

STOMACH RELIEF ULTRA- 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 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 **1-877-753-3935** Monday-Friday 9AM-5PM EST

Principal Display Panel

COMPARE TO PEPTO-BISMOL® ULTRA active ingredient*

Ultra

Stomach Relief

Bismuth Subsalicylate 525 mg per 15 mL

Upset Stomach Reliever / Antidiarrheal

Relieves

Heartburn, Indigestion, Nausea, Upset Stomach, Diarrhea

2x Strength per Ounce†

Alcohol Free

Sugar Free

FL OZ (mL)

†vs Original Pepto-Bismol®

*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.

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DUBLIN, OHIO 43017

www.myleader.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
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 ■ 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 ½ hour or 30 mL (2 doses) every hour as needed for diarrhea/traveler's diarrhea
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 *vs. Original Pepto-Bismol®
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 DUBLIN, OHIO 43017
 www.myleader.com 1-800-200-5315
100% Money Back Guarantee
 Return to place of purchase if not satisfied.
 PLD-A494A LB007548

LEADER™

NDC 70000-0045-1

Ultra
Stomach Relief
 Bismuth Subsalicylate, 525 mg per 15 mL
 Upset Stomach Reliever / Antidiarrheal

Relieves
 Heartburn, Indigestion,
 Nausea, Upset Stomach,
 Diarrhea

2x Strength per Ounce†
 Alcohol-Free
 Sugar-Free

**COMPARE TO
 PEPTO-BISMOL®
 ULTRA
 active ingredient***

**100% Money
 Back Guarantee**

12 FL OZ (355 mL)

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Active ingredient **Purpose**
 (in each 15 mL dose)
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LEADER Ultra Stomach Relief

STOMACH RELIEF ULTRA			
bismuth subsalicylate liquid			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0045
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 15 mL
Inactive Ingredients			
Ingredient Name		Strength	
BENZOIC ACID (UNII: 8SKN0B0MIM)			
D&C RED NO. 22 (UNII: 1678RKX8RT)			
D&C RED NO. 28 (UNII: 7671POY5NH)			
GLYCERIN (UNII: PDC6A3C0OX)			
WATER (UNII: 059QF0KO0R)			
SUCRALOSE (UNII: 96K6UQ3ZD4)			
XANTHAN GUM (UNII: TTV12P4NEE)			
Packaging			

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0045-1	355 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 (063997360)

Revised: 11/2022

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