FAMILY CARE STOMACH RELIEF- bismuth subsalicylate liquid
United Exchange Corp.

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.

Active ingredient (in each 30 mL dose cup) Purpose

Bismuth subsalicylate 525 mg.....Upset stomach reliever and antidiarrheal

Uses

relieves

- diarrhea
- heartburn
- indigestion
- nausea
- gas
- belching
- fullness

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 salicytate 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 before use if you are taking any drug for

- anticoagulation (thinning the blood)
- diabetes
- gout
- arthritis

When using this product a temporary, but harmless, darkening of the stool and/or tongue may occur

Stop use and ask a doctor if

- diarrhea lasts more than 2 days
- symptoms get worse
- ringing in the ears or loss of hearing occurs

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.

Directions

- shake well before use
- for accurate dosing, use dose cup
- adults and children 12 years and over: 1 dose (2 Tbsp or 30 mL) every 1/2 to 1 hour as needed
- do not exceed 8 doses (16 Tbsp or 240 mL) in 24 hours
- use until diarrhea stops but not more than 2 days
- children under 12 years: ask a doctor
- drink plenty of clear fluids to help prevent dehydration caused by diarrhea

Other information

- each 30 mL dose cup contains: sodium 10 mg
- salicylate 202 mg
- magnesium 25 mg
- protect from freezing
- avoid excessive heat (over 104° or 40°C)
- low sodium

Inactive ingredients

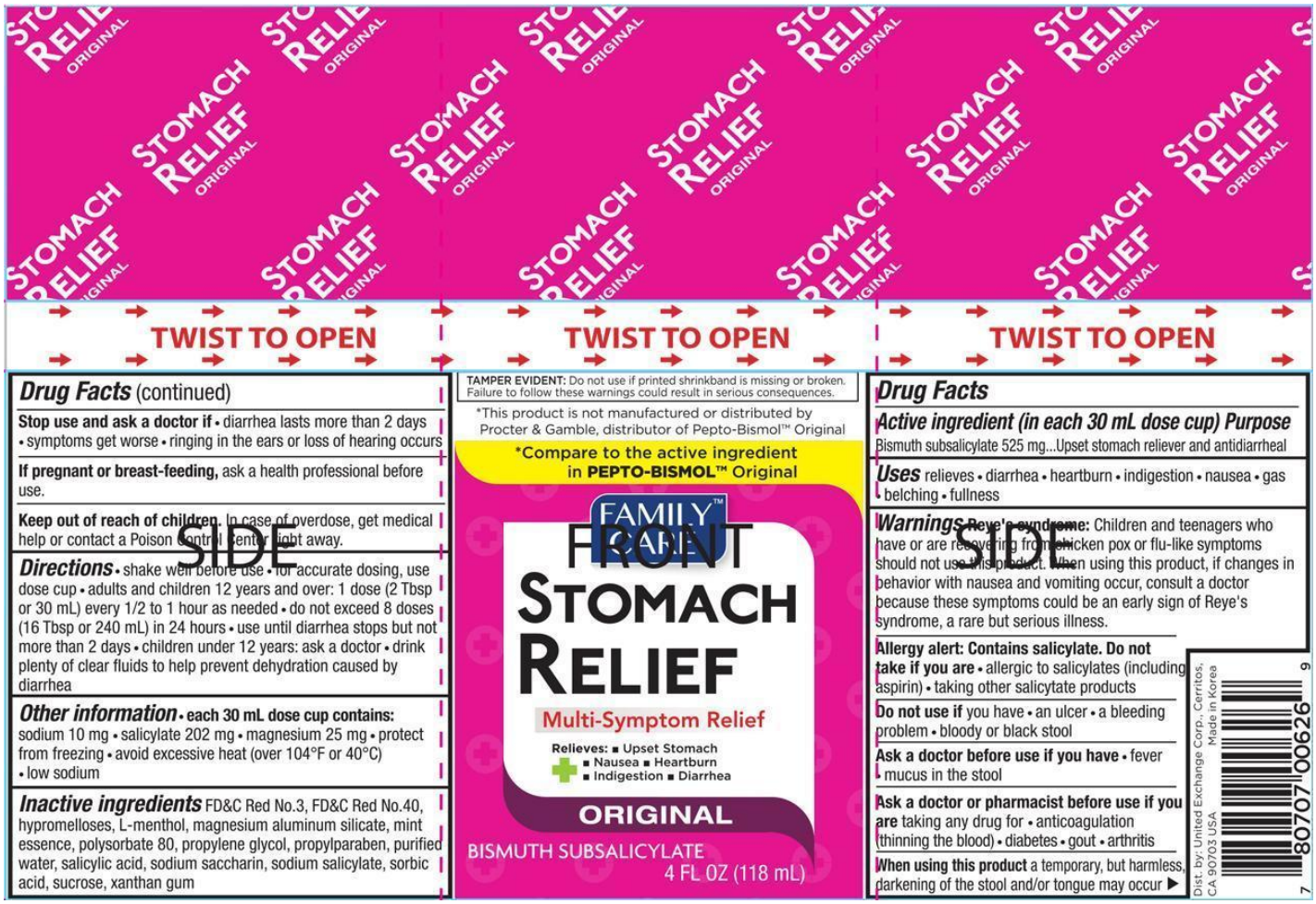
FD&C Red No. 3, FD&C Red No. 40, hypromelloses, L-menthol, magnesium aluminum silicate, mint essence, polysorbate 80, propylene glycol, propylparaben, purified water, salicylic acid, sodium saccharin, sodium salicylate, sorbic acid, sucrose, xanthan gum

Distributed by:

United Exchange Corp.

Cerritos, CA 90703 USA

Made in Korea



FAMILY CARE STOMACH RELIEF

bismuth subsalicylate liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:65923-626
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BISMUTH SUBSALICYLATE (UNII: 62TEY51RR1) (SALICYLIC ACID - UNII:O414PZ4LPZ)	BISMUTH SUBSALICYLATE	1050 mg in 30 mL

Inactive Ingredients	
Ingredient Name	**Strength**
FD&C RED NO. 3 (UNII: PN2ZH5LOQY)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MENTHOL (UNII: L7T10EIP3A)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SALICYLIC ACID (UNII: O414PZ4LPZ)	
SODIUM SALICYLATE (UNII: WIQ1H85SYP)	
SORBIC ACID (UNII: X045WJ989B)	
SUCROSE (UNII: C151H8M554)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65923-626-04	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part335	07/31/2015	

Labeler - United Exchange Corp. (840130579)

Revised: 7/2015 United Exchange Corp.