# STOMACH RELIEF ORIGINAL STRENGTH- bis muth subsalicylate liquid Ameris ourceBergen (Good Neighbor Pharmacy) 46122

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.

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# **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
  - o nausea
  - o gas
  - fullness
  - belching

#### Warnings

**Reye's syndrome**: Children and teenagers who have or are recovering from chicken pox or flu-like symptoms ahould 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

- a sodium-restricted diet
- 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 childen.

In case of overdose, get medical help or contact a Posion Control Center right away. (1-800-222-1222)

#### **Directions**

- shake well before using
- mL = milliliter
- measure only with dosing cup provided. Do not use other dosing device
- keep dosing cup with product
- adults and children 12 years and over
  - o 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 10 mg
- each 30 mL contains: salicylate 243 mg
- sugar free
- 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 1-877-753-3935 Monday-Friday 9AM-5PM EST

### **Principal Display Panel**

Compare to Original Strength Pepto-Bismol® active ingredient\*

Stomach Relief

Original Strength

Bismuth subsalicylate 525 mg

upset stomach reliever/antidiarrheal

Soothing relief for 5 symptoms

Indigestion, upset stomach, nausea, heartburn, diarrhea

Original flavor

FL OZ (mL)

\*This product is not manufactured or distributed by Procter & Gamble, Pepto-Bismol® is a registered trademark of The Procter & Gamble Company.

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

Distributed by AmerisourceBergen

1300 Morris Drive, Chesterbrook, PA 19087

Questions or Concerns?

www.mygnp.com

#### **Package Label**



Good Neighbor Stomach Relief

bismuth subsalicylate liquid

Product Information	roduct Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:46122-306	
Route of Administration	ORAL			

	Active Ingredient/Active Moiety		
ı	Ingredient Name	<b>Basis of Strength</b>	Strength
	<b>BISMUTH SUBSALICYLATE</b> (UNII: 62TEY51RR1) (BISMUTH CATION - UNII:ZS9CD1I8YE, SALICYLIC ACID - UNII:O414PZ4LPZ)		525 mg in 30 mL

Inactive Ingredients		
Ingredient Name	Strength	
BENZOIC ACID (UNII: 8 SKN0 B0 MIM)		
<b>D&amp;C RED NO. 22</b> (UNII: 1678 RKX8 RT)		
<b>D&amp;C RED NO. 28</b> (UNII: 767IP0 Y5NH)		
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)		
WATER (UNII: 059QF0KO0R)		
SACCHARIN SODIUM (UNII: SB8ZUX40TY)		
SALICYLIC ACID (UNII: O414PZ4LPZ)		
SODIUM SALICYLATE (UNII: WIQ 1H85SYP)		
SORBIC ACID (UNII: X045WJ989B)		
METHYLCELLULOSE (1500 CPS) (UNII: PONTE48364)		

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:46122-306- 34	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/31/2015	12/31/2020

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC MONOGRAPH FINAL	part335	07/31/2015	12/31/2020	

# Labeler - AmerisourceBergen (Good Neighbor Pharmacy) 46122 (007914906)

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