

STOMACH RELIEF REGULAR STRENGTH- bismuth subsalicylate liquid TOP CARE (Topco Associates LLC)

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 248 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, sucralose

Questions or comments?

Call toll free **1-888-423-0139**

Principal Display Panel

COMPARE TO PEPTO-BISMOL® ACTIVE INGREDIENT*

REGULAR STRENGTH

Stomach Relief

BISMUTH SUBSALICYLATE 525 mg

UPSET STOMACH RELIEVER/ANTIDIARRHEAL

5 SYMPTOM DIGESTIVE RELIEF

- Heartburn
- Indigestion
- nausea
- Upset Stomach
- diarrhea

FL OZ (mL)

CHERRY FLAVOR

SUGAR-FREE

ALCOHOL-FREE

*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:TOPCO ASSOCIATES LLC

ELK GROVE VILLAGE, IL 60007

topcare@topco.com

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
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Questions or comments?	Call toll free 1-888-423-0139

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This TopCare® product is laboratory tested to guarantee its highest quality. Your total satisfaction is guaranteed.

PLD-C384C LB006431



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NDC:36800-625-16



COMPARE TO PEPTO-BISMOL® ACTIVE INGREDIENT*

REGULAR STRENGTH

Stomach Relief

BISMUTH SUBSALICYLATE 525 mg
 UPSET STOMACH RELIEVER/ANTIDIARRHEAL

5 SYMPTOM DIGESTIVE RELIEF

- Heartburn
- Indigestion
- Nausea
- Upset Stomach
- Diarrhea



CHERRY FLAVOR



16 FL OZ (1 PT) 473 mL

SUGAR-FREE
ALCOHOL-FREE

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)	Bismuth subsalicylate 525 mg	Purpose 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. 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>	

TOPCARE HEALTH Regular Strength Stomach Relief

STOMACH RELIEF REGULAR STRENGTH

bismuth subsalicylate liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-625
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: 7671P0Y5NH)	
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)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-625-16	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/31/2019	12/31/2024
2	NDC:36800-625-08	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/31/2019	12/31/2024

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M008	03/31/2019	12/31/2024

Labeler - TOP CARE (Topco Associates LLC) (006935977)

Revised: 10/2023

TOP CARE (Topco Associates LLC)