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

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Pepto Bismol ® ULTRA

**Drug Facts** 

## Active ingredient (in each 15 mL dose)

Bismuth subsalicylate 525 mg

## **Purpose**

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**

- shake well before use
- only use dose cup provided
- adults and children 12 years and over:
- 15 mL (1 dose) every ½ hour or 30 mL (2 doses) every hour as needed for diarrhea/traveler's diarrhea
- 15 mL (1 dose) every ½ hour as needed for overindulgence (upset stomach, heartburn, indigestion, nausea)
- do not exceed 8 doses (120 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 15 mL dose cup contains: magnesium 3 mg, sodium 2 mg
  - o salicylate 230 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 - 236 mL Bottle Label

## P epto

**Bismol®ULTRA** 

Bismuth Subsalicylate Upset Stomach Reliever/ Antidiarrheal

2x CONCENTRATED FORMULA\*

#### **5 SYMPTOMRELIEF**

NAUSEA
HEARTBURN
INDIGESTION
UPSET STOMACH
DIARRHEA

8 FL OZ (236 mL)



## bismuth subsalicylate suspension

## **Product Information**

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37000-440
Flounct Lybe	HOMAN OTC DIOG	item code (Source)	NDC.37000-440

**Route of Administration** ORAL

# Active Ingredient/Active Moiety Ingredient Name BISMUTH SUBSALICYLATE (UNII: 62TEY51RR1) (SALICYLIC ACID - UNII: 0414PZ4LPZ) BISMUTH SUBSALICYLATE (UNII: 62TEY51RR1) (SALICYLIC ACID - UNII: 0414PZ4LPZ) BISMUTH SUBSALICYLATE in 15 mL

Inactive Ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		
METHYLCELLULOSE, UNSPECIFIED (UNII: Z944H5SN0H)		
GELLAN GUM (HIGH ACYL) (UNII: W1L7G7ROMD)		
BENZOIC ACID (UNII: 85KN0B0MIM)		
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)		
D&C RED NO. 22 (UNII: 1678RKX8RT)		
<b>D&amp;C RED NO. 28</b> (UNII: 767IP0Y5NH)		
SUCRALOSE (UNII: 96K6UQ3ZD4)		
SALICYLIC ACID (UNII: O414PZ4LPZ)		
SODIUM SALICYLATE (UNII: WQ1H85SYP)		
SORBIC ACID (UNII: X045W989B)		

Product Characteristics			
Color	pink	Score	
Shape		Size	
Flavor	WNTERGREEN	Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37000- 440-04	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/01/2018	
2	NDC:37000- 440-08	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/01/2018	
3	NDC:37000- 440-12	354 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/01/2018	
4	NDC:37000- 440-36	3 in 1 CELLO PACK	07/01/2024	
4		354 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 Drug	M008	03/01/2018	

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

Revised: 6/2024 The Procter & Gamble Manufacturing Company