

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

*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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**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 **1-800-645-2158**

## **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 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.

†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)

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**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  
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**RUGBY® LABORATORIES**  
 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)**  
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 ■ 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
BISMUTH SUBSALICYLATE (UNII: 62TEY51RR1) (BISMUTH CATION - UNII:ZS9CD1I8 YE, SALICYLIC ACID - UNII:O414PZ4LPZ)	BISMUTH SUBSALICYLATE	525 mg in 15 mL

### Inactive Ingredients

Ingredient Name	Strength
BENZOIC ACID (UNII: 8 SKN0 B0 MIM)	
D&C RED NO. 22 (UNII: 1678RKX8RT)	
D&C RED NO. 28 (UNII: 767IP0 Y5NH)	
GLYCERIN (UNII: PDC6 A3C0 OX)	
WATER (UNII: 059QF0 KO0R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

### Packaging

#	Item Code	Package Description	Marketing Start	Marketing End
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#	Item Code	Package Description	Date	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>				
	<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
	OTC MONOGRAPH FINAL	part335	03/29/2020	

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

Revised: 3/2020

Rugby Laboratories, Inc.