STOMACH RELIEF LIQUID MAXIMUM STRENGTH- bis muth subsalicylate suspension Sunmark

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 ingredients

Bismuth Subsalicylate 525 mg

Purpose

upset stomach reliever-antidiarrheal

Uses

relieves, upset stomach, heartburn indigestion, diarrhea, nausea

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 or 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- taking other salicylate products, allergic to salicylates (including aspirin)

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 stool

Ask a doctor or pharmacist before use if you are taking any drug for

anticoagulation (thinning 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 this and all drugs out of the reach of children

In case of accidental overdose, seek professional assistance or contact a Poison Control Center immediately.

Directions

shake well before use for accurate dosing, use dose cup adults and children 12 years and over: 1 dose (2 tablespoons or 30 ml) every hour as needed

do not exceed 4 doses (8 tablespoons 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 tablespoon contains: sodium 6 mg sugar free, low sodium, keep tightly closed avoid excessive heat (over 104°F or 40°C) protect from freezing.

Total salicylate per tablespoon, 236 mg Visit www.peptic-drug-facts.com

Inactive ingredients

benzoic acid, flavor, magnesium aluminum silicate, methyl cellulose, purified water, red 22, red 28, saccharin sodium, salicylic acid, sodium salicylate, sorbic acid

Principal Display Panel

COMPARE TO PEPTO BISMOL ACTIVE INGREDIENT

NDC 49348-923-37

STOMACH RELIEF LIQUID MAXIMUM STRENGTH
SOOTHING RELIEF FOR UPSET STOMACH
NAUSEA, INDIGESTION
HEARTBURN AND DIARRHEA
BISMUTH SUBSALICYLATE 525 mg
PROTECTIVE COATING ACTION
8 FL OZ (473 mL)



STOMACH RELIEF LIQUID MAXIMUM STRENGTH

maximum strength pepto bismol suspension

Product Information			
Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:49348-923
Route of Administration	ORAL	DEA Schedule	

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
BISMUTH SUBSALICYLATE (SALICYLIC ACID)	BISMUTH SUBSALICYLATE	525 mg in 15 mL

Inactive Ingredients		
Ingredient Name	Strength	
BENZOIC ACID		
MAGNESIUM ALUMINUM SILICATE		
METHYLCELLULOSE (100 CPS)		
SALICYLIC ACID		

SACCHARIN SO DIUM	
SORBIC ACID	
D&C RED NO. 22	
D&C RED NO. 28	

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	MINT (mint)	Imprint Code	
Contains			

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49348-923-37	237 mL in 1 BOTTLE, PLASTIC		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part335	11/08/2013	

Labeler - Sunmark (177667227)

Registrant - Aaron Industries, Inc. (101896231)

Establishment				
Name	Address	ID/FEI	Business Operations	
Aaron Industries, Inc.		101896231	manufacture(49348-923), analysis(49348-923)	

Revised: 11/2013 Sunmark