

STOMACH RELIEF ULTRA STRENGTH- bismuth subsalicylate liquid

P & L Development, 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 hour or 30 mL (2 doses) every hour as needed for diarrhea/traveler's diarrhea
 - 15 mL (1 dose) every 1/2 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 Stomach Relief

Bismuth subsalicylate 525 mg

upset stomach reliever/antidiarrheal

Relieves:

- heartburn
- indigestion
- nausea
- 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.

Manufactured by:

PL Developments

11865 S. Alameda St

Lynwood, CA 90262

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

Other information ■ each 15 mL contains: sodium 5 mg
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†vs. Original Pepto-Bismol®



Manufactured by:
PL Developments
 11865 S. Alameda St
 Lynwood, CA 90262



Compare to the active ingredient in
Pepto-Bismol® Ultra*
 NDC 49580-0737-2



relieves:

- heartburn
- indigestion
- nausea
- upset stomach
- diarrhea

2x strength per ounce†

alcohol free
 sugar free

12 fl oz (355 mL)

Drug Facts

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Active ingredient (in each 15 mL dose)
 Bismuth subsalicylate 525 mg.....Upset stomach reliever/Antidiarrheal

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READYinCASE Ultra Stomach Relief**STOMACH RELIEF ULTRA STRENGTH**

bismuth subsalicylate liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49580-0737
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BISMUTH SUBSALICYLATE (UNII: 62TEY51RR1) (BISMUTH CATION - UNII:ZS9CD1I8YE)	BISMUTH SUBSALICYLATE	525 mg in 15 mL

Inactive Ingredients

Ingredient Name	Strength
BENZOIC ACID (UNII: 8SKNOB0MIM)	
D&C RED NO. 22 (UNII: 1678RKX8RT)	
D&C RED NO. 28 (UNII: 767IP0Y5NH)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging

Marketing Start Marketing End

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49580-0737-8	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/30/2019	
2	NDC:49580-0737-2	355 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/30/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M008	09/30/2019	

Labeler - P & L Development, LLC (101896231)

Revised: 10/2023

P & L Development, LLC