

STOMACH RELIEF ULTRA- bismuth subsalicylate liquid **McKesson (Health Mart)**

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 (1dose) 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 6 mg
- **each 15 mL contains:** salicylate 227 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, magnesium aluminum silicate, methylcellulose, purified water, saccharin sodium, salicylic acid, sodium salicylate, sorbic acid

Questions or comments?

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

Principal Display Panel

Compare to 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.

Distributed by McKesson

One Post Street, San Francisco, CA 94104

www.healthmart.com

Package Label

<p>Drug Facts (continued) In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.</p> <p>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 hour as needed for overindulgence (upset stomach, heartburn, indigestion, nausea) ■ children under 12 years of age: ask a doctor</p> <p>Other information ■ each 15 mL contains: sodium 6 mg ■ each 15 mL contains: salicylate 227 mg ■ low sodium ■ keep tightly closed ■ protect from freezing ■ avoid excessive heat (over 104°F or 40°C)</p> <p>Inactive ingredients benzoic acid, D&C red #22, D&C red #28, flavor, magnesium aluminum silicate, methylcellulose, purified water, saccharin sodium, salicylic acid, sodium salicylate, sorbic acid</p> <p>Questions or comments? Call 1-877-753-3935 Monday-Friday 9AM-5PM EST</p> <p><small>*This product is not manufactured or distributed by The Procter & Gamble Company. Pepto-Bismol® is a registered trademark of The Procter & Gamble Company. *vs. Original Pepto-Bismol®</small></p> <p>MCKESSON Distributed by McKesson One Post Street, San Francisco, CA 94104 Money Back Guarantee healthmart.com</p> <p>PLD-A559A LB006483</p>  <p>0 52569 14249 3</p>	<p>NDC 62011-0394-1</p>  <p>Health Mart.</p> <p>Compare to the active ingredient in Pepto-Bismol® Ultra†</p> <p>ULTRA</p> <p>Stomach Relief</p> <p>Bismuth Subsalicylate 525 mg</p> <p>Upset Stomach Reliever/Antidiarrheal</p> <p>Relieves: Heartburn, Indigestion, Nausea, Upset Stomach, Diarrhea</p> <p>2x Strength Per Ounce* Alcohol Free • Sugar Free</p> <p>8 Fl oz (237 mL)</p>	<p>Drug Facts TAMPER EVIDENT; DO NOT USE IF PRINTED SAFETY SEAL AROUND DOSAGE CUP OR UNDER CAP IS BROKEN OR MISSING.</p> <table border="1"><thead><tr><th>Active ingredient (in each 15 mL)</th><th>Purpose</th></tr></thead><tbody><tr><td>Bismuth subsalicylate 525 mg.....</td><td>Upset stomach reliever/ Antidiarrheal</td></tr></tbody></table> <p>Uses relieves ■ travelers' diarrhea ■ diarrhea ■ upset stomach due to overindulgence in food and drink, including ■ heartburn ■ indigestion ■ nausea ■ gas ■ fullness ■ belching</p> <p>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</p> <p>Do not use if you have ■ an ulcer ■ a bleeding problem ■ bloody or black stool</p> <p>Ask a doctor before use if you have ■ fever ■ mucus in the stool</p> <p>Ask a doctor or pharmacist before use if you are taking any drug for ■ diabetes ■ gout ■ arthritis ■ anticoagulation (thinning the blood)</p> <p>When using this product a temporary, but harmless, darkening of the stool and/or tongue may occur.</p> <p>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</p> <p>If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children.</p>	Active ingredient (in each 15 mL)	Purpose	Bismuth subsalicylate 525 mg.....	Upset stomach reliever/ Antidiarrheal
Active ingredient (in each 15 mL)	Purpose					
Bismuth subsalicylate 525 mg.....	Upset stomach reliever/ Antidiarrheal					

HEALTH MART Ultra Stomach Relief

STOMACH RELIEF ULTRA

bismuth subsalicylate liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62011-0394
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 15 mL

Inactive Ingredients

Ingredient Name	Strength
BENZOIC ACID (UNII: 8SKN0B0MIM)	
D&C RED NO. 22 (UNII: 1678RXX8RT)	
D&C RED NO. 28 (UNII: 767IP0Y5NH)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
WATER (UNII: 059QF0K00R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SALICYLIC ACID (UNII: O414PZ4LPZ)	
SODIUM SALICYLATE (UNII: WIQ1H85SYP)	
SORBIC ACID (UNII: X045WJ989B)	
METHYLCELLULOSE (1500 CPS) (UNII: P0NTE48364)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62011-0394-1	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/31/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part335	12/31/2018	

Labeler - McKesson (Health Mart) (177667227)