

# **STOMACH RELIEF ULTRA STRENGTH- bismuth subsalicylate liquid**

## **P & L Development, LLC**

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### **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 (1 dose) every 1/2 hour or 30 mL (2 doses) every hour as needed for diarrhea/traveler's diarrhea
  - 15 mL (1 dose) every 1/2 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 6 mg
- **each 15 mL contains:** salicylate 227 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, magnesium aluminum silicate, methylcellulose, purified water, saccharin sodium, salicylic acid, sodium salicylate, sorbic acid

### **Questions or comments?**

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

### **Principal Display Panel**

Compare to the active ingredient in **Pepto-Bismol® Ultra\***

### **Ultra Stomach Relief**

Bismuth subsalicylate 525 mg

upset stomach reliever/antidiarrheal

Relieves:

- heartburn
- indigestion
- nausea
- upset stomach
- diarrhea

2x strength per ounce†

alcohol free

sugar free

FL OZ (mL)

\*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.**

Manufactured by:

PL Developments

11865 S. Alameda St

Lynwood, CA 90262

### **Package Label**

**Drug Facts** (continued)

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 1/2 hour or 30 mL (2 doses) every hour as needed for 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

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vs. Original Pepto-Bismol®

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Manufactured by:  
**PL Developments**  
 11865 S. Alameda St  
 Lynwood, CA 90262



Compare to the active ingredient in  
**Pepto-Bismol® Ultra\***  
 NDC 49580-0842-8

Ultra  
 stomach  
 relief

bismuth  
 subsalicylate 525 mg  
 upset stomach reliever/  
 antidiarrheal

relieves:

- heartburn
- indigestion
- nausea
- upset stomach
- diarrhea

2x strength per ounce†

alcohol free  
 sugar free

8 fl oz (237 mL)

**Drug Facts**

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 Antidiarrheal

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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.**

**READYinCASE Stomach Relief Ultra****STOMACH RELIEF ULTRA STRENGTH**

bismuth subsalicylate liquid

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:49580-0842
<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)	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>MAGNESIUM ALUMINUM SILICATE</b> (UNII: 6M3P64V0NC)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>SALICYLIC ACID</b> (UNII: O414PZ4LPZ)	
<b>SODIUM SALICYLATE</b> (UNII: WQ1H85SYP)	
<b>SORBIC ACID</b> (UNII: X045WJ989B)	
<b>METHYLCELLULOSE (1500 CPS)</b> (UNII: PONTE48364)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49580-0842-8	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/28/2019	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M008	02/28/2019	

**Labeler** - P & L Development, LLC (101896231)

Revised: 4/2024

P &amp; L Development, LLC