# TOPCARE STOMACH RELIEF REGULAR STRENGTH- bismuth subsalicylate suspension TOPCO ASSOCIATES LLC

-----

TopCare Regular Strength Stomach Relief Bismuth Subsalicylate 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?

1-888-423-0139

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

## **Principal Display Panel**

TopCare<sub>®</sub> health™

#### COMPARE TO PEPTO-BISMOL® REGULAR STRENGTH ACTIVE INGREDIENT\*

REGULAR STRENGTH

Stomach Relief

Bismuth Subsalicylate 525 mg per 30 mL

UPSET STOMACH RELIEVER/ANTIDIARRHEAL

OUR PHARMACIST RECOMMEND

5 SYSMPTOM DIGESTIVE RELIEF

- Heartburn
- Indigestion
- Upset Stomach
- Nausea
- Diarrhea

#### **OUALITY GURANTEE**

DISTRIBUTED BY TOPCO ASSOCIATES LLC

ELK GROVE VILLAGE, IL 60007

QUESTIONS? 1-888-423-0139

topcare@topco.com, www.topcarebrand.com

\*This product is not manufactured or distributed by Procter & Gamble, distributor Pepto-Bismol<sup>®</sup>.

Package Label 354 mL





COMPARE TO PEPTO-BISMOL® REGULAR STRENGTH ACTIVE INGREDIENT\*

#### **REGULAR STRENGTH**

## Stomach Relief

BISMUTH SUBSALICYLATE 525 mg per 30 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 30 mL dose) Bismuth subsalicylate 525 mg

Purposes

..Upset stomach reliever and antidiarrhea

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 womiting 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

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

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®.

## Package Label 236 mL

#### Drug Facts (continued)

If pregnant or breast-feeding, ask a health professional

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 a shake well before use a only use dose cup provided adults and children 12 years and over:

30 mt. (1 dose) every ½ hour or 60 mt. (2 doses) every hour as needed for diarrhea/traveler's diarrhea a 30mt. (1 dose) every ½ hour as needed for overindulgence (upset stomach, heartburn, indigestion, nausea) a do not exceed a doses (240 mt.) in 24 hours a use until diarrhea stops but not more than 2 days a children under 12 years: ask a doctor a drink plenty of clear fluids to help prevent dehydration caused by diarrhea 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

UNVARNISHED AREA

70608TOPLR

DISTRIBUTED BY TOPCO ASSOCIATES LLC, ELK GROVE VILLAGE, IL 60007 DTOPCO RARAGE21 DUESTIONS? 1-688-423-0139



DC36800-338-08 **+**TopCare®

COMPARE TO PEPTO-BISMOL® REGULAR STRENGTH ACTIVE INGREDIENT\*

#### **REGULAR STRENGTH**

# Stomach

BISMUTH SUBSALICYLATE 525 mg per 30 mL UPSET STOMACH RELIEVER/ANTIDIARRHEAL

#### **5 SYMPTOM DIGESTIVE RELIEF**

- Heartburn
- Indigestion
- Upset Stomach
- Nausea
- Diarrhea

8 FL 0Z (236 mL)

DO NOT USE IF IMPRINTED SHRINK BAND IS MISSING OR BROKEN

#### **Drug Facts**

Active ingredient (in each 30 mL dose)

...Upset stomach reliever Bismuth subsalicylate 525 mg.

Purposes

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) adiabetes 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 a symptoms get worse or last more than 2 days ringing in the ears or loss of hearing occurs ■ diarrhea lasts more than 2 days

**✓**QUALITY GUARANTEED

## TOPCARE STOMACH RELIEF REGULAR STRENGTH

bismuth subsalicylate suspension

#### **Product Information**

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-338
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
<b>BISMUTH SUBSALICYLATE</b> (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: K6790BS311)		
D&C RED NO. 22 (UNII: 1678RKX8RT)		
<b>D&amp;C RED NO. 28</b> (UNII: 767IP0Y5NH)		
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)		
POTASSIUM HYDROXIDE (UNII: WZ H3C48M4T)		
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)		
WATER (UNII: 059QF0KO0R)		
SALICYLIC ACID (UNII: O414PZ4LPZ)		
DIMETHICONE (UNII: 92RU3N3Y10)		
SODIUM BENZOATE (UNII: OJ245FE5EU)		
SUCRALOSE (UNII: 96K6UQ3ZD4)		
XANTHAN GUM (UNII: TTV12P4NEE)		

Product Characteristics			
Color	PINK (viscous)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

F	Packaging			
#	tem Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-338- 12	354 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/07/2019	
2	NDC:36800-338- 08	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/07/2019	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M008	03/07/2019	

## Labeler - TOPCO ASSOCIATES LLC (006935977)

Revised: 11/2023 TOPCO ASSOCIATES LLC