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.

Pepto-Bismol ™

Drug Facts

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

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

PEPTO-BISMOL

bismuth subsalicylate kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37000-402

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37000-402-01	1 in 1 PACKAGE; Type 0: Not a Combination Product	09/12/2011	

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	
Item Code (Source)	NDC:37000-032
Route of Administration	ORAL

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
BISMUTH SUBSALICYLATE (UNII: 62TEY51RR1) (BISMUTH CATION - UNII:ZS9CD1I8YE, 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			
Color	pink	Score	
Shape		Size	

Flavor	WINTERGREEN	**Imprint Code**	
Contains			

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	
Item Code (Source)	NDC:37000-477
Route of Administration	ORAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BISMUTH SUBSALICYLATE (UNII: 62TEY51RR1) (BISMUTH CATION - UNII:ZS9CD1I8YE, 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: LMI26O6933)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 3OWL53L36A)	
POVIDONE (UNII: FZ989GH94E)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics			
Color	pink	**Score**	no score
Shape	ROUND	**Size**	16mm

Flavor	WINTERGREEN	**Imprint Code**	Pepto;Bismol
Contains			

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)

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