

STOMACH RELIEF ORIGINAL STRENGTH- bismuth subsalicylate liquid
Cardinal Health (Leader) 70000

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

Principal Display Panel

COMPARE TO PEPTO-BISMOL® active ingredient*

Original Strength**Stomach Relief**

Bismuth Subsalicylate, 525 mg per 30 mL

Up[set Stomach Reliever / Antidiarrheal

Relieves 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 CARDINAL HEALTH, DUBLIN, OHIO 43017

www.myleader.com

Package Label

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL AROUND BOTTLE OR UNDER CAP IS BROKEN OR MISSING. PLD-A492A LB007550

*This product is not manufactured or distributed by The Procter & Gamble Company. Pepto-Bismol® is a registered trademark of The Procter & Gamble Company.

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www.myleader.com 1-800-200-6313

Drug Facts (continued)

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← PEEL HERE **Drug Facts (continued under label)**

LEADER²

NDC 70000-0044-1

Original Strength Stomach Relief

Bismuth Subsalicylate, 525 mg per 30 mL
Upset Stomach Reliever / Antidiarrheal

Relieves
Heartburn, Indigestion,
Nausea, Upset Stomach,
Diarrhea

Alcohol-Free
Sugar-Free

COMPARE TO PEPTO-BISMOL® active ingredient*

100% Money Back Guarantee

4 FL OZ (118 mL)

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LEADER Original Strength Stomach Relief

STOMACH RELIEF ORIGINAL STRENGTH			
bismuth subsalicylate liquid			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0044
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
BISMUTH SUBSALICYLATE (UNII: 62TEY51RR1) (BISMUTH CATION - UNII:ZS9CD118 YE, 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: 059QF0K00R)			

XANTHAN GUM (UNII: TTV12P4NEE)

SUCRALOSE (UNII: 96K6UQ3ZD4)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0044-1	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/25/2020	
2	NDC:70000-0044-2	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/25/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part335	02/25/2020	

Labeler - Cardinal Health (Leader) 70000 (097537435)

Revised: 2/2020

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