# STOMACH RELIEF ULTRA- bismuth subsalicylate liquid Publix Supermarkets, Inc.

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 15 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
  - aas
  - 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 (1-800-222-1222) right away.

#### **Directions**

- do not take more than 8 doses (120 mL) in 24 hours
- use until diarrhea stops but not more than 2 days
- drink plenty of clear fluids to help prevent dehydration caused by diarrhea
- 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:
  - 15 mL (1dose) every 1/2 or 30 mL (2 doses) every hour as needed diarrhea/traveler's diarrhea
  - 15 mL (1 dose) every 1/2 hour as needed for overindulgence (upset stomach, heartburn, indigestion, nausea)
- children under 12 years of age: ask a doctor

#### Other information

• each 15 mL contains: sodium 6 mg

- each 15 mL contains: salicylate 227 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

## **Principal Display Panel**

\*Compare to active ingredient in Pepto-Bismol® Ultra

STOMACH RELIEF

ultrastrength

## **BISMUTH SUBSALICYLATE** 525 mg

UPSET STOMACH RELIEVER/ANTIDIARRHEAL

#### Relieves

- Heartburn
- Indigestion
- Nausea
- Upset stomach
- Diarrhea

2x STRENGTH PER OUNCET

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.

tvs. Original Peptic-Bismol®

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

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3300 PUBLIX CORPORATE PARKWAY, LAKELAND, FL 33811

publix.com 1-888-267-3037

Package Label





## STOMACH RELIEF ultrastrength

### **BISMUTH SUBSALICYLATE 525 mg**

UPSET STOMACH RELIEVER/ ANTIDIARRHEAL

#### Relieves

- Heartburn
- Indigestion
- Nausea
- Upset stomach Diarrhea

2X STRENGTH PER OUNCE<sup>†</sup>

ALCOHOL FREE SUGAR FREE

PLD-A559A



\*Compare to active ingredient

12 FL OZ (355 mL)

## **PUBLIX Stomach Relief Ultra Strength**

#### Drug Facts TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL AROUND DOSAGE CUP OR UNDER CAP IS BROKEN OR MISSIN Active ingredient (in each 15 mL) Bismuth subsalicylate 525 mg...... 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 varianting occus, volume a coccus occused views symptoms of 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

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

## STOMACH RELIEF ULTRA

bismuth subsalicylate liquid

#### **Product Information**

**Product Type** HUMAN OTC DRUG Item Code (Source) NDC:56062-842

**Route of Administration ORAL** 

## **Active Ingredient/Active Moiety**

Ingredient Name	Strength	Strength	
<b>BISMUTH SUBSALICYLATE</b> (UNII: 62TEY51RR1) (BISMUTH CATION - UNII:ZS9CD118YE, SALICYLIC ACID - UNII:O414PZ4LPZ)	BISMUTH SUBSALICYLATE	525 mg in 15 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:56062- 842-12	355 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/31/2019	07/31/2024	

Marketing In	arketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph final	part335	07/31/2019	07/31/2024		

Labeler - Publix Supermarkets, Inc. (006922009)

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