LEADER MAXIMUM STRENGTH STOMACH RELIEF- bismuth subsalicylate liquid
CARDINAL HEALTH 110, LLC. DBA LEADER

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.

Leader Maximum Strength Stomach Relief

ACTIVE INGREDIENT(in each 30 mL)

Bismuth subsalicylate 1050 mg

PURPOSE

Upset stomach reliever and anti-diarrheal

USE(S)

relieves:

- diarrhea
- heartburn
- indigestion
- nausea
- upset stomach associated with these symptoms

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
- bloody or black stool
- a bleeding problem

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 of 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 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 immediately.

DIRECTIONS

- **shake well before use**
- mL = milliliter
- TBSP = tablespoon
- adults and children 12 years and over: 1 dose (2 TBSP or 30 mL) every hour as needed
- do not exceed 4 doses (8 TBSP or 120 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 or 2 TBSP contains:**

- potassium 25 mg
- salicylate 471 mg
- sodium 8 mg
- protect from freezing
- avoid excessive heat (over 104ºF or 40ºC)
- dosage cup provided

INACTIVE INGREDIENTS

benzoic acid, D&C red # 22, D&C red # 28, flavor, hydroxyethyl cellulose, potassium hydroxide, purified water, saccharin sodium, salicylic acid, simethicone, xanthan gum

PRINCIPAL DISPLAY PANEL

LEADER
NDC 70000-0440-1

Maximum Strength
Stomach Relief

Bismuth Subsalicylate, 1050 mg
Upset Stomach Reliever / Antidiarrheal)
COMPARE TO PEPTO-BISMOL ULTRA active ingredient*

5 Symptom Digestive Relief:

Diarrhea, Heartburn, Indigestion, Nausea & Upset Stomach
12 FL OZ (354 mL)

LEADER MAXIMUM STRENGTH STOMACH RELIEF

bismuth subsalicylate liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:70000-0440
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**
BENZOIC ACID (UNII: 8SKN0B0MIM)	
D&C RED NO. 22 (UNII: 1678RKX8RT)	
D&C RED NO. 28 (UNII: 767IP0Y5NH)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SALICYLIC ACID (UNII: O414PZ4LPZ)	
HYDROXYETHYL CELLULOSE (1500 MPA.S AT 1%) (UNII: L605B5892V)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics			
Color	PINK	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:70000-0440-1	354 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/25/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part335	07/25/2019	

Labeler - CARDINAL HEALTH 110, LLC. DBA LEADER (063997360)

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