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 ®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

QUALITY 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 $^{\$}$.

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®.

Purposes

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.

Uses relieves travelers' diarrhea diarrhea upset stomach due to overindulgence in food and drink, including:

■ heartburn ■ indigestion ■ nausea ■ gas ■ belching ■ fullness

Warnings

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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 | |
| 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: K6790BS311) | | |
| D&C RED NO. 22 (UNII: 1678RKX8RT) | | |
| D&C RED NO. 28 (UNII: 767IP0Y5NH) | | |
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U) | | |
| POTASSIUM HYDROXIDE (UNII: WZ H3C48M4T) | | |
| POTASSIUM SORBATE (UNII: 1VPU26JZZ4) | | |
| WATER (UNII: 059QF0KO0R) | | |
| SALICYLIC ACID (UNII: O414PZ4LPZ) | | |
| DIMETHICONE, UNSPECIFIED (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: 11/2025 TOPCO ASSOCIATES LLC