

**PEPTO DIARRHEA- bismuth subsalicylate suspension**  
**The Procter & Gamble Manufacturing Company**

-----  
**Pepto<sup>®</sup> Diarrhea**

***Drug Facts***

**Active ingredient (in each 10 mL dose)**

Bismuth subsalicylate 525 mg

**Purpose**

Antidiarrheal

**Uses**

relieves

- travelers' diarrhea
- diarrhea

**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
- 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
- adults and children 12 years and over:
  - 10 mL (1 dose) every ½ hour to 1 hour or 20 mL (2 doses) every hour as needed for diarrhea/travelers' diarrhea
  - do not exceed 8 doses (80 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 10 mL dose contains:** salicylate 212 mg
  - low sodium
  - store at no greater than 30°C
  - 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, gellan gum, magnesium aluminum silicate, methylcellulose, salicylic acid, sodium salicylate, sorbic acid, sucralose, water

**Questions?**

**1-800-717-3786**

**Tamper Evident: Do not use if printed shrinkband seal around the neck is broken or missing**

**DIST. BY PROCTER & GAMBLE,  
CINCINNATI OH 45202**

**PRINCIPAL DISPLAY PANEL - 118 mL Bottle Label**

\*vs. Original Pepto Bismol®

Pepto®

Diarrhea

Bismuth Subsalicylate

Antidiarrheal

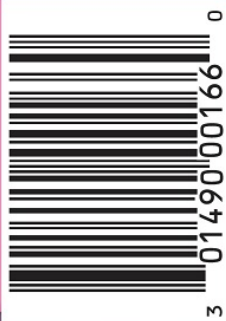
CHERRY

COATS & KILLS BACTERIA THAT CAUSE DIARRHEA

4 FL OZ

(118 mL)

Tamper Evident: Do not use if printed shrinkband seal around the neck is broken or missing



83838316

PEEL BACK FOR DRUG FACTS

DIST. BY: PROCTER & GAMBLE, CINCINNATI, OH 45202

**P&G**  
www.pg.com  
Patents: www.pg.com/patents

# Pepto<sup>®</sup> Diarrhea

Bismuth Subsalicylate  
Antidiarrheal



**COATS & KILLS  
BACTERIA THAT  
CAUSE DIARRHEA**

4 FL OZ (118 mL)

pepto-bismol.com



LOT

EXP

\*vs. Original Pepto Bismol<sup>®</sup>

## Drug Facts

### Active ingredient

(in each 10 mL dose)

Bismuth subsalicylate 525 mg..... Antidiarrheal

### Purpose

### Uses

relieves  
• travelers' diarrhea • diarrhea

## Drug Facts (continued)

### 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 • 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.

## Drug Facts (continued)

### Directions

- shake well before use
- adults and children 12 years and over:
  - 10 mL (1 dose) every ½ hour to 1 hour or 20 mL (2 doses) every hour as needed for diarrhea/travelers' diarrhea
- do not exceed 8 doses (80 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 10 mL dose contains: salicylate 212 mg
- low sodium
- store at no greater than 30°C
- 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, gellan gum, magnesium aluminum silicate, methylcellulose, salicylic acid, sodium salicylate, sorbic acid, sucralose, water

**Questions? 1-800-717-3786**

## PEPTO DIARRHEA

bismuth subsalicylate suspension

### Product Information

**Product Type**

HUMAN OTC DRUG

**Item Code (Source)**

NDC:37000-538

Route of Administration ORAL

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>BISMUTH SUBSALICYLATE</b> (UNII: 62TEY51RR1) (SALICYLIC ACID - UNII:O414PZ4LPZ)	BISMUTH SUBSALICYLATE	525 mg in 30 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>BENZOIC ACID</b> (UNII: 8SKN0B0MIM)	
<b>MAGNESIUM ALUMINUM SILICATE</b> (UNII: 6M3P64V0NC)	
<b>D&amp;C RED NO. 22</b> (UNII: 1678RKX8RT)	
<b>D&amp;C RED NO. 28</b> (UNII: 767IP0Y5NH)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>SALICYLIC ACID</b> (UNII: O414PZ4LPZ)	
<b>SODIUM SALICYLATE</b> (UNII: MQ1H85SYP)	
<b>SORBIC ACID</b> (UNII: X045WJ989B)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>GELLAN GUM (HIGH ACYL)</b> (UNII: W1L7G7ROMD)	
<b>METHYLCELLULOSE, UNSPECIFIED</b> (UNII: Z944H5SN0H)	

### Product Characteristics

<b>Color</b>	pink	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	CHERRY	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37000-538-04	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/01/2019	06/30/2026

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M008	03/01/2018	06/30/2026

**Labeler** - The Procter & Gamble Manufacturing Company (004238200)