

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

*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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**Pepto-Bismol™**

**Drug Facts**

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<b>Active ingredient (in each 30 mL dose cup)</b>	<b>Purposes</b>
Bismuth subsalicylate 525 mg	Upset stomach reliever and antidiarrheal
<b>Active ingredient (in each tablet)</b>	
Bismuth subsalicylate 262 mg	Upset stomach reliever and antidiarrheal

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**Uses**

relieves

- travelers' 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**

- 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

### **Liquid**

- shake well before use
- use dose cup or tablespoon (TBSP)
- adults and children 12 years and over: 1 dose (30 mL or 2 TBSP) every ½ to 1 hour as needed
- do not exceed 8 doses (240 mL or 16 TBSP) in 24 hours

### **Chewable Tablets**

- chew or dissolve in mouth
- adults and children 12 years and over: 2 tablets every 1/2 to 1 hour as needed
- do not exceed 8 doses (16 tablets) in 24 hours

### **Other information**

- protect from freezing
- avoid excessive heat (over 104°F, 40°C)

### **Pepto-Bismol Liquid**

- **each 30 mL dose cup contains:**
- magnesium 25 mg, sodium 8 mg
- salicylate 261 mg
- low sodium

### **Pepto-Bismol Chewable Tablets**

- **each tablet contains:**
- calcium 140 mg, magnesium 9 mg
- salicylate 101 mg
- very low sodium

## **Inactive ingredients**

### **Liquid**

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

### **Chewable Tablets**

calcium carbonate, D&C Red No. 27 aluminum lake, flavor, magnesium stearate, mannitol, povidone, saccharin sodium, talc

## **Questions?**

**1-800-717-3786**

**Dist. by Procter & Gamble,  
Cincinnati OH 45202**

## **PRINCIPAL DISPLAY PANEL - Kit Carton**

**NDC 37000-402-01**

***Pepto-  
Bismol***™

**BISMUTH SUBSALICYLATE  
UPSET STOMACH RELIEVER/ANTIDIARRHEAL**

**5**

**SYMPTOM**

**Digestive Relief**

- **heartburn**
- **indigestion**
- **nausea**
- **upset stomach**
- **diarrhea**

**TOTAL 32 FL OZ (946 ml) • TWO 16 FL OZ (473 ml) BOTTLES | 48 CHEWABLE TABLETS**



<p><b>TAMPER EVIDENT:</b> Do not use if printed shrinkband on liquid bottle is missing or broken.</p> <p><b>Drug Facts</b></p> <p><b>Active Ingredient (in each 30 mL dose cup)</b> <span style="float: right;"><b>Purposes</b></span> Bismuth subsalicylate 525 mg.....Upset stomach reliever and antidiarrheal</p> <p><b>Active ingredient (in each tablet)</b> Bismuth subsalicylate 262 mg.....Upset stomach reliever and antidiarrheal</p> <p><b>Uses</b> relieves • travelers' diarrhea • diarrhea • upset stomach due to overindulgence in food and drink, including: • heartburn • indigestion • nausea • gas • belching • fullness</p> <p><b>Warnings</b> 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.</p> <p><b>Allergy alert:</b> Contains salicylate. Do not take if you are allergic to salicylates (including aspirin) • taking other salicylate products</p> <p><b>Do not use if you have</b> • an ulcer • a bleeding problem • bloody or black stool</p> <p><b>Ask a doctor before use if you have</b> • fever • mucus in the stool</p> <p><b>Ask a doctor or pharmacist before use if you are taking any drug for</b> • anticoagulation (thinning the blood) • diabetes • gout • arthritis</p> <p><b>When using this product a temporary, but harmless, darkening of the stool and/or tongue may occur.</b></p> <p><b>Stop use and ask a doctor if</b> • symptoms get worse or last more than 2 days • ringing in the ears or loss of hearing occurs • diarrhea lasts more than 2 days</p> <p><b>If pregnant or breast feeding, ask a health professional before use.</b></p>	<p><b>TAMPER EVIDENT:</b> Do not use if the tablet printed inner wrap is broken or missing.</p> <p><b>Drug Facts (continued)</b></p> <p><b>Keep out of reach of children.</b> In case of overdose, get medical help or contact a Poison Control Center right away.</p> <p><b>Directions</b> • 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</p> <p><b>Liquid:</b> • shake well before use • use dose cup or tablespoon (TBS) • adults and children 12 years and over: 1 dose (30 mL or 2 TBS) every ½ to 1 hour as needed • do not exceed 8 doses (240 mL or 16 TBS) in 24 hours</p> <p><b>Chewable Tablets:</b> • chew or dissolve in mouth • adults and children 12 years and over: 2 tablets every 1/2 to 1 hour as needed • do not exceed 8 doses (16 tablets) in 24 hours</p> <p><b>Other information</b> • protect from freezing • avoid excessive heat (over 104°F, 40°C)</p> <p><b>Pepto-Bismol Liquid</b> <span style="float: right;"><b>Pepto-Bismol Chewable Tablets</b></span> • each 30 mL dose cup contains: • each tablet contains: • magnesium 25 mg, sodium 8 mg • calcium 140 mg, magnesium 9 mg • salicylate 261 mg • salicylate 101 mg • low sodium • very low sodium</p> <p><b>Inactive ingredients</b> Liquid: benzoic acid, D&amp;C Red No. 22, D&amp;C Red No. 28, flavor, magnesium aluminum silicate, methylcellulose, saccharin sodium, salicylic acid, sodium salicylate, sorbic acid, water Chewable Tablets: calcium carbonate, D&amp;C Red No. 27 aluminum lake, flavor, magnesium stearate, mannitol, polydioxane, saccharin sodium, talc</p> <p><b>Questions?</b> 1-800-717-3786</p>
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**PEPTO-BISMOL**  
bismuth subsalicylate kit

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:37000-402
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### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37000-402-01	1 in 1 PACKAGE		

### Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	2 BOTTLE, PLASTIC	946 mL
Part 2	8 CELLO PACK	48

### Part 1 of 2

#### PEPTO-BISMOL

bismuth subsalicylate suspension

### Product Information

<b>Item Code (Source)</b>	NDC:37000-032
<b>Route of Administration</b>	ORAL

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BISMUTH SUBSALICYLATE (UNII: 62TEY51RR1) (BISMUTH CATION - UNII:ZS9CD1I8 YE, SALICYLIC ACID - UNII:O414PZ4LPZ)	BISMUTH SUBSALICYLATE	525 mg in 30 mL

### Inactive Ingredients

Ingredient Name	Strength
BENZOIC ACID (UNII: 8SKN0B0MIM)	
D&C RED NO. 22 (UNII: 1678RKX8RT)	
D&C RED NO. 28 (UNII: 767IP0Y5NH)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SALICYLIC ACID (UNII: O414PZ4LPZ)	
SODIUM SALICYLATE (UNII: WIQ1H85SYP)	
SORBIC ACID (UNII: X045WJ989B)	
WATER (UNII: 059QF0KO0R)	

### Product Characteristics

<b>Color</b>	pink	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	

<b>Flavor</b>	WINTERGREEN	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37000-032-04	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part335	03/31/1989	

### Part 2 of 2

### PEPTO-BISMOL

bismuth subsalicylate tablet

### Product Information

<b>Item Code (Source)</b>	NDC:37000-477
<b>Route of Administration</b>	ORAL

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BISMUTH SUBSALICYLATE (UNII: 62TEY51RR1) (BISMUTH CATION - UNII:ZS9CD118 YE, SALICYLIC ACID - UNII:O414PZ4LPZ)	BISMUTH SUBSALICYLATE	262 mg

### Inactive Ingredients

Ingredient Name	Strength
CALCIUM CARBONATE (UNII: H0G9379FGK)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
ALUMINUM OXIDE (UNII: LM26O6933)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 3OWL53L36A)	
POVIDONES (UNII: FZ989GH94E)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
TALC (UNII: 7SEV7J4R1U)	

### Product Characteristics

<b>Color</b>	pink	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	16mm

<b>Flavor</b>	WINTERGREEN	<b>Imprint Code</b>	Pepto;Bismol
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37000-477-10	8 in 1 CARTON		
1		6 in 1 CELLO PACK; Type 0: Not a Combination Product		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part335	03/01/2012	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part335	09/12/2011	

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