

**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 RAR40521  
QUESTIONS? 1-888-423-0139  
topcare@topco.com  
www.topcarebrand.com

LOT: 70712T0PLR

UNVARNISHED AREA

EXP:

36800 13585 7

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

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 RAR40521 QUESTIONS? 1-888-423-0139  
topcare@topco.com www.topcarebrand.com

LOT: 70708T0PLR

UNVARNISHED AREA

EXP:

36800 99329 7

Visit here for more information: HTTP://TOPBRNDS.COM/48ZSB

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 (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)

