

STOMACH RELIEF REGULAR STRENGTH- bismuth subsalicylate liquid

Rugby Laboratories, Inc.

Drug Facts

Active ingredient (in each 30 mL dose)

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

- 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
 - 30 mL (1 dose) every 1/2 or 60 mL (2 doses) every hour as needed for diarrhea/traveler's diarrhea
 - 30 mL (1 dose) every 1/2 hour as needed for overindulgence (upset stomach, heartburn, indigestion, nausea)
 - do not exceed 8 doses (240 mL) in 24 hours
 - use until diarrhea stops but not more than 2 days
- children under 12 years of age: ask a doctor
- drink plenty of clear fluids to help prevent dehydration caused by diarrhea

Other information

- **each 30 mL contains:** potassium 8 mg sodium 9 mg
- **each 30 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®*

Regular Strength

Stomach Relief

Bismuth Subsalicylate

Upset Stomach Reliever/Antidiarrheal

Relieves:

• Heartburn • Indigestion • Nausea

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

Distributed by:

RUGBY LABORATORIES

17177 N Laurel Park Drive

Suite 233, Livonia, MI 48152

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 ■ 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: ■ 30 mL (1 dose) every ½ hour or 60 mL (2 doses) every hour as needed for diarrhea/traveler's diarrhea ■ 30 mL (1 dose) every ½ hour as needed for overindulgence (upset stomach, heartburn, indigestion, nausea) ■ do not exceed 8 doses (240 mL) in 24 hours ■ use until diarrhea stops but not more than 2 days ■ children under 12 years of age: ask a doctor ■ drink plenty of clear fluids to help prevent dehydration caused by diarrhea

Other information ■ each 30 mL contains: potassium 8 mg, sodium 9 mg ■ each 30 mL contains: salicylate 206 mg ■ low sodium ■ keep tightly closed ■ protect from freezing ■ avoid excessive heat (over 104°F or 40°C)

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RUGBY[®] LABORATORIES
17177 N Laurel Park Drive
Suite 233, Livonia, MI 48152
www.rugbylaboratories.com
PLD-A492B LB007561



NDC 0536-1286-36

Compare to the active ingredient in Pepto-Bismo[®]**

Regular Strength Stomach Relief

Bismuth Subsalicylate

Upset Stomach Reliever/Antidiarrheal

525 mg

Relieves:

- Heartburn ▪ Indigestion ▪ Nausea

Alcohol Free • Sugar Free

8 FL OZ (237 mL)

Drug Facts

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STOMACH RELIEF REGULAR STRENGTH

bismuth subsalicylate liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0536-1286
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BISMUTH SUBSALICYLATE (UNII: 62TEY51RR1) (BISMUTH CATION - UNII:ZS9CD1I8YE, SALICYLIC ACID - UNII:O414PZ4LPZ)	BISMUTH SUBSALICYLATE	525 mg in 30 mL

Inactive Ingredients

Ingredient Name	Strength
BENZOIC ACID (UNII: 8SKN0B0MIM)	
D&C RED NO. 22 (UNII: 1678RKX8RT)	
D&C RED NO. 28 (UNII: 767IP0Y5NH)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
XANTHAN GUM (UNII: TTV12P4NEE)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0536-1286-36	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/29/2020	
Marketing Information				
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.