

**STOMACH RELIEF ULTRA- bismuth subsalicylate liquid**  
**Rugby Laboratories, Inc.**

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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 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 **1-800-645-2158**

### **Principal Display Panel**

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

Extra Strength

Stomach Relief

Bismuth Subsalicylate 525 mg

Upset Stomach Reliever/Antidiarrheal

Relieves:

- Heartburn
- Indigestion
- Nausea

2x Strength Per Ouncet

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.

†vs Original Pepto-Bismol®

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

Distributed by:

RUGBY® LABORATORIES

17177 N Laurel Park Drive

Suite 233, Livonia, MI 48152

[www.rugbylaboratories.com](http://www.rugbylaboratories.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 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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17177 N Laurel Park Drive  
Suite 233, Livonia, MI 48152  
www.rugbylaboratories.com  
PLD-A494A LB007597

Rev. 03/20 R-58 Re-order No. 371022



NDC 0536-1287-36

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

# Extra Strength Stomach Relief Bismuth Subsalicylate

Upset Stomach Reliever/Antidiarrheal

**525 mg**

Relieves:

- Heartburn ▪ Indigestion ▪ Nausea

2x Strength Per Ounce†

Alcohol Free ▪ Sugar Free

**8 FL OZ (237 mL)**

**Drug Facts**

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

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**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

## RUGBY Extra Strength Stomach Relief

# STOMACH RELIEF ULTRA

bismuth subsalicylate liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0536-1287
<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 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: 7671P0Y5NH)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0536-1287-36	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/29/2020	
<b>Marketing Information</b>				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M008	03/29/2020		

**Labeler** - Rugby Laboratories, Inc. (079246066)

Revised: 4/2024

Rugby Laboratories, Inc.