STOMACH RELIEF- bismuth subsalicylate liquid McKesson (Health Mart)

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

- travelers' diarrhea
- diarrhea
- upset stomach due to overindulgence in food and drink, including:
 - heartburn
 - o gas
 - indigestion
 - o nausea
 - 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 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 (1dose) every 1/2 to 1 hour as needed
 - o 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 active ingredient in Pepto-Bismol®†

REGULAR STRENGTH

Stomach Relief

Bismuth subsalicylate 525 mg

Upset Stomach Reliever/Antidiarrheal

Relieves:

Heartburn, Indigestion, Nausea, 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 Mckesson

One Post Street, San Francisco, CA 94104

www.healthmart.com

Package Label



HEALTH MART Regular Strength Stomach Relief

STOMACH RELIEF

bismuth subsalicylate liquid

| Product Information | | | |
|-------------------------|----------------|--------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:62011-0393 |
| 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 30 mL |

| Inactive Ingredients | | |
|---|----------|--|
| Ingredient Name | Strength | |
| BENZOIC ACID (UNII: 8 SKN0 B0 MIM) | | |
| D&C RED NO. 22 (UNII: 1678 RKX8 RT) | | |
| D&C RED NO. 28 (UNII: 767IP0 Y5NH) | | |
| MAGNESIUM ALUMINUM SILICATE (UNII: 6 M3P6 4V0 NC) | | |
| WATER (UNII: 059QF0KO0R) | | |
| SACCHARIN SO DIUM (UNII: SB8 ZUX40 TY) | | |
| SALICYLIC ACID (UNII: O414PZ4LPZ) | | |
| SODIUM SALICYLATE (UNII: WIQ 1H8 5S YP) | | |
| SORBIC ACID (UNII: X045WJ989B) | | |
| METHYLCELLULOSE (1500 CPS) (UNII: PONTE48364) | | |

| l | Packaging | | | | |
|---|-----------|----------------------|--|-------------------------|-----------------------|
| | # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| | | NDC:62011- 0393-1 | 237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 12/31/2018 | |

| Marketing Information | | | | |
|-----------------------|--|----------------------|--------------------|--|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| OTC MONOGRAPH FINAL | part335 | 12/31/2018 | | |
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Labeler - McKesson (Health Mart) (177667227)

Revised: 1/2019 McKesson (Health Mart)