STOMACH RELIEF ULTRA- bismuth 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 15 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
 - o nausea
 - aas
 - 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 (1-800-222-1222) right away.

Directions

- do not take more than 8 doses (120 mL) in 24 hours
- use until diarrhea stops but not more than 2 days
- drink plenty of clear fluids to help prevent dehydration caused by diarrhea
- 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:
 - 15 mL (1dose) every 1/2 or 30 mL (2 doses) every hour as needed diarrhea/traveler's diarrhea
 - 15 mL (1 dose) every 1/2 hour as needed for overindulgence (upset stomach, heartburn, indigestion, nausea)
- children under 12 years of age: ask a doctor

Other information

• each 15 mL contains: sodium 6 mg

- each 15 mL contains: salicylate 227 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® ULTRA

ULTRA

Stomach Relief

Bismuth Subsalicylate 525 mg

Upset Stomach Reliever/Antidiarrheal

RELIEVES:

HEARTBURN, INDIGESTION, NAUSEA, UPSET STOMACH, DIARRHEA

2x STRENGTH PER OUNCET

ALCOHOL FREE AND 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.

tvs Original Pepto-Bismol®

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 KANSAS AVE

KANSAS CITY, KS 66106

www.bestchoicebrand.com

Package Label

SODIUM SALICYLATE (UNII: WQ1H85SYP)



BEST CHOICE Ultra Stomach Relief

STOMACH RELIEF ULTRA bismuth subsalicylate liquid **Product Information Product Type** HUMAN OTC DRUG Item Code (Source) NDC:63941-842 **Route of Administration ORAL Active Ingredient/Active Moiety Basis of Ingredient Name** Strength Strength BISMUTH SUBSALICYLATE (UNII: 62TEY51RR1) (BISMUTH CATION - UNII: ZS9CD1I8YE, BISMUTH 525 mg SALICYLIC ACID - UNII: 0414PZ4LPZ) SUBSALICYLATE in 15 mL **Inactive Ingredients Ingredient Name** Strength BENZOIC ACID (UNII: 85KN0B0MIM) **D&C RED NO. 22** (UNII: 1678RKX8RT) **D&C RED NO. 28** (UNII: 767IP0Y5NH) MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC) WATER (UNII: 059QF0KO0R) **SACCHARIN SODIUM** (UNII: SB8ZUX40TY) SALICYLIC ACID (UNII: O414PZ4LPZ)

SORBIC ACID (UNII: X045WJ989B)	
METHYLCELLULOSE (1500 CPS) (UNII: PONTE48364)	

F	Packaging						
#	tem Code	Package Description	Marketing Start Date	Marketing End Date			
1	NDC:63941- 842-08	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/30/2019	12/27/2024			
2	NDC:63941- 842-12	355 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/30/2019	12/27/2024			

Marketing In	Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph final	part335	04/30/2019	12/27/2024		

Labeler - Best Choice (Valu Merchandisers Company) (868703513)

Revised: 10/2022 Best Choice (Valu Merchandisers Company)