

## **STOMACH RELIEF ULTRA- bismuth subsalicylate liquid** **Cardinal Health (Leader) 70000**

*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.*

-----

### **Drug Facts**

#### **Active ingredient (in each 15 mL)**

Bismuth subsalicylate 525 mg

#### **Purpose**

Upset stomach reliever/Antidiarrheal

#### **Uses**

relieves

- travelers' diarrhea
- diarrhea
- upset stomach due to overindulgence in food and drink, including:
  - heartburn
  - indigestion
  - nausea
  - gas
  - fullness
  - 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

- diabetes
- gout
- arthritis
- anticoagulation (thinning the blood)

### **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 (1-800-222-1222) right away.

### **Directions**

- do not take more than 8 doses (120 mL) in 24 hours
- use until diarrhea stops but not more than 2 days
- drink plenty of clear fluids to help prevent dehydration caused by diarrhea
- mL = milliliter
- shake well before using
- measure only with dosing cup provided. Do not use any other dosing device
- keep dosing cup with product
- adults and children 12 years and over:
  - 15 mL (1dose) every 1/2 or 30 mL (2 doses) every hour as needed diarrhea/traveler's diarrhea
  - 15 mL (1 dose) every 1/2 hour as needed for overindulgence (upset stomach, heartburn, indigestion, nausea)
- children under 12 years of age: ask a doctor

### **Other information**

- **each 15 mL contains:** sodium 5 mg
- **each 15 mL contains:** salicylate 206 mg
- low sodium
- keep tightly closed
- protect from freezing
- avoid excessive heat (over 104°F or 40°C)

### **Inactive ingredients**

benzoic acid, D&C red #22, D&C red #28, flavor, glycerin, purified water, sucralose, xanthan gum

### **Questions or comments?**

Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

### **Principal Display Panel**

COMPARE TO PEPTO-BISMOL® ULTRA active ingredient\*

Ultra

Stomach Relief

Bismuth Subsalicylate 525 mg per 15 mL

Upset Stomach Reliever / Antidiarrheal

Relieves

Heartburn, Indigestion, Nausea, Upset Stomach, Diarrhea

2x Strength per Ounce<sup>†</sup>

Alcohol Free

Sugar Free

FL OZ (mL)

<sup>†</sup>vs Original Pepto-Bismol®

\*This product is not manufactured or distributed by The Procter & Gamble Company. Pepto-Bismol® is a registered trademark of The Procter & Gamble Company.

**TAMPER EVIDENT; DO NOT USE IF PRINTED SAFETY SEAL AROUND DOSAGE CUP OR UNDER CAP IS BROKEN OR MISSING.**

DISTRIBUTED BY CARDINAL HEALTH

DUBLIN, OHIO 43017

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

### **Package Label**

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

**Directions** ■ do not take more than 8 doses (120 mL) in 24 hours  
 ■ use until diarrhea stops but not more than 2 days  
 ■ drink plenty of clear fluids to help prevent dehydration caused by diarrhea  
 ■ mL = milliliter ■ shake well before using  
 ■ measure only with dosing cup provided. Do not use any other dosing device.  
 ■ keep dosing cup with product  
 ■ 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)  
 ■ children under 12 years of age: ask a doctor

**Other information** ■ each 15 mL contains: sodium 5 mg  
 ■ each 15 mL contains: salicylate 206 mg ■ low sodium ■ keep tightly closed  
 ■ protect from freezing ■ avoid excessive heat (over 104°F or 40°C)

**Inactive ingredients** benzoic acid, D&C red #22, D&C red #28, flavor, glycerin, purified water, sucralose, xanthan gum

**Questions or comments?**  
 Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

\*This product is not manufactured or distributed by The Procter & Gamble Company. Pepto-Bismol® is a registered trademark of The Procter & Gamble Company.  
 vs. Original Pepto-Bismol®  
 ©2020 CARDINAL HEALTH, LEADER, and LOGOs are trademarks of Cardinal Health. All other marks are the property of their respective owners.  
 DISTRIBUTED BY CARDINAL HEALTH  
 DUBLIN, OHIO 43017  
 www.myleader.com 1-800-200-6335  
**100% Money Back Guarantee**  
 Return to place of purchase if not satisfied.  
 PLD-A494A LBO07548

**Drug Facts** TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL AROUND DOSAGE CUP OR UNDER CAP IS BROKEN OR MISSING.

**Active ingredient** (in each 15 mL dose)  
 Bismuth subsalicylate 525 mg.....Upset stomach reliever/Antidiarrheal

**Purpose**

**Uses** relieves ■ travelers' diarrhea ■ diarrhea  
 ■ upset stomach due to overindulgence in food and drink, including  
 ■ heartburn ■ gas ■ indigestion  
 ■ nausea ■ fullness ■ 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 ■ diabetes ■ gout ■ arthritis  
 ■ anticoagulation (thinning the blood)

**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

**LEADER Ultra Stomach Relief**

**STOMACH RELIEF ULTRA**

bismuth subsalicylate liquid

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70000-0045
<b>Route of Administration</b>	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 15 mL

**Inactive Ingredients**

Ingredient Name	Strength
BENZOIC ACID (UNII: 8SKN0B0MIM)	
D&C RED NO. 22 (UNII: 1678RKX8RT)	
D&C RED NO. 28 (UNII: 767IP0Y5NH)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0K00R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

**Packaging**

#	Item Code	Package Description	Marketing Start	Marketing End
---	-----------	---------------------	-----------------	---------------

#	Item Code	Package Description	Date	Date
1	NDC:70000-0045-1	355 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/25/2020	

  

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part335	02/25/2020	

**Labeler** - Cardinal Health (Leader) 70000 (097537435)

Revised: 2/2020

Cardinal Health (Leader) 70000