

**STOMACH RELIEF REGULAR STRENGTH- bismuth subsalicylate suspension  
CARDINAL HEALTH 110, LLC. DBA LEADER**

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**Regular Strength Stomach Relief Drug Facts**

**Active ingredient (in each 30 mL dose )**

Bismuth subsalicylate 525 mg

**Purposes**

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

**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 (1-800-222-1222).

### **Directions**

- shake well before use
- Only use dose cup provided
- **adults and children 12 years and over:** 30 mL (1 dose) every ½ hour or 60 mL (2 doses) every hour as needed for diarrhea/traveler's diarrhea
- 30 mL (1 dose) every ½ hour as needed for overindulgence (upset stomach, heartburn, indigestion, nausea)
- do not exceed 8 doses (240 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 30 mL contains:** potassium 14 mg, sodium 10 mg
- salicylate 260 mg
- low sodium
- sugar free
- store at room temperature

- protect from freezing
- avoid excessive heat (more than over 104°F or 40°C).

### **Inactive ingredients**

carboxymethylcellulose sodium, D&C red #22, D&C red #28, flavor, gellan gum, microcrystalline cellulose, potassium hydroxide, potassium sorbate, purified water, salicylic acid, Simethicone emulsion, sodium benzoate, sucralose, xanthan gum

### **Questions or comments?**

**1-866-467-2748**

**Safety Sealed: DO NOT USE IF IMPRINTED SHRINK BAND IS MISSING OR BROKEN**

### **Principal Display Panel**

NDC 70000-0698-1

COMPARE TO PEPTO-BISMOL® ORIGINAL LIQUID active ingredient\*

LEADER™

Regular Strength

Stomach Relief

**Bismuth Subsalicylate, 525 mg**

Upset Stomach Reliever/Antidiarrheal

**Original Flavor**

Relieves:

- Nausea
- Heartburn
- Indigestion
- Upset Stomach
- Diarrhea

8 FL OZ (236 mL)

100% Money Back Guarantee

Dist. By CAH DUBLIN, OH 43017

[www.myleader.com](http://www.myleader.com)

1-800-200-6313

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\*This product is not manufactured or distributed by Procter & Gamble, distributor of Pepto-Bismol® Original Liquid.

6.75" Width

3.25" Height

**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 at 1-800-222-1222.  
**Directions** ■ shake well before use ■ only use dose cup provided ■ adults and children 12 years and over: ■ 30 mL (1 dose) every ½ hour or 60 mL (2 doses) every hour as needed for diarrhea/traveler's diarrhea ■ 30 mL (1 dose) every ½ hour as needed for overindulgence (upset stomach, heartburn, indigestion, nausea) ■ do not exceed 8 doses (240 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 30 mL contains: potassium 14 mg, sodium 10 mg ■ salicylate 260 mg ■ low sodium ■ sugar free ■ store at room temperature ■ protect from freezing ■ avoid excessive heat (over 104°F or 40°C)  
**Inactive ingredients** carboxymethylcellulose sodium, D&C Red No. 22, D&C Red No. 28, flavor, gellan gum, microcrystalline cellulose, potassium hydroxide, potassium sorbate, purified water, salicylic acid, simethicone emulsion, sodium benzoate, sucralose, xanthan gum  
**Questions or comments?** 1-866-467-2748

LOT: 70608LDRLFE DIST. BY CAH DUBLIN, OH 43017  
 www.myleader.com 1-800-200-6313  
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 CIN 5920020 REV. 06/24  
 0 96295 14382 9  
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**LEADER**<sup>™</sup>

NDC 70000-0698-1

**Regular Strength**

**Stomach Relief**

Bismuth Subsalicylate, 525 mg  
 Upset Stomach Reliever / Antidiarrheal

**Original Flavor**

Relieves:

- Nausea
- Heartburn
- Indigestion
- Upset Stomach
- Diarrhea

COMPARE TO PEPTO-BISMOL® ORIGINAL LIQUID active ingredient\*

100% Money Back Guarantee

8 FL OZ (236 mL)

Do not use if imprinted shrink band is missing or broken

**Drug Facts**

Active ingredient (in each 30 mL dose)	Purpose
Bismuth subsalicylate 525 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

\*This product is not manufactured or distributed by Procter & Gamble, distributor of Pepto-Bismol® Original Liquid.

## STOMACH RELIEF REGULAR STRENGTH

bismuth subsalicylate suspension

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70000-0698
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>BISMUTH SUBSALICYLATE</b> (UNII: 62TEY51RR1) (BISMUTH CATION - UNII:ZS9CD1I8YE, SALICYLIC ACID - UNII:O414PZ4LPZ)	BISMUTH SUBSALICYLATE	525 mg in 30 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED</b> (UNII: K679OBS311)	
<b>D&amp;C RED NO. 22</b> (UNII: 1678RKX8RT)	
<b>D&amp;C RED NO. 28</b> (UNII: 7671P0Y5NH)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POTASSIUM HYDROXIDE</b> (UNII: WZH3C48M4T)	
<b>POTASSIUM SORBATE</b> (UNII: 1VPU26JZZ4)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SALICYLIC ACID</b> (UNII: O414PZ4LPZ)	
<b>DIMETHICONE, UNSPECIFIED</b> (UNII: 92RU3N3Y1O)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	

<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>GELLAN GUM (HIGH ACYL)</b> (UNII: W1L7G7ROMD)	

### Product Characteristics

<b>Color</b>	PINK (viscous)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	WINTERGREEN (ORIGINAL)	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0698-1	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/21/2024	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M008	10/21/2024	

**Labeler** - CARDINAL HEALTH 110, LLC. DBA LEADER (063997360)

Revised: 11/2024

CARDINAL HEALTH 110, LLC. DBA LEADER