

HEB STOMACH RELIEF REGULAR STRENGTH- bismuth subsalicylate suspension

H E B

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.

Regular Strength Stomach Relief Bismuth Subsalicylate 525 mg Drug Facts

Active ingredient (in each 30 mL dose cup)

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

Directions

- shake well before use
- for accurate dosing, use dose cup
- **adults and children 12 years and over:** 1 dose (30 mL) every ½ 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:** sodium 10 mg
- **salicylate 261 mg**
- low sodium

- sugar free
- store at room temperature
- protect from freezing
- avoid excessive heat (more than 104°F or 40°C)

Inactive ingredients

carboxymethylcellulose sodium, D&C Red No. 22, D&C Red No. 28, flavor, microcrystalline cellulose, potassium hydroxide, potassium sorbate, purified water, salicylic acid, simethicone emulsion, sodium benzoate, sucralose, xanthan gum

Questions or comments?

1-866-467-2748

DO NOT USE IF IMPRINTED SHRINK BAND IS MISSING OR BROKEN.

Principal Display Panel

HEB®

Compare To Pepto-Bismol® Regular Strength active ingredient*

REGULAR STRENGTH

Stomach Relief

Bismuth Subsalicylate 525 mg per 30 mL

UPSET STOMACH RELIEVER/ANTIDIARRHEAL

Multi-Symptom Relief

Relief of:

- Nausea
- Heartburn
- Indigestion
- Upset Stomach
- Diarrhea

Original Flavor

MADE WITH PRIDE & CARE FOR HEB®

SAN ANTONIO, TX 78204

100% GUARANTEE promise

If you aren't completely pleased with this product, we'll be happy to replace it or refund your money. You have our word on it.

***This product is not manufactured or distributed by Procter & Gamble, distributor Pepto-Bismol®.**

Package Label 473 mL

<p>Drug Facts (continued)</p> <p>Directions ■ shake well before use ■ for accurate dosing, use dose cup ■ 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</p> <p>Other information ■ each 30 mL contains: sodium 10 mg ■ salicylate 261 mg ■ low sodium ■ sugar free ■ store at room temperature ■ protect from freezing ■ avoid excessive heat (more than 104°F or 40°C)</p> <p>Inactive ingredients carboxymethylcellulose sodium, D&C Red #22, D&C Red #28, flavor, microcrystalline cellulose, potassium hydroxide, potassium sorbate, purified water, salicylic acid, simethicone emulsion, sodium benzoate, sucralose, xanthan gum</p> <p>Questions or comments? 1-866-467-2748</p> <p>MADE WITH PRIDE & CARE FOR H-E-B® SAN ANTONIO, TX 78204</p> <div style="border: 1px solid black; padding: 2px;"> <p>100% GUARANTEE promise</p> <p>If you aren't completely pleased with this product, we'll be happy to replace it or refund your money. You have our word on it.</p> </div> <p>70616HEBLR 8586-1810</p> <p>LOT: UNVARNISHED AREA EXP: 0 4 1220 54786 9</p>	<p>Compare to <i>Pepto-Bismol® Regular Strength</i> active ingredient*</p> <div style="border: 1px solid black; border-radius: 50%; width: 100px; height: 100px; margin: 0 auto; display: flex; align-items: center; justify-content: center;"> </div> <p>Regular Strength Stomach Relief</p> <p>Bismuth Subsalicylate 525 mg / Upset Stomach Reliever/Antidiarrheal</p> <div style="border: 1px solid black; border-radius: 15px; padding: 5px; width: fit-content; margin: 0 auto;"> Multi-Symptom Relief </div> <p>Relief of:</p> <ul style="list-style-type: none"> • Nausea • Heartburn • Indigestion • Upset Stomach • Diarrhea <p>original flavor</p> <p>16 FL OZ (473 mL)</p>	<p>Do not use if imprinted shrink band is missing or broken</p> <p>Drug Facts</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: left;">Active ingredient (in each 30 mL dose cup)</th> <th style="text-align: left;">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 ■ travelers' diarrhea ■ diarrhea ■ upset stomach due to overindulgence in food and drink, including: ■ heartburn ■ indigestion ■ nausea ■ gas ■ 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 or 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 ■ 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 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. In case of overdose, get medical help or contact a Poison Control Center right away at 1-800-222-1222.</p> <p><small>*This product is not manufactured or distributed by Procter & Gamble, distributor of Pepto-Bismol® Regular Strength.</small></p>	Active ingredient (in each 30 mL dose cup)	Purposes	Bismuth subsalicylate 525 mg	Upset stomach reliever and antidiarrheal
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Bismuth subsalicylate 525 mg	Upset stomach reliever and antidiarrheal					

Package Label 236 mL

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HEB STOMACH RELIEF REGULAR STRENGTH

bismuth subsalicylate suspension

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37808-607
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BISMUTH SUBSALICYLATE (UNII: 62TEY51RR1) (BISMUTH CATION - UNII:ZS9CD1I8YE, SALICYLIC ACID - UNII:O414PZ4LPZ)	BISMUTH SUBSALICYLATE	525 mg in 30 mL

Inactive Ingredients

Ingredient Name	Strength
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K679OBS311)	
D&C RED NO. 22 (UNII: 1678RKX8RT)	
D&C RED NO. 28 (UNII: 767IP0Y5NH)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
WATER (UNII: 059QF0KO0R)	
SALICYLIC ACID (UNII: O414PZ4LPZ)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37808-607-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/07/2019	
2	NDC:37808-607-08	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/07/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part335	03/07/2019	

