

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

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**Pepto Bismol® ULTRA COATS & COOLS WITH INSTACOOOL™**

***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
  - 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 - 354 mL Bottle Label**

### **Pepto**

### **Bismol<sup>®</sup> ULTRA**

Bismuth Subsalicylate

Upset Stomach Reliever/ Antidiarrheal

COATS & COOLS

WITH

INSTACOOOL

### **5 SYMPTOM**

### **RELIEF**

NAUSEA

HEARTBURN

INDIGESTION

UPSET STOMACH

DIARRHEA

12 FL OZ (354 mL)

**Drug Facts** (continued)

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**

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• each 15 mL dose cup contains: magnesium 3 mg, sodium 2 mg  
• 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 seal around the neck is broken or missing

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**P&G**  
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**Pepto Bismol**<sup>®</sup>**ULTRA**

Bismuth Subsalicylate  
Upset Stomach Reliever/Antidiarrheal

**COATS & COOLS**  
WITH **INSTACOO**L™

**5 SYMPTOM RELIEF**

NAUSEA  
HEARTBURN  
INDIGESTION  
UPSET STOMACH  
DIARRHEA

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LOT

EXP

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## PEPTO BISMOL ULTRA

bismuth subsalicylate suspension

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69423-966
<b>Route of Administration</b>	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 15 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: 7671P0Y5NH)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>SALICYLIC ACID</b> (UNII: O414PZ4LPZ)	
<b>SODIUM SALICYLATE</b> (UNII: WMQ1H85SYP)	
<b>SORBIC ACID</b> (UNII: X045WJ989B)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>METHYLCELLULOSE (1500 MPA.S)</b> (UNII: PONTE48364)	
<b>GELLAN GUM (HIGH ACYL)</b> (UNII: W1L7G7ROMD)	
<b>METHYLCELLULOSE, UNSPECIFIED</b> (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:69423-966-12	354 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/07/2022	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M008	03/07/2022	

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

Revised: 10/2024

The Procter & Gamble Manufacturing Company