

relieves

- traveler's diarrhea
- diarrhea
- upset stomach due to overindulgence in food and drink, including:
- heartburn
- indigestion
- nausea
- gas
- belching
- fullness

Warnings

Reye's syndrome:

Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.

Allergy alert: Contains salicylate. Do not take if you are

- allergic to salicylates (including aspirin)
- taking other salicylate products

Do not use if you have

- an ulcer
- a bleeding problem
- bloody or black stool

Ask a doctor before use if you have

- fever
- mucus in the stool

Ask a doctor or pharmacist before use if you are taking any drug for

- anticoagulation (thinning the blood)
- diabetes
- gout
- arthritis

When using this product a temporary, but harmless, darkening of the stool and/or tongue may occur

Stop use and ask a doctor if

- symptoms get worse or last more than 2 days
- ringing in the ears or loss of hearing occurs
- diarrhea lasts more than 2 days

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

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- shake well before use
- only use dose cup provided
- adults and children 12 years and over:
 - 30 mL (1 dose) every ½ hour or 60 mL (2 doses) every hour as needed for diarrhea/traveler's diarrhea
 - 30mL (1 dose) every ½ hour as needed for overindulgence (upset stomach, heartburn, indigestion, nausea)
- do not exceed 8 doses (240 mL) in 24 hours
- use until diarrhea stops but not more than 2 days
- children under 12 years: ask a doctor
- drink plenty of clear fluids to help prevent dehydration caused by diarrhea

Other information

- **each 30 mL dose contains:** magnesium 3 mg, sodium 4 mg
 - salicylate 261 mg
 - low sodium
 - protect from freezing
 - avoid excessive heat (over 104°F or 40°C)
- **TAMPER EVIDENT:** Do not use if printed shrinkband is missing or broken.

Inactive ingredients

benzoic acid, D&C Red No. 22, D&C Red No. 28, flavor, gellan gum, magnesium aluminum silicate, methylcellulose, salicylic acid, sodium salicylate, sorbic acid, sucralose, water

Questions?

1-800-717-3786

DIST. BY PROCTER & GAMBLE,
CINCINNATI OH 45202

PRINCIPAL DISPLAY PANEL - 473 mL Bottle Label

Pepto

Bismol®

Bismuth Subsalicylate
Upset Stomach Reliever
Antidiarrheal

COATS & SOOTHES

5 SYMPTOM

RELIEF

NAUSEA
HEARTBURN
INDIGESTION
UPSET STOMACH
DIARRHEA

16 FL OZ (473 mL)



5 SYMPTOM RELIEF



Drug Facts (continued)

Directions

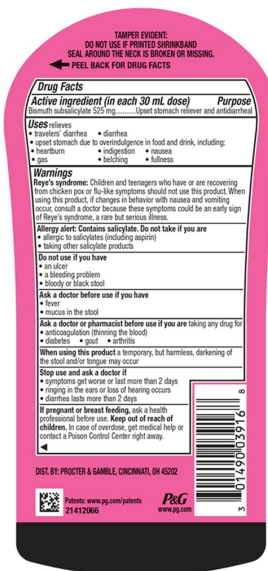
- shake well before use
- only use dose cup provided
- adults and children 12 years and over:
 - 30 mL (1 dose) every 1 to 2 hours or 60 mL (2 doses) every hour as needed for diarrhea/heartburn/indigestion
- 30 mL (1 dose) every 1 to 2 hours as needed for overindulgence (upset stomach, heartburn, indigestion, nausea)
- do not exceed 8 doses (240 mL) in 24 hours
- use until diarrhea stops but not more than 2 days
- children under 12 years: ask a doctor
- drink plenty of clear fluids to help prevent dehydration caused by diarrhea

Other information

- each 30 mL dose contains: magnesium 5 mg, sodium 4 mg, salicylate 261 mg, low sodium
- protect from freezing
- avoid excessive heat (over 104°F or 40°C)

Inactive ingredients benzoic acid, D&C Red No. 22, D&C Red No. 28, flavor, gelatin gum, magnesium aluminum silicate, methylcellulose, salicylic acid, sodium salicylate, sorbic acid, sucralose, water

Questions? 1-800-717-3786



PEPTO-BISMOL

bismuth subsalicylate suspension

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37000-438
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BISMUTH SUBSALICYLATE (UNII: 62TEY51RR1) (SALICYLIC ACID - UNII:O414PZ4LPZ, BISMUTH CATION - UNII:ZS9CD1I8YE)	BISMUTH SUBSALICYLATE	525 mg in 30 mL

Inactive Ingredients

Ingredient Name	Strength
GELLAN GUM (HIGH ACYL) (UNII: WLL7G7ROMD)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
D&C RED NO. 22 (UNII: 1678RKX8RT)	
D&C RED NO. 28 (UNII: 767IP0Y5NH)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
SALICYLIC ACID (UNII: O414PZ4LPZ)	
SODIUM SALICYLATE (UNII: MQ1H85SYP)	
SORBIC ACID (UNII: X045WJ989B)	
WATER (UNII: 059QF0KO0R)	
METHYLCELLULOSE, UNSPECIFIED (UNII: Z944H5SN0H)	

Product Characteristics

Color	pink	Score	
Shape		Size	
Flavor	WINTERGREEN	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37000-438-04	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/01/2018	
2	NDC:37000-438-08	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/01/2018	
3	NDC:37000-438-12	354 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/01/2018	
4	NDC:37000-438-16	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/01/2018	
5	NDC:37000-438-24	2 in 1 CELLO PACK	03/01/2018	
6		354 mL in 1 BOTTLE, PLASTIC; Type 0: Not a		

5		Combination Product		
6	NDC:37000-438-32	2 in 1 CELLO PACK	06/11/2024	
6		473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
7	NDC:37000-438-34	100 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/01/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M008	03/01/2018	

Labeler - The Procter & Gamble Manufacturing Company (004238200)