LEADER STOMACH RELIEF- bismuth subsalicylate liquid
Cardinal Health

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.

Cardinal Health Stomach Relief Drug Facts

Active ingredient (in each 15 mL Tablespoon)

Bismuth subsalicylate 262 mg

Purposes

Upset stomach reliever/antidiarrheal

Uses

relieves

- travelers' diarrhea
- diarrhea
- upset stomach due to overindulgence in food and drink, including:
- 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 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

- 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

- symptoms get worse
- 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

- 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 Tbsp contains: magnesium 5 mg, potassium 5 mg and sodium 5 mg
- salicylate 123 mg
- protect from freezing
- sugar free
- low sodium
- store at 20°-25°C (68°-77°F)
- does not meet USP requirements for pH
- for health information visit http://www.more-info.info/

Inactive ingredients

D&C red #22, D&C red #28, flavor, magnesium aluminum silicate, methylcellulose, purified water, saccharin sodium, salicylic acid, sodium salicylate, sorbic acid, xanthan gum

Questions or comments?

1-800-719-9260

Principal Display Panel

Compare to Original Pepto-Bismol® active ingredient

ORIGINAL STRENGTH

Stomach Relief

Upset Stomach Reliever/Antidiarrheal

Bismuth Subsalicylate 262 mg

Protective Coating Action

Soothing Relief for 5 Symptoms:

Heartburn

Indigestion

Upset Stomach

Nausea

Diarrhea

LEADER STOMACH RELIEF

bismuth subsalicylate liquid

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:37205-951
Route of Administration	ORAL	**DEA Schedule**	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BISMUTH SUBSALICYLATE (UNII: 62TEY51RR1) (BISMUTH CATION - UNII:ZS9CD1I8YE, SALICYLIC ACID - UNII:O414PZ4LPZ)	BISMUTH SUBSALICYLATE	262 mg in 15 mL

Inactive Ingredients

Ingredient Name	Strength
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)	
SODIUM SALICYLATE (UNII: WIQ1H85SYP)	
SORBIC ACID (UNII: X045WJ989B)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	PINK (viscous)	**Score**	
Shape		**Size**	
Flavor	MINT	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37205-951-40	355 mL in 1 BOTTLE		
2	NDC:37205-951-34	237 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part335	04/15/1990	

Labeler - Cardinal Health (097537435)