# STOMACH RELIEF MAXIMUM STRENGTH- bismuth subsalicylate liquid Best Choice (Valu Merchandisers Company)

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
  - 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

- 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
  - o do not take more than 4 doses (120 mL) in 24 hours
  - use until diarrhea stops but not more than 2 days
  - 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**

COMPARE TO THE ACTIVE INGREDIENT IN MAXIMUM STRENGTH PEPTO-BISMOL®\*

#### Stomach Relief

BISMUTH SUBSALICYLATE 1050 mg

UPSET STOMACH RELIEVER/ANTIDIARRHEAL

SOOTHING RELIEF FOR:

INDIGESTION, UPSET STOMACH, NAUSEA, HEARTBURN, DIARRHEA

ALCOHOL FREE

SUGAR FREE

**MAXIMUM STRENGTH** 

FL OZ (mL)

\*This product is not manufactured or distributed by 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.

PROUDLY DISTRIBUTED BY:

VALU MERCHANDISERS, CO.

5000 KANSAS AVE

KANSAS CITY, KS 66106

#### **Package Label**



bismuth subsalicylate liquid

Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63941-371		
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)		1050 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)		
SO DIUM SALICYLATE (UNII: WIQ 1H8 5 S YP)		
SORBIC ACID (UNII: X045WJ989B)		
METHYLCELLULOSE (1500 CPS) (UNII: PONTE48364)		

Packaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
1 NDC:63941-371- 08	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	0 3/3 1/2 0 15		
2 NDC:63941-371- 12	354 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	0 3/31/20 15		

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC MONOGRAPH FINAL	part335	03/31/2015			

# Labeler - Best Choice (Valu Merchandisers Company) (868703513)