

STOMACH RELIEF REGULAR STRENGTH- bismuth subsalicylate liquid ASSURED / DOLLAR TREE (Greenbrier International, 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.

Drug Facts

Active ingredient (in each 30 mL)

Bismuth subsalicylate 525 mg

Purpose

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

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 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 active ingredient in **Pepto-Bismol®**

REGULAR STRENGTH

Stomach Relief

Bismuth subsalicylate 525 mg

Upset Stomach Reliever

Anti-diarrheal

Multi-Symptom Relief of Nausea, Upset Stomach, Heartburn, Diarrhea, Indigestion

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 BOTTLE OR UNDER CAP IS BROKEN OR MISSING.

DISTRIBUTED BY

GREENBRIER INTERNATIONAL, INC.

500 VOLVO PARKWAY, CHESAPEAKE, VA 23320

Package Label

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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
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Do not use if you have ■ an ulcer
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***COMPARE TO ACTIVE INGREDIENT IN
PEPTO-BISMOL®**
NDC 33992-0372-4

ASSURED
REGULAR STRENGTH
Stomach Relief

• **Bismuth subsalicylate 525 mg**
*Upset Stomach Reliever
Anti-diarrheal*
*Multi-Symptom Relief of Nausea,
Upset Stomach, Heartburn, Diarrhea,
Indigestion*

4 FL OZ (118 mL)

Drug Facts (continued)

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)

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LB006181 6 39277 33384 1

Drug Facts (continued under label) PEEL HERE

Drug Facts (continued)

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■ symptoms get worse or last more than 2 days
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■ 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
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■ 30 mL (1 dose) every ½ to 1 hour as needed
■ do not exceed 8 doses (240 mL) in 24 hours
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Drug Facts (continued)

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ASSURED Regular Strength Stomach Relief

| STOMACH RELIEF REGULAR STRENGTH | | | |
|--|----------------|---------------------------|-----------------|
| bismuth subsalicylate liquid | | | |
| Product Information | | | |
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:33992-0372 |
| Route of Administration | ORAL | | |
| Active Ingredient/Active Moiety | | | |
| Ingredient Name | | Basis of Strength | Strength |
| BISMUTH SUBSALICYLATE (UNII: 62TEY51RR1) (BISMUTH CATION - UNII:Z59CD1I8YE, SALICYLIC ACID - UNII:O414PZ4LPZ) | | BISMUTH SUBSALICYLATE | 525 mg in 30 mL |
| Inactive Ingredients | | | |
| Ingredient Name | | | Strength |
| BENZOIC ACID (UNII: 8SKN0B0MIM) | | | |
| D&C RED NO. 22 (UNII: 1678RKX8RT) | | | |
| D&C RED NO. 28 (UNII: 7671P0Y5NH) | | | |
| 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:33992-0372-4 | 118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 04/30/2016 | 01/31/2025 |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part335 | 04/30/2016 | 01/31/2025 |

Labeler - ASSURED / DOLLAR TREE (Greenbrier International, Inc.) (610322518)

Revised: 10/2022

ASSURED / DOLLAR TREE (Greenbrier International, Inc.)