

# **STOMACH RELIEF REGULAR STRENGTH- bismuth subsalicylate liquid Care One (American Sales Company)**

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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 children.**

In case of overdose, get medical help or contact a Poison 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 as needed
- do not exceed 8 doses (240 mL) in 24 hours
- 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:** sodium 6 mg
- **each 30 mL contains:** salicylate 243 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 Pepto-Bismol®\*

#### **REGULAR STRENGTH**

#### **STOMACH RELIEF**

Bismuth Subsalicylate 525mg

Upset Stomach Reliever/Antidiarrheal

Original Flavor

5 SYMPTOM DIGESTIVE RELIEF:

NAUSEA, HEARTBURN, INDIGESTION, UPSET STOMACH, DIARRHEA

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: FOODHOLD U.S.A., LLC, LANDOVER, MD 20785

For product questions or concerns, contact us at 1-877-846-9949

### **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 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 ½ to 1 hour as needed ■ do not exceed 8 doses (240 mL) in 24 hours ■ 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: sodium 6 mg ■ each 30 mL contains: salicylate 243 mg ■ low sodium ■ keep tightly closed ■ protect from freezing ■ avoid excessive heat (over 104°F or 40°C)

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Quality guaranteed or  
your money back.

PLD-A383B  
LB006145



**CAREone**®

NDC 41520-372-08

Compare to the active ingredient  
in Pepto-Bismol®

**REGULAR STRENGTH  
STOMACH  
RELIEF**

**Bismuth Subsalicylate 525mg  
Upset Stomach Reliever/Antidiarrheal**

**Original Flavor**

**5 SYMPTOM DIGESTIVE RELIEF:  
NAUSEA, HEARTBURN, INDIGESTION,  
UPSET STOMACH, DIARRHEA**



ALCOHOL FREE  
SUGAR FREE

8 FL OZ (237mL)

**Drug Facts**

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**Ask a doctor or pharmacist before use if you are** taking any drug for ■ diabetes ■ gout ■ arthritis ■ anticoagulation (thinning the blood)

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**CAREONE Regular Strength Stomach Relief**

**STOMACH RELIEF REGULAR STRENGTH**

bismuth subsalicylate liquid

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:41520-372
<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 30 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: 7671P0Y5NH)	
<b>MAGNESIUM ALUMINUM SILICATE</b> (UNII: 6M3P64V0NC)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>SALICYLIC ACID</b> (UNII: O414PZ4LPZ)	
<b>SODIUM SALICYLATE</b> (UNII: WQ1H85SYP)	
<b>SORBIC ACID</b> (UNII: X045WJ989B)	
<b>METHYLCELLULOSE (1500 CPS)</b> (UNII: PONTE48364)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41520-372-08	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/30/2018	
2	NDC:41520-372-16	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/30/2018	
3	NDC:41520-372-12	355 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/30/2018	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M008	09/30/2018	

**Labeler** - Care One (American Sales Company) (809183973)

Revised: 10/2023

Care One (American Sales Company)