STOMACH RELIEF REGULAR STRENGTH- bis muth subsalicylate liquid Best Choice (Valu Merchandisers Company)

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 dosng device
- keep dosing cup with product
- adults and children 12 years and over:
 - 30 mL (1 dose) every 1/2 or 60 mL (2 doses) every hour as needed for diarrhea/traveler's diarrhea
 - 30 mL (1 dose) every 1/2 as needed for overindulgence (upset stomach, heartburn, indigestion, nausea)
 - 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: potassium 8 mg, sodium 6 mg
- each 30 mL contains: salicylate 206 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, glycerin, purified water, sucralose, xanthan gum

Principal Display Panel

COMPARE TO THE ACTIVE INGREDIENT IN REGULAR STRENGTH PEPTO-BISMOL®*

Symptom Relief

BISMUTH SUBSALICYLATE 525 mg

UPSET STOMACH RELIEVER/ANTIDIARRHEAL

SOOTHING RELIEF FOR:

INDIGESTION, UPSET STOMACH, NAUSEA, HEARTHBURN, DIARRHEA

ALCOHOL FREE

SUGAR FREE

REGULAR STRENGTH

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.

PROUDLY DISTRIBUTED BY:

VALU MERCHANDISERS, CO.

5000 KANKAS AVE

KANSAS CITY, KS 66106

Package Label



BEST CHOICE Stomach Relief Regular Strength

STOMACH RELIEF REGULAR STRENGTH

bismuth subsalicylate liquid

| Product Information | duct Information | | | | |
|----------------------------|------------------|--------------------|---------------|--|--|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:63941-724 | | |
| Route of Administration | ORAL | | | | |

| Active Ingredient/Active Moiety | | | |
|-----------------------------------|--------------------------|----------|--|
| Ingredient Name | Basis of Strength | Strength | |
| | | 525 mg | |
| SALICYLIC ACID - UNII:O414PZ4LPZ) | SUBSALICYLATE | 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) | | |
| WATER (UNII: 059QF0KO0R) | | |
| SUCRALOSE (UNII: 96K6UQ3ZD4) | | |
| XANTHAN GUM (UNII: TTV12P4NEE) | | |

| 1 | Packaging | | | | |
|---|----------------------|--|-------------------------|-----------------------|--|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date | |
| 1 | NDC:63941-724- 08 | 237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 11/29/2019 | | |
| 2 | NDC:63941-724- 12 | 355 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 11/29/2019 | | |

| Marketing Information | | | | |
|-----------------------|--|----------------------|--------------------|--|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| OTC MONOGRAPH FINAL | part335 | 11/29/2019 | | |
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Labeler - Best Choice (Valu Merchandisers Company) (868703513)

Revised: 1/2020 Best Choice (Valu Merchandisers Company)