

**LEADER STOMACH RELIEF - bismuth subsalicylate liquid**  
**CARDINAL HEALTH 110, LLC. DBA LEADER**

*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.*

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**Leader Stomach Relief Liquid**

**ACTIVE INGREDIENT(in each 30 mL)**

Bismuth subsalicylate 525 mg

**PURPOSE**

Upset stomach reliever and anti-diarrheal

**USE(S)**

relieves:

- diarrhea
- heartburn
- indigestion
- nausea
- upset stomach associated with these symptoms

**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
- bloody or black stool

- a bleeding problem

### **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 of 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 DOCTOR IF**

- symptoms get worse
- 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 immediately.

### **DIRECTIONS**

- **shake well before use**
- mL = milliliter
- TBSP = tablespoon
- adults and children 12 years and over: 1 dose (2 TBSP or 30 mL) every 1/2 to 1 hour as needed
- do not exceed 8 doses (16 TBSP or 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 fluids to help prevent dehydration caused by diarrhea

### **OTHER INFORMATION**

- **each 30 mL or 2 TBSP contains:**
- potassium 25 mg
- salicylate 260 mg
- sodium 8 mg
- protect from freezing
- avoid excessive heat (over 104°F or 40°C)
- dosage cup provided

## **INACTIVE INGREDIENTS**

benzoic acid, D&C red # 22, D&C red # 28, flavor, hydroxyethyl cellulose, potassium hydroxide, purified water, saccharin sodium, salicylic acid, simethicone, xanthan gum

## **PRINCIPAL DISPLAY PANEL**

**LEADER™**

NDC 70000-0439-2

**Stomach Relief**

Bismuth Subsalicylate, 525 mg

Upset Stomach Reliever/Anti-diarrheal

5 Symptom Digestive Relief:

Diarrhea, Heartburn, Indigestion, Nausea & Upset Stomach

COMPARE TO PEPTO-BISMOL active ingredient\*

8 FL OZ (236 mL)

**Drug Facts** DO NOT USE IF IMPRINTED SHRINKBAND IS MISSING OR BROKEN.

**Active ingredient (in each 30 mL)** *Purpose*  
Bismuth subsalicylate 525 mg .....Upset stomach reliever and anti-diarrheal

**Uses** relieves: ■ diarrhea ■ heartburn ■ indigestion ■ nausea ■ upset stomach associated with these symptoms

**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 ■ bloody or black stool ■ a bleeding problem  
**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 of 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 ■ 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 immediately.

◀ *Drug Facts continued*

**LEADER<sup>2</sup>**

NDC 70000-0439-2

# Stomach Relief

**Bismuth Subsalsicylate, 525 mg**  
**Upset Stomach Reliever / Anti-diarrheal**

**COMPARE TO PEPTO-BISMOL<sup>®</sup> active ingredient\***

**100% Money Back Guarantee**

5 Symptom Digestive Relief  
Diarrhea, Heartburn, Indigestion, Nausea & Upset Stomach

8 FL OZ (236 mL)

**Drug Facts (continued)**

**Directions** ■ shake well before use  
■ mL = milliliter ■ TBSP = tablespoon ■ adults and children 12 years and over: 1 dose (2 TBSP or 30 mL) every 1/2 to 1 hour as needed ■ do not exceed 8 doses (16 TBSP or 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 or 2 TBSP contains:  
• potassium 25 mg • salicylate 260 mg • sodium 8 mg  
■ protect from freezing. ■ avoid excessive heat (over 104°F or 40°C). ■ dosage cup provided

**Inactive ingredients** benzoic acid, D&C red # 22, D&C red # 28, flavor, hydroxyethyl cellulose, potassium hydroxide, purified water, saccharin sodium, salicylic acid, simethicone, xanthan gum.

\*This product is not manufactured or distributed by Procter & Gamble, owner of the registered trademark Pepto-Bismol®.

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CardinalHealth™ MFR# 53041

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100% Money Back Guarantee

Return to place of purchase.

CIN 5489356 REV 3/19



Questions? 609-860-2600 (Ext. 700)

## LEADER STOMACH RELIEF

bismuth subsalsicylate liquid

### Product Information

|                                |                |                           |                |
|--------------------------------|----------------|---------------------------|----------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:70000-0439 |
| <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 30 mL |

### Inactive Ingredients

| Ingredient Name   | Strength |
|---|----------|
| <b>BENZOIC ACID</b> (UNII: 8SKN0B0MIM)                              |          |
| <b>D&amp;C RED NO. 22</b> (UNII: 1678RKX8RT)                        |          |
| <b>D&amp;C RED NO. 28</b> (UNII: 7671P0Y5NH)                        |          |
| <b>POTASSIUM HYDROXIDE</b> (UNII: WZ H3C48M4T)                      |          |
| <b>WATER</b> (UNII: 059QF0KO0R)                                     |          |
| <b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)                          |          |
| <b>SALICYLIC ACID</b> (UNII: O414PZ4LPZ)                            |          |
| <b>HYDROXYETHYL CELLULOSE (1500 MPA.S AT 1%)</b> (UNII: L605B5892V) |          |
| <b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)                               |          |
| <b>XANTHAN GUM</b> (UNII: TTV12P4NEE)                               |          |

**Product Characteristics**

|                 |      |                     |  |
|-----------------|------|---------------------|--|
| <b>Color</b>    | PINK | <b>Score</b>        |  |
| <b>Shape</b>    |      | <b>Size</b>         |  |
| <b>Flavor</b>   |      | <b>Imprint Code</b> |  |
| <b>Contains</b> |      |                     |  |

**Packaging**

| # | Item Code        | Package Description                                   | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:70000-0439-2 | 236 mL in 1 BOTTLE; Type 0: Not a Combination Product | 06/07/2019           |                    |
| 2 | NDC:70000-0439-1 | 118 mL in 1 BOTTLE; Type 0: Not a Combination Product | 06/07/2019           |                    |

**Marketing Information**

| Marketing Category  | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC MONOGRAPH FINAL | part335                                  | 06/07/2019           |                    |

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

Revised: 1/2022

CARDINAL HEALTH 110, LLC. DBA LEADER