

STOMACH RELIEF REGULAR STRENGTH- bismuth subsalicylate liquid
The Kroger Co.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Drug Facts

Active ingredient (in each 30 mL)

Bismuth subsalicylate 525 mg

Purpose

Upset stomach reliever/Antidiarrheal

Uses

relieves

- travelers' diarrhea
- diarrhea
- upset stomach due to overindulgence in food and drink, including:
 - heartburn
 - indigestion
 - nausea
 - gas
 - fullness
 - belching

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

- diabetes
- gout
- arthritis
- anticoagulation (thinning the blood)

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. (1-800-222-1222)

Directions

- mL = milliliter
- shake well before using
- measure only with dosing cup provided. Do not use any other dosing device.
- keep dosing cup with product
- adults and children 12 years and over:
 - 30 mL (1 dose) every 1/2 to 1 hour as needed
 - do not exceed 8 doses (240 mL) in 24 hours
 - use until diarrhea stops but not more than 2 days
- children under 12 years of age: ask a doctor
- drink plenty of clear fluids to help prevent dehydration caused by diarrhea

Other information

- **each 30 mL contains:** sodium 6 mg
- **each 30 mL contains:** salicylate 243 mg
- low sodium
- keep tightly closed
- protect from freezing
- avoid excessive heat (over 104°F or 40°C)

Inactive ingredients

benzoic acid, D&C red #22, D&C red #28, flavor, magnesium aluminum silicate, methylcellulose, purified water, saccharin sodium, salicylic acid, sodium salicylate, sorbic acid

Questions or comments?

Call 1-800-632-6900

Principal Display Panel

COMPARE TO the active ingredient in PEPTO-BISMOL® *See side panel

REGULAR STRENGTH

Stomach Relief

UPSET STOMACH RELIEVER / ANTIDIARRHEAL

Bismuth Subsalicylate 525 mg

Soothing Relief for 5 Symptoms:

- Heartburn
- Indigestion
- Upset Stomach
- Nausea
- Diarrhea

ALCOHOL FREE

SUGAR FREE

FL OZ (mL)

*PEPTO-BISMOL® IS A REGISTERED TRADEMARK OF PROCTER & GAMBLE, CINCINNATI, OH 45202. PROCTER & GAMBLE IS NOT AFFILIATED WITH THE KROGER CO. OR THIS PRODUCT

TAMPER EVIDENT; DO NOT USE IF PRINTED SAFETY SEAL AROUND DOSAGE CUP OR UNDER CAP IS BROKEN OR MISSING.

DISTRIBUTED BY THE KROGER CO.

CINCINNATI, OHIO 45202

www.kroger.com

Package Label

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. (1-800-222-1222)
Directions ■ mL = milliliter ■ shake well before using ■ measure only with dosing cup provided. Do not use any other dosing device. ■ keep dosing cup with product ■ adults and children 12 years and over: ■ 30 mL (1 dose) every ½ to 1 hour as needed ■ do not exceed 8 doses (240 mL) in 24 hours ■ use until diarrhea stops but not more than 2 days ■ children under 12 years of age: ask a doctor ■ drink plenty of clear fluids to help prevent dehydration caused by diarrhea
Other information ■ each 30 mL contains: sodium 6 mg ■ each 30 mL contains: salicylate 243 mg ■ low sodium ■ keep tightly closed ■ protect from freezing ■ avoid excessive heat (over 104°F or 40°C)
Inactive ingredients benzoic acid, D&C red #22, D&C red #28, flavor, magnesium aluminum silicate, methylcellulose, purified water, saccharin sodium, salicylic acid, sodium salicylate, sorbic acid
Questions or comments? 1-800-632-6900

DISTRIBUTED BY THE KROGER CO. **QUALITY GUARANTEE**
CINCINNATI, OHIO 45202 www.kroger.com

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PLD-B3838 LB006189 0 11110 79608 0

COMPARE TO the active ingredient of
PEPTO-BISMOL® *See side panel

NDC 30142-372-08



REGULAR STRENGTH

Stomach Relief

**UPSET STOMACH RELIEVER/
ANTIDIARRHEAL**

Bismuth Subsalicylate 525 mg

Soothing Relief for 5 Symptoms:

- Heartburn • Indigestion
- Upset Stomach • Nausea
- Diarrhea

ALCOHOL FREE
SUGAR FREE



TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL AROUND DOSAGE CUP OR UNDER CAP IS BROKEN OR MISSING.

8 FL OZ (236 mL)

Drug Facts	
Active ingredient (in each 30 mL) Bismuth subsalicylate 525 mg	Purpose Upset stomach reliever/ Antidiarrheal
Uses relieves ■ diarrhea ■ travelers' diarrhea ■ upset stomach due to overindulgence in food and drink, including ■ heartburn ■ gas ■ indigestion ■ nausea ■ fullness ■ belching	
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 ■ diabetes ■ gout ■ arthritis ■ anticoagulation (thinning the blood)	
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	

KROGER Regular Strength Stomach Relief

STOMACH RELIEF REGULAR STRENGTH

bismuth subsalicylate liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:30 142-372
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
BENZOIC ACID (UNII: 8SKN0B0MIM)	
D&C RED NO. 22 (UNII: 1678RKX8RT)	
D&C RED NO. 28 (UNII: 767IP0Y5NH)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SALICYLIC ACID (UNII: O414PZ4LPZ)	
SODIUM SALICYLATE (UNII: WIQ1H85SYP)	
SORBIC ACID (UNII: X045WJ989B)	
METHYLCELLULOSE (1500 CPS) (UNII: P0NTE48364)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:30 142-372-08	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/31/20 15	
2	NDC:30 142-372-12	354 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/31/20 15	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part335	10/31/20 15	

Labeler - The Kroger Co. (006999528)