

STOMACH RELIEF REGULAR STRENGTH- bismuth subsalicylate liquid
Safeway, 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.

Drug Facts

Active ingredient (in each 30 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 right away. (1-800-222-1222)

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 6 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 1-877-753-3935 Monday-Friday 9AM-5PM EST

Principal Display Panel

Compare to Pepto-Bismol® active ingredient*

Regular Strength

Stomach Relief

BISMUTH SUBSALICYLATE 525 mg

Upset Stomach Reliever/Antidiarrheal

Relief of:

Heartburn, indigestion, nausea,

upset stomach, diarrhea

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: BETTER LIVING BRANDS LLC

P.O. BOX 99, PLEASANTON, CA 94566-0009

www.betterlivingbrandsLLC.com

Package Label

Drug Facts (continued)

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 6 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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3 21130 77792 2



Scan here for more information

Alcohol free
Sugar free

12 FL OZ (355 mL)

Signature Care
Quality Guaranteed

Compare to Pepto-Bismol® active ingredient*
NDC 21130-624-12

Drug Facts

Active ingredient (in each 30 mL dose)	Purpose
Bismuth subsalicylate 525 mg.....Upset stomach reliever/Antidiarrheal	

Uses relieves ■ diarrhea ■ travelers' diarrhea ■ upset stomach due to overindulgence in food and drink, including ■ heartburn ■ gas ■ indigestion ■ nausea ■ fullness ■ belching

Warnings
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Ask a doctor or pharmacist before use if you are taking any drug for
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When using this product a temporary, but harmless, darkening of the stool and/or tongue may occur.

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■ ringing in the ears or loss of hearing occurs
■ diarrhea lasts more than 2 days

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SIGNATURE CARE Regular Strength Stomach Relief

STOMACH RELIEF REGULAR STRENGTH

bismuth subsalicylate liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:21130-624
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BISMUTH SUBSALICYLATE (UNII: 62TEY51RR1) (BISMUTH CATION - UNII:ZS9CD118YE, 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:21130-624-08	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/29/2019	
2	NDC:21130-624-12	355 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/29/2019	
3	NDC:21130-624-16	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/29/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part335	11/29/2019	

Labeler - Safeway, Inc. (009137209)