

STOMACH RELIEF- bismuth subsalicylate suspension

Shopko Stores Operating Co., LLC

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.

Shopko Stomach Relief Drug Facts

Active ingredient (in each 30 mL)

Bismuth subsalicylate 525 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 1/2 to 1 hour as needed
- do not exceed 8 doses (240 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 254 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 Pepto-Bismol® Active Ingredient

Regular Strength

Stomach Relief

Bismuth Subsalicylate

525 mg per 30 mL

Upset Stomach Reliever/Antidiarrheal

5 Symptom Relief Of:

Indigestion

Upset Stomach

Nausea

Heartburn

Diarrhea

Original Flavor

12 FL OZ (354 mL)

<p>Drug Facts (continued)</p> <p>Directions</p> <ul style="list-style-type: none">shake well before useonly use the dose cup providedadults and children 12 years and over: 1 dose (30 mL) every 1/2 to 1 hour as neededdo not exceed 8 doses (240 mL) in 24 hoursuse until diarrhea stops but not more than 2 dayschildren under 12 years: ask a doctordrink plenty of clear fluids to help prevent dehydration caused by diarrhea <p>Other information</p> <ul style="list-style-type: none">each 30 mL contains: magnesium 15 mg, potassium 5 mg and sodium 12 mgsalicylate 254 mglow sodiumstore at 20-25°C (68-77°F). Avoid excessive heat over 104°F (40°C).protect from freezingdoes not meet USP requirements for pHfor health information visit www.more-info.info <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>NDC 37012-302-40</p> <p>SHOPKO</p> <p>*Compare to Pepto-Bismol® Active Ingredient</p> <p>Regular Strength</p> <h1>Stomach Relief</h1> <p>Bismuth Subsalicylate 525 mg per 30 mL</p> <p>Upset Stomach Reliever/Antidiarrheal</p> <p>5 Symptom Relief Of:</p> <p>Indigestion Upset Stomach Nausea Heartburn Diarrhea</p> <p>Original Flavor</p>	<p>Drug Facts</p> <table border="1"><thead><tr><th>Active ingredient (in each 30 mL)</th><th>Purposes</th></tr></thead><tbody><tr><td>Bismuth subsalicylate 525 mg.....</td><td>Upset stomach reliever and antidiarrheal</td></tr></tbody></table> <p>Uses relieves</p> <ul style="list-style-type: none">travelers' diarrheadiarrheaupset stomach due to overindulgence in food and drink, including:heartburnindigestionnauseagasbelchingfullness <p>Warnings</p> <p>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.</p> <p>Allergy alert: Contains salicylate. Do not take if you are</p> <ul style="list-style-type: none">allergic to salicylates (including aspirin)taking other salicylate products <p>Do not use if you have</p> <ul style="list-style-type: none">an ulcera bleeding problembloody or black stool <p>Ask a doctor before use if you have</p> <ul style="list-style-type: none">fevermucus in the stool <p>Ask a doctor or pharmacist before use if you are taking any drug for</p> <ul style="list-style-type: none">anticoagulation (thinning the blood)diabetesgoutarthritis <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</p> <ul style="list-style-type: none">symptoms get worseringing in the ears or loss of hearing occursdiarrhea lasts more than 2 days <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>	Active ingredient (in each 30 mL)	Purposes	Bismuth subsalicylate 525 mg.....	Upset stomach reliever and antidiarrheal
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Bismuth subsalicylate 525 mg.....	Upset stomach reliever and antidiarrheal					
<p>DO NOT USE IF PRINTED NECKBAND IS BROKEN OR MISSING</p> <p>*This product is not manufactured or distributed by Procter & Gamble, distributor of Pepto-Bismol®.</p> <p>GLUTEN FREE</p> <p>Distributed by Shopko Stores Operating Co., LLC ©2014 Shopko Stores Operating Co., LLC 700 Pilgrim Way Green Bay, WI 54307 www.shopko.com</p>  <p>3 70030 67753 5</p>	<p>12 FL OZ (354 mL)</p>	<p>30240 & C F4</p>				

STOMACH RELIEF

bismuth subsalicylate suspension

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:370 12-302
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BISMUTH SUBSALICYLATE (UNII: 62TEY51RR1) (BISMUTH CATION - UNII:ZS9CD118 YE, SALICYLIC ACID - UNII:O414PZ4LPZ)	BISMUTH SUBSALICYLATE	525 mg in 30 mL

Inactive Ingredients

Ingredient Name	Strength
D&C RED NO. 22 (UNII: 1678RXX8RT)	
D&C RED NO. 28 (UNII: 767IP0Y5NH)	
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)	
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:370 12-302-40	354 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/14/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part335	11/14/2013	

