

## **SOOTHE- bismuth subsalicylate liquid**

### **Walgreens**

*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 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 Pepto-Bismol® active ingredient††

**Soothe®**

BISMUTH SUBSALICYLATE 525mg /

UPSET STOMACH RELIEVER /

ANTIDIARRHEAL

SUGAR FREE ALCOHOL FREE

- Provides protective coating action to relieve heartburn, indigestion, nausea, upset stomach & diarrhea

FL OZ (mL)

≠This product is not manufactured or distributed by 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: WALGREEN CO.

200 WILMOT RD, DEERFIELD, IL 60015

walgreens.com

## 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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**Questions or comments?**  
Call 1-877-753-3935 Monday-Friday 9AM-5PM EST  
Walgreens Pharmacist Recommended  
Walgreens Pharmacist Survey  
†† This product is not manufactured or distributed by The Procter & Gamble Company. Pepto-Bismol® is a registered trademark of The Procter & Gamble Company.  
PLD-C383B LB006194

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200 WILMOT RD., DEERFIELD, IL 60015  
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REV1118-RF 3 11917 08387 2

**Walgreens**

Compare to Pepto-Bismol® active ingredient††

**Soothe®** NDC 0363-0073-08

BISMUTH SUBSALICYLATE 525 mg /  
UPSET STOMACH RELIEVER /  
ANTIDIARRHEAL

SUGAR FREE ALCOHOL FREE

• Provides protective coating action to relieve heartburn, indigestion, nausea, upset stomach & diarrhea

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 (in each 30 mL)** Purpose  
Bismuth subsalicylate 525 mg.....Upset stomach reliever/  
Antidiarrheal

**Uses** relieves ■ diarrhea ■ travelers' diarrhea ■ upset stomach due to overindulgence in food and drink, including ■ heartburn ■ gas ■ indigestion ■ nausea ■ 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

WALGREENS Soothe

**SOOTHE**

bismuth subsalicylate liquid

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0363-0073
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>BISMUTH SUBSALICYLATE</b> (UNII: 62TEY51RR1) (BISMUTH CATION - UNII:ZS9CD1I8YE, SALICYLIC ACID - UNII:O414PZ4LPZ)	BISMUTH SUBSALICYLATE	525 mg in 30 mL

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<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>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: WIQ1H85SYP)	
<b>SORBIC ACID</b> (UNII: X045WJ989B)	
<b>METHYLCELLULOSE (1500 CPS)</b> (UNII: P0NTE48364)	

**Packaging**

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:0363-0073-08	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/31/2015	
2	NDC:0363-0073-16	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/31/2015	

**Marketing Information**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC MONOGRAPH FINAL	part335	01/31/2015	

**Labeler** - Walgreens (008965063)