**STOMACH RELIEF ULTRA- bismuth subsalicylate liquid**
**Care One (Retail Business Services, LLC.)**

*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 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**

- 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 104ºF or 40ºC)

**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 active ingredient in Pepto-Bismol® Ultra*

**ULTRA**

**STOMACH RELIEF**

Bismuth Subsalicylate 525 mg

Upset Stomach Reliever/Antidiarrheal

Original Flavor

5 SYMPTOM DIGESTIVE RELIEF:

NAUSEA, HEARTBURN, INDIGESTION, UPSET STOMACH, DIARRHEA

ALCOHOL FREE

2X STRENGTH PER OUNCE†

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.

†vs. Original Pepto-Bismol®

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

DISTRIBUTED BY: FOODHOLD U.S.A., LLC

LANDOVER, MD 20785

**Package Label**


**CARE ONE Stomach Relief Ultra**

# STOMACH RELIEF ULTRA

bismuth subsalicylate liquid

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:72476-642 |
| **Route of Administration** | ORAL | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **BISMUTH SUBSALICYLATE** (UNII: 62TEY51RR1) (BISMUTH CATION - UNII:ZS9CD1I8YE, SALICYLIC ACID - UNII:O414PZ4LPZ) | BISMUTH SUBSALICYLATE | 525 mg in 15 mL |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **BENZOIC ACID** (UNII: 8SKN0B0MIM) | |
| **D&C RED NO. 22** (UNII: 1678RKX8RT) | |
| **D&C RED NO. 28** (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: P0NTE48364) | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| 1 | NDC:72476-642-12 | 355 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 06/30/2019 | 01/31/2025 |
| 2 | NDC:72476-642-08 | 237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 06/30/2019 | 01/31/2025 |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC monograph final | part335 | 06/30/2019 | 01/31/2025 |

## Labeler - Care One (Retail Business Services, LLC.) (967989935)

Revised: 1/2023

Care One (Retail Business Services, LLC.)