

STOMACH RELIEF REGULAR STRENGTH- bismuth subsalicylate liquid P & L Development, 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.

Drug Facts

Active ingredient (in each 30 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 right away. (1-800-222-1222)

Directions

- 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
 - 30 mL (1 dose) 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 of age: ask a doctor
- drink plenty of clear fluids to help prevent dehydration caused by diarrhea

Other information

- **each 30 mL contains:** sodium 10 mg
- **each 30 mL contains:** salicylate 243 mg
- sugar free
- 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

regular strength

Stomach Relief

Bismuth subsalicylate 525 mg

upset Stomach reliever

antidiarrheal

relieves

- heartburn
- Indigestion
- nausea
- upset stomach
- diarrhea

alcohol free

sugar free

FL OZ (mL)

*Compare to the active ingredient in Pepto-Bismol®

*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: PL Developments

200 Hicks Street, Westbury, NY 11590

Package Label

Drug Facts (continued)	
Directions	<ul style="list-style-type: none"> ■ 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 ■ 30 mL (1 dose) 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 of age: ask a doctor ■ drink plenty of clear fluids to help prevent dehydration caused by diarrhea
Other information	<ul style="list-style-type: none"> ■ each 30 mL contains: sodium 6 mg ■ each 30 mL contains: salicylate 243 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

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*Compare to the active ingredient in Pepto-Bismol®

Drug Facts	
<small>TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL AROUND DOSAGE CUP OR UNDER CAP IS BROKEN OR MISSING.</small>	
Active ingredient (in each 30 mL)	Purpose
Bismuth subsalicylate 525 mg	Upset stomach reliever/Antidiarrheal
Uses	<ul style="list-style-type: none"> relieves ■ diarrhea ■ travelers' diarrhea ■ upset stomach due to overindulgence in food and drink, including ■ heartburn ■ gas ■ indigestion ■ nausea ■ fullness ■ belching
Warnings	
<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 ulcer ■ a bleeding problem ■ bloody or black stool 	
<p>Ask a doctor before use if you have</p> <ul style="list-style-type: none"> ■ fever ■ mucus 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"> ■ diabetes ■ gout ■ arthritis ■ anticoagulation (thinning the blood) 	
<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 worse or last more than 2 days ■ ringing in the ears or loss of hearing occurs ■ diarrhea lasts more than 2 days 	
<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. (1-800-222-1222)</p>	

WELLNESS BASICS Regular Strength Stomach Relief

STOMACH RELIEF REGULAR STRENGTH

bismuth subsalicylate liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49580-0872
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
BENZOIC ACID (UNII: 8SKN0B0MIM)	
D&C RED NO. 22 (UNII: 1678RKX8RT)	
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: WMQ1H85SYP)	
SORBIC ACID (UNII: X045WJ989B)	
METHYLCELLULOSE (1500 CPS) (UNII: PONTE48364)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49580-0872-6	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/30/2018	06/30/2025

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part335	06/30/2018	06/30/2025

Labeler - P & L Development, LLC (101896231)

Revised: 6/2023

P & L Development, LLC