

## **STOMACH RELIEF ULTRA- bismuth subsalicylate liquid** **Family Dollar (FAMILY WELLNESS)**

*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
  - 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 children.**

In case of overdose, get medical help or contact a Poison 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 (1 dose) 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 5 mg

- **each 15 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, glycerin, purified water, sucralose, xanthan gum

### **Questions or comments?**

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

### **Principal Display Panel**

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

Stomach Relief Ultra

Bismuth Subsalicylate 525 mg

Upset Stomach Reliever/Antidiarrheal

RELIEVES 5 Major Symptoms

Heartburn

Indigestion

Upset Stomach

Diarrhea

Nausea

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.

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

DISTRIBUTED BY:

MIDWOOD BRANDS, LLC

500 VOLVO PARKWAY,

CHESAPEAKE, VA 23320

# Package Label

**Drug Facts** (continued)

**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.

**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 (1 dose) every ½ hour or 30 mL (2 doses) every hour as needed for diarrhea/traveler's diarrhea ■ 15 mL (1 dose) every ½ 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 5 mg  
■ each 15 mL contains: salicylate 206 mg ■ low sodium ■ keep tightly closed ■ protect from freezing ■ avoid excessive heat (over 104°F or 40°C)

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†vs. Original Pepto-Bismol®

**NOT 100% SATISFIED?** Return package and unused product within 30 days to any Family Dollar store for a refund (with receipt) or exchange.

DISTRIBUTED BY:  
MIDWOOD BRANDS, LLC  
500 VOLVO PARKWAY,  
CHESAPEAKE, VA 23320

SKU 0914325 PLD-A494A LB007283



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

## FAMILY wellness™

NDC 55319-737-08

# Stomach Relief Ultra

Bismuth Subsalicylate 525 mg  
Upset Stomach Reliever/Antidiarrheal

**RELIEVES 5  
Major Symptoms**

Heartburn      Diarrhea  
Indigestion    Nausea  
Upset Stomach

**2x**  
STRENGTH  
per ounce†

Alcohol Free  
Sugar Free

**8 FL OZ (237 mL)**




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

**Active ingredient** **Purpose**  
(in each 15 mL dose)  
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

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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

## FAMILY WELLNESS Stomach relief Ultra

## STOMACH RELIEF ULTRA

bismuth subsalicylate liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:55319-737
<b>Route of Administration</b>	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)	BISMUTH SUBSALICYLATE	525 mg in 15 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>BENZOIC ACID</b> (UNII: 8SKN0B0MIM)	
<b>D&amp;C RED NO. 22</b> (UNII: 1678RKX8RT)	
<b>D&amp;C RED NO. 28</b> (UNII: 767IP0Y5NH)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	

**XANTHAN GUM** (UNII: TTV12P4NEE)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55319-737-08	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/30/2019	10/30/2025

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part335	10/30/2019	10/30/2025

**Labeler** - Family Dollar (FAMILY WELLNESS) (024472631)

Revised: 1/2023

Family Dollar (FAMILY WELLNESS)