

TOPCARE REGULAR STRENGTH- bismuth subsalicylate suspension
TOPCO ASSOCIATES LLC

TopCare Regular Strength Stomach Relief Pink Bismuth Subsalsicylate 525 mg
Drug Facts

Active ingredient (in each 30 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:** (30 mL) 1 dose every 1/2 or 60 mL every hour as needed for overindulgence (upset stomach, heartburn, indigestion, nausea)
- 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 (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?

1-866-467-2748

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

Principal Display Panel

TopCare® health™

***Compare to the Active Ingredient Pepto-Bismol® Regular Strength**

REGULAR STRENGTH

Pink Bismuth

Bismuth Subsalicylate 525 mg per 30 mL

Upset Stomach Reliever/Antidiarrheal

Relieves:

- Nausea
- Heartburn
- Indigestion
- Upset Stomach
- Diarrhea

Cherry Flavor

Naturally and Artificially Flavored

DISTRIBUTED BY TOPCO ASSOCIATES LLC

ELK GROVE VILLAGE, IL 60007

TOPCO RARA1217

QUESTIONS? 1-888-423-0139

topcare@topco.com, www.topcarebrand.com

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

Package Label 473 mL

Drug Facts (continued)

Directions ■ shake well before use ■ only use dose cup provided ■ **adults and children 12 years and over:** ■ 30 mL (1 dose) every ½ hour or 60 mL (2 doses) every hour as needed for diarrhea/traveler's diarrhea ■ 30 mL (1 dose) every ½ hour as needed for overindulgence (upset stomach, heartburn, indigestion, nausea) ■ 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? 1-888-423-0139

DISTRIBUTED BY TOPCO ASSOCIATES LLC, ELK GROVE VILLAGE, IL 60007
©TOPCO RARA0819 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® Regular Strength.

Scan here for more information

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

706CH16T0PLR

LOT: UNVARNISHED AREA EXP: 0 36800 13317 4



COMPARE TO PEPTO-BISMOL®
REGULAR STRENGTH ACTIVE INGREDIENT*

REGULAR STRENGTH

Stomach Relief

BISMUTH SUBSALICYLATE 525 mg
UPSET STOMACH RELIEVER/ANTI-DIARRHEAL

5 SYMPTOM DIGESTIVE RELIEF

- Heartburn
- Indigestion
- Nausea
- Upset Stomach
- Diarrhea

CHERRY FLAVOR



NATURALLY & ARTIFICIALLY FLAVORED

16 FL OZ (473 mL)

Do not use if imprinted shrink band is missing or broken

Drug Facts

Active ingredient (in each 30 mL dose)	Purposes
Bismuth subsalicylate 525 mgUpset stomach reliev ^r and anti ^d iarrheal

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.

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:** ■ 30 mL (1 dose) every ½ hour or 60 mL (2 doses) every hour as needed for diarrhea/traveler's diarrhea ■ 30 mL (1 dose) every ½ hour as needed for overindulgence (upset stomach, heartburn, indigestion, nausea) ■ 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? 1-888-423-0139

DISTRIBUTED BY TOPCO ASSOCIATES LLC, ELK GROVE VILLAGE, IL 60007
©TOPCO RARA0819 QUESTIONS? 1-888-423-0139
topcare@topco.com www.topcarebrand.com
Visit here for more information: <http://topbmds.com/48v08>

Scan here for more information

706CH08T0PLR

LOT: UNVARNISHED AREA EXP: 0 36800 13316 7



COMPARE TO PEPTO-BISMOL®
REGULAR STRENGTH ACTIVE INGREDIENT*

REGULAR STRENGTH

Stomach Relief

BISMUTH SUBSALICYLATE 525 mg
UPSET STOMACH RELIEVER/ANTI-DIARRHEAL

5 SYMPTOM DIGESTIVE RELIEF

- Heartburn
- Indigestion
- Nausea
- Upset Stomach
- Diarrhea

CHERRY FLAVOR



NATURALLY & ARTIFICIALLY FLAVORED

8 FL OZ (236 mL)

Do not use if imprinted shrink band is missing or broken

Drug Facts

Active ingredient (in each 30 mL dose)	Purposes
Bismuth subsalicylate 525 mgUpset stomach reliev ^r and anti ^d iarrheal

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® Regular Strength. **QUALITY GUARANTEED**

TOPCARE REGULAR STRENGTH

bismuth subsalicylate suspension

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-661
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: 7671P0Y5NH)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
WATER (UNII: 059QF0K00R)	
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	CHERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-661-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/07/2019	
2	NDC:36800-661-08	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/07/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M008	05/07/2019	

Labeler - TOPCO ASSOCIATES LLC (006935977)

