

STOMACH RELIEF- bismuth subsalicylate suspension

CVS Pharmacy

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.

CVS Pharmacy, Inc. Stomach Relief Drug Facts

Active ingredient (in each 30 mL)

Bismuth subsalicylate 1050 mg

Purposes

Upset stomach reliever and antidiarrheal

Uses

relieves

- travelers' diarrhea
- diarrhea
- upset stomach due to overindulgence in food and drink, including:
- heartburn
- indigestion
- nausea
- gas
- belching
- fullness

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

- anticoagulation (thinning the blood)
- diabetes
- gout
- arthritis

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
- 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 right away (1-800-222-1222).

Directions

- shake well before use
- only use the dose cup provided
- adults and children 12 years and over: 1 dose (30 mL) every hour as needed
- do not exceed 4 doses (120 mL) in 24 hours
- use until diarrhea stops but not more than 2 days
- children under 12 years: ask a doctor
- drink plenty of clear fluids to help prevent dehydration caused by diarrhea

Other information

- each 30 mL contains: magnesium 15 mg, potassium 5 mg and sodium 12 mg
- salicylate 461 mg
- low sodium
- store at 20-25°C (68-77°F). Avoid excessive heat over 104°F (40°C).
- protect from freezing
- does not meet USP requirements for pH
- for health information visit www.more-info.info

Inactive ingredients

D&C red #22, D&C red #28, magnesium aluminum silicate, methyl salicylate, methylcellulose, purified water, saccharin sodium, salicylic acid, sodium salicylate, sorbic acid, xanthan gum

Questions or comments?

1-800-719-9260

Principal Display Panel

Compare to the active ingredient in Pepto-Bismol®

MAXIMUM STRENGTH

Stomach Relief

BISMUTH SUBSALICYLATE

1050 mg PER 30 mL

Upset Stomach Reliever/Antidiarrheal

Soothing relief for 5 symptoms:

Heartburn

Indigestion

Upset stomach

Nausea

Diarrhea

8 FL OZ (237 mL)

<p>Drug Facts (continued)</p> <p>■ ringing in the ears or loss of hearing occurs</p> <p>If pregnant or breast-feeding, ask a health professional before use.</p> <p>Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).</p> <p>Directions ■ shake well before use ■ only use the dose cup provided ■ adults and children 12 years and over: 1 dose (30 mL) every hour as needed ■ do not exceed 4 doses (120 mL) in 24 hours ■ use until diarrhea stops but not more than 2 days ■ children under 12 years: ask a doctor ■ drink plenty of clear fluids to help prevent dehydration caused by diarrhea</p> <p>Other information ■ each 30 mL contains: magnesium 15 mg, potassium 5 mg and sodium 12 mg ■ salicylate 461 mg ■ low sodium ■ store at 20-25°C (68-77°F). Avoid excessive heat over 104°F (40°C). ■ protect from freezing ■ does not meet USP requirements for pH ■ for health information visit www.more-info.info</p> <p>Inactive ingredients D&C red #22, D&C red #28, magnesium aluminum silicate, methyl salicylate, methylcellulose, purified water, saccharin sodium, salicylic acid, sodium salicylate, sorbic acid, xanthan gum</p> <p>Questions or comments? 1-800-719-9260</p> <p>Distributed by: CVS Pharmacy, Inc. *This product is not manufactured or distributed by Procter & Gamble, distributor of Pepto-Bismol®. One CVS Drive #317858 Woonsocket, RI 02895 © 2016 CVS/pharmacy CVS.com 1-800-SHOP CVS V-16467</p> 	<p>CVS Health.</p> <p>Compare to the active ingredient in Pepto-Bismol®* NDC 59779-699-34</p> <p>MAXIMUM STRENGTH</p> <p>Stomach Relief</p> <p>BISMUTH SUBSALICYLATE 1050 mg PER 30 mL Upset Stomach Reliever/Antidiarrheal</p> <p>Soothing relief for 5 symptoms:</p> <ul style="list-style-type: none">• Heartburn• Indigestion• Upset stomach• Nausea• Diarrhea <p>8 FL OZ (237 mL)</p> 	<p>Drug Facts DO NOT USE IF PRINTED NECKBAND IS BROKEN OR MISSING</p> <p>Active ingredient (in each 30 mL) Bismuth subsalicylate 1050 mg.....Purposes Upset stomach reliever and antidiarrheal</p> <p>Uses relieves ■ travelers' diarrhea ■ diarrhea ■ upset stomach due to overindulgence in food and drink, including: ■ heartburn ■ indigestion ■ nausea ■ gas ■ belching ■ fullness</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 ■ anticoagulation (thinning the blood) ■ diabetes ■ gout ■ arthritis</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 ■ diarrhea lasts more than 2 days ▶</p> <p>33734 17 F10</p>
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STOMACH RELIEF

bismuth subsalicylate suspension

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59779-699
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BISMUTH SUBSALICYLATE (UNII: 62TEY51RR1) (SALICYLIC ACID - UNII:O414PZ4LPZ, BISMUTH CATION - UNII:ZS9CD1I8YE)	BISMUTH SUBSALICYLATE	1050 mg in 30 mL

Inactive Ingredients

Ingredient Name	Strength
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SALICYLIC ACID (UNII: O414PZ4LPZ)	
SODIUM SALICYLATE (UNII: WIQ1H85SYP)	
SORBIC ACID (UNII: X045WJ989B)	
XANTHAN GUM (UNII: TTV12P4NEE)	
D&C RED NO. 22 (UNII: 1678RXX8RT)	
D&C RED NO. 28 (UNII: 767IP0Y5NH)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	

Product Characteristics

Color	PINK (viscous)	Score	
Shape		Size	
Flavor	WINTERGREEN	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59779-699-34	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/05/2005	
2	NDC:59779-699-40	355 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/24/1992	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part335	06/24/1992	

Labeler - CVS Pharmacy (062312574)

