

**TOPCARE STOMACH RELIEF ULTRA STRENGTH- bismuth
subsalicylate suspension
TOPCO ASSOCIATES LLC**

**TopCare Stomach Relief Ultra Strength Bismuth Subsalicylate 525 mg Drug
Facts**

Active ingredient (in each 15 mL dose)

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
- Only use dose cup provided
- **adults and children 12 years and over:** 15 mL (1 dose) every 1/2 or 30 mL (2 doses) every hour as needed for diarrhea/traveler's diarrhea.
- 15 mL (1 dose) every 1/2 hour as needed for overindulgence (upset stomach, heartburn, indigestion, nausea)
- do not exceed 8 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 15 mL contains:** sodium 10 mg
- **salicylate 230 mg**
- low sodium
- sugar free
- store at room temperature
- protect from freezing
- avoid excessive heat (over 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?

1-888-423-0139

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

Principal Display Panel

TopCare ®health ™

COMPARE TO PEPTO-BISMOL ® ULTRA STRENGTH ACTIVE INGREDIENT*

ULTRA STRENGTH

Stomach Relief

BISMUTH SUBSALICYLATE 525 mg per 15 mL

UPSET STOMACH RELIEVER/ANTIDIARRHEAL

5 SYMPTOM DIGESTIVE RELIEF

- Heartburn
- Indigestion
- Upset Stomach
- Nausea
- Diarrhea

OUR PHARMACISTS RECOMMEND

QUALITY GUARANTEED

DISTRIBUTED BY TOPCO ASSOCIATES LLC

ELK GROVE VILLAGE, IL 60007

©TOPCO RARA0919

QUESTIONS? 1-888-423-0139

topcare@topco.com, www.topcarebrand.com

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

Package Label 354 mL

Drug Facts (continued)

Directions ■ shake well before use ■ only use dose cup provided ■ **adults and children 12 years and over** ■ 15 mL (1 dose) every ½ hour or 30mL (2 doses) every hour as needed for diarrhea/traveler's diarrhea. ■ 15 mL (1 dose) every ½ hour as needed for overindulgence (upset stomach, heartburn, indigestion, nausea) ■ do not exceed 8 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 15 mL contains: sodium 10 mg
 ■ salicylate 230 mg ■ low sodium ■ sugar free
 ■ store at room temperature
 ■ protect from freezing
 ■ avoid excessive heat (over 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? 1-888-423-0139

DISTRIBUTED BY TOPCO ASSOCIATES LLC,
 ELK GROVE VILLAGE, IL 60007
 © TOPCO RARA0521
 QUESTIONS? 1-888-423-0139
 topcare@topco.com
 www.topcarebrand.com

Scan here for more information or call 1-888-423-0139

LOT: 70712TOPLR
 UNVARNISHED AREA
 EXP:

0 36800 13585 7

NDC 36800-341-12



COMPARE TO PEPTO-BISMOL® ULTRA STRENGTH ACTIVE INGREDIENT*

ULTRA STRENGTH

Stomach Relief

BISMUTH SUBSALICYLATE 525 mg per 15 mL
 UPSET STOMACH RELIEVER/ANTIDIARRHEAL

5 SYMPTOM DIGESTIVE RELIEF

- Heartburn
- Indigestion
- Upset Stomach
- Nausea
- Diarrhea

12 FL OZ (354 mL)

DO NOT USE IF IMPRINTED SHRINK BAND IS MISSING OR BROKEN

Drug Facts

Active ingredient (in each 15 mL dose) Bismuth subsalicylate 525 mg.....Upset stomach reliever and antidiarrheal

Purpose

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 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.

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

✓ **QUALITY GUARANTEED**

Package Label 236 mL

Drug Facts (continued)

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 ■ only use dose cup provided ■ **adults and children 12 years and over** ■ 15 mL (1 dose) every ½ hour or 30mL (2 doses) every hour as needed for diarrhea/traveler's diarrhea. ■ 15 mL (1 dose) every ½ hour as needed for overindulgence (upset stomach, heartburn, indigestion, nausea) ■ do not exceed 8 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 15 mL contains: sodium 10 mg ■ salicylate 230 mg ■ low sodium ■ sugar free ■ store at room temperature ■ protect from freezing ■ avoid excessive heat (over 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? 1-888-423-0139

DISTRIBUTED BY TOPCO ASSOCIATES LLC, ELK GROVE VILLAGE, IL 60007
 © TOPCO RARA0521 QUESTIONS? 1-888-423-0139
 topcare@topco.com www.topcarebrand.com

LOT: 70708TOPLR
 UNVARNISHED AREA
 EXP:

0 36800 99329 7

NDC 36800-341-08



COMPARE TO PEPTO-BISMOL® ULTRA STRENGTH ACTIVE INGREDIENT*

ULTRA STRENGTH

Stomach Relief

BISMUTH SUBSALICYLATE 525 mg per 15 mL
 UPSET STOMACH RELIEVER/ANTIDIARRHEAL

5 SYMPTOM DIGESTIVE RELIEF

- Heartburn
- Indigestion
- Upset Stomach
- Nausea
- Diarrhea

8 FL OZ (236 mL)

DO NOT USE IF IMPRINTED SHRINK BAND IS MISSING OR BROKEN

Drug Facts

Active ingredient (in each 15 mL dose) Bismuth subsalicylate 525 mg.....Upset stomach reliever and antidiarrheal

Purpose

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 or last more than 2 days ■ ringing in the ears or loss of hearing occurs ■ diarrhea lasts more than 2 days

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

✓ **QUALITY GUARANTEED**

TOPCARE STOMACH RELIEF ULTRA STRENGTH

bismuth subsalicylate suspension

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:36800-341

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 15 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, UNSPECIFIED (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:36800-341-12	354 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/14/2019	
2	NDC:36800-341-08	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/14/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M008	03/14/2019	

Labeler - TOPCO ASSOCIATES LLC (006935977)

