

STOMACH RELIEF ULTRA STRENGTH- bismuth subsalicylate liquid Care One (Retail Business Services, LLC.)

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 the active ingredient in Pepto-Bismol® Ultra*

ULTRA Strength

STOMACH RELIEF

Bismuth Subsalicylate 525 mg

Upset Stomach Reliever / Antidiarrheal

Original Flavor

5 SYMPTOM DIGESTIVE RELIEF

NAUSEA, HEARTBURN, INDIGESTION, UPSET STOMACH, DIARRHEA

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.

TAMPER EVIDENT; DO NOT USE IF PRINTED SAFETY SEAL AROUND DOSAGE CUP OR UNDER CAP IS BROKEN OR MISSING.

DISTRIBUTED BY: FOODHOLD U.S.A., LLC LANDOVER, MD 20785

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 ■ 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 ½ hour or 30 mL (2 doses) every hour as needed for diarrhea/traveler's diarrhea ■ 15 mL (1 dose) every ½ hour as needed for overindulgence (upset stomach, heartburn, indigestion, nausea) ■ children under 12 years of age: ask a doctor

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For product questions or concerns, contact us at 1-877-846-9949 © 2020 Ahold Delhaize Licensing Sàrl Quality guaranteed or your money back. PLD-A494A LB007278

NDC 72476-737-08

CAREone®

Compare to the active ingredient in Pepto-Bismol® Ultra*

ULTRA STRENGTH STOMACH RELIEF

Bismuth Subsalicylate 525 mg Upset Stomach Reliever/Antidiarrheal

Original Flavor

5 SYMPTOM DIGESTIVE RELIEF: NAUSEA, HEARTBURN, INDIGESTION, UPSET STOMACH, DIARRHEA

ALCOHOL FREE
SUGAR FREE
2X STRENGTH PER OUNCE†

8 FL OZ (237mL)



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CARE ONE Ultra Strength Stomach Relief

STOMACH RELIEF ULTRA STRENGTH

bismuth subsalicylate liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72476-737
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BISMUTH SUBSALICYLATE (UNII: 62TEY51RR1) (BISMUTH CATION - UNII:Z59CD1I8YE, 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: 7671P0Y5NH)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
SUCRALOSE (UNII: 96K6UQ3Z D4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72476-737-12	355 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/27/2019	
2	NDC:72476-737-08	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/27/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M008	12/27/2019	

Labeler - Care One (Retail Business Services, LLC.) (967989935)

Revised: 3/2024

Care One (Retail Business Services, LLC.)