# STOMACH RELIEF MAXIMUM STRENGTH- bismuth subsalicylate liquid AmerisourceBergen (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 1050 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
  - aas
  - 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

- 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 (1-800-222-1222) right away.

#### **Directions**

- shake well before using
- mL = milliliter
- 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 hour as needed
  - $\circ~$  do not take more than 4 doses (120 mL) in 24 hours
  - $\circ\;$  use until diarrhea stops but not more than 2 days
  - o children under 12 years of age: ask a doctor
- drink plently of clear fluids to help prevent dehydration caused by diarrhea

#### Other information

- each 30 mL contains: sodium 12 mg
  each 30 mL contains: salicylate 455 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 1-877-753-3935 Monday-Friday 9AM-5PM EST

# **Principal Display Panel**

Compre to Maximum Strength Pepto-Bismol® active ingredient\*

Stomach Relief

### **Maximum Strength**

Upset Stomach Reliever/Antidiarrheal

(Bismuth Subsalicylate 1050)

Soothing Relief for 5 Symptoms:

- Upset Stomach
- Indigestion
- Heartburn
- Diarrhea
- Nausea

Alcohol Free

Sugar Free

FL OZ (mL)

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

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

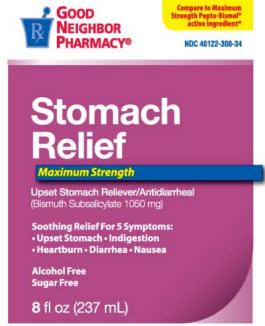
Distributed by AmerisourceBergen

1300 Morris Drive, Chesterbrook, PA 19087

www.mygnp.com

# Package Label





Drug Facts Active ingredient (in each 30 mL) Purpose Bismuth subsalicylate 1050 mg. .Antidiarrheal Uses relieves ■ travelers' diarrhea ■ diarrhea ■ upset stomach due to overindulgence in food and drink, including ■ heartburn ■ indigestion ■ nausea ■ fullness 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 in ringing in the ears or loss of hearing occurs in diarrhea lasts more than 2 days

#### GOOD NEIGHBOR PHARMACY Stomach Relief

#### STOMACH RELIEF MAXIMUM STRENGTH

PLD-B390C LB006209

bismuth subsalicylate liquid

87701 42699

Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:46122-308		
Route of Administration	ORAL				

#### **Active Ingredient/Active Moiety Basis of Ingredient Name** Strength Strength BISMUTH SUBSALICYLATE (UNII: 62TEY51RR1) (BISMUTH CATION -**BISMUTH** 1050 mg UNII:ZS9CD1I8YE, SALICYLIC ACID - UNII:O414PZ4LPZ) **SUBSALICYLATE** in 30 mL

Inactive Ingredients			
Ingredient Name	Strength		
BENZOIC ACID (UNII: 85KN0B0MIM)			
<b>D&amp;C RED NO. 22</b> (UNII: 1678RKX8RT)			
<b>D&amp;C RED NO. 28</b> (UNII: 767IP0Y5NH)			
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)			
WATER (UNII: 059QF0KO0R)			
SACCHARIN SODIUM (UNII: SB8ZUX40TY)			
SALICYLIC ACID (UNII: O414PZ4LPZ)			
SODIUM SALICYLATE (UNII: WQ1H85SYP)			
SORBIC ACID (UNII: X045WJ989B)			
METHYLCELLULOSE (1500 CPS) (UNII: PONTE48364)			

Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:46122- 308-34	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/30/2015	09/30/2024	

Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC monograph final	part335	09/30/2015	09/30/2024			

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

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