

**ULTRA STRENGTH STOMACH RELIEF - bismuth subsalicylate liquid**  
**Guardian Drug Company**

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**Ultra Strength Stomach Relief Liquid**

**ACTIVE INGREDIENT(in each 15 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 (1 TBSP or 15 mL) every 1/2 hour as needed
- 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 fluids to help prevent dehydration caused by diarrhea

## **OTHER INFORMATION**

- **each 15 mL or 1 TBSP contains:**
- potassium 15 mg
- salicylate 236 mg
- sodium 5 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**

### GUARDIAN

\*Compare to the active ingredient of **Pepto-Bismol® Ultra Strength**  
NDC 53041-529-04

### **Pink-Bismuth Ultra Strength**

### **Protective Coating**

### **Bismuth Subsalicylate 525 mg/ 15 mL**

Anti-diarrheal/Upset stomach reliever

### **Soothing Relief For:**

- Upset stomach
- Indigestion
- Nausea
- Heartburn
- Diarrhea

8 FL OZ (236 mL)

**Drug Facts**

DO NOT USE IF IMPRINTED SHRINKBAND IS MISSING OR BROKEN.

**Active ingredient (per 15 mL)**

Bismuth subsalicylate 525 mg .....Upset stomach reliever and anti-diarrheal

**Purpose****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



\*Compare to the active ingredient of Pepto-Bismol® Ultra Strength.

NDC 53041-529-04

# Pink-Bismuth

## Ultra Strength

### Protective Coating

**Bismuth Subsalicylate 525 mg/ 15 mL**

Anti-diarrheal/Upset stomach reliever

### Soothing Relief For:

- Upset stomach
- Indigestion
- Nausea
- Heartburn
- Diarrhea

**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 (1 TBSP or 15 mL) every 1/2 hour as needed ■ 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 or 1 TBSP contains:

- potassium 15 mg • salicylate 236 mg • sodium 5 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 &amp; Gamble, Inc., the distributor of Pepto-Bismol® Ultra Strength.

**Guardian Drug Company**2 Charles Court  
Dayton, NJ 08810

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REV 01/25  
MFR# 53041

## ULTRA STRENGTH STOMACH RELIEF

bismuth subsalicylate liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:53041-529
<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>D&amp;C RED NO. 22</b> (UNII: 1678RKX8RT)	
<b>D&amp;C RED NO. 28</b> (UNII: 767IP0Y5NH)	
<b>POTASSIUM HYDROXIDE</b> (UNII: WZH3C48M4T)	
<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:53041-529-04	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/10/2025	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M008	02/10/2025	

**Labeler** - Guardian Drug Company (119210276)

## Establishment

Name	Address	ID/FEI	Business Operations
Guardian Drug Company		119210276	MANUFACTURE(53041-529)

Revised: 3/2025

Guardian Drug Company