# STOMACH RELIEF REGULAR STRENGTH- bismuth subsalicylate liquid P & L Development, LLC

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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
  - 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 childen.

In case of overdose, get medical help or contact a Posion 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 or 60 mL (2 doses) every hour as needed for diarrhea/traveler's diarrhea
  - 30 mL (1 dose) every 1/2 hour as needed for overindulgence (upset stomach, heartburn, indigestion, nausea)
  - do not exceed 8 doses (240 mL) in 24 hours
  - o 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: potassium 8 mg sodium 6 mg
- each 30 mL contains: salicylate 206 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, purified water, sucralose, xanthan gum

### Questions or comments?

Call **1-877-753-3935** Monday-Friday 9AM-5PM EST

## **Principal Display Panel**

regular strength

### Stomach Relief

Bismuth subsalicylate 525 mg

upset Stomach reliever

antidiarrheal

#### relieves

- heartburn
- Indigestion
- nausea
- upset stomach
- diarrhea

alcohol free

sugar free

FL OZ (mL)

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

Distributed by: PL Developments

200 Hicks Street, Westbury, NY 11590

## Package Label

<sup>\*</sup>Compare to the active ingredient in Pepto-Bismol®

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



## **WELLNESS BASICS Regular Strength Stomach Relief**

## STOMACH RELIEF REGULAR STRENGTH

bismuth subsalicylate liquid

Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49580-0624		
Route of Administration	ORAL				

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
<b>BISMUTH SUBSALICYLATE</b> (UNII: 62TEY51RR1) (BISMUTH CATION - UNII:ZS9CD118YE, SALICYLIC ACID - UNII:O414PZ4LPZ)	BISMUTH SUBSALICYLATE	525 mg 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)			
GLYCERIN (UNII: PDC6A3C0OX)			
WATER (UNII: 059QF0KO0R)			
SUCRALOSE (UNII: 96K6UQ3ZD4)			
XANTHAN GUM (UNII: TTV12P4NEE)			

F	Packaging			
#	# Item Code	Package Description	Marketing Start Date	Marketing End Date

	F73 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/30/2019		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Dru	ıg M008	09/30/2019		

# Labeler - P & L Development, LLC (101896231)

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