STOMACH RELIEF- bismuth subsalicylate liquid
PAI Holdings, LLC

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 30 mL dose)

Bismuth subsalicylate 525 mg

Purpose

Upset stomach reliever/Antidiarrheal

Uses

relieves

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

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

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

- 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

- mL = milliliter
- shake well before using
- only use dose ready dosing cup provided. Do not use any other dosing device
- adults and children 12 years and over:

- 30 mL (1 dose) every 1/2 hour or 60 mL (2 doses) every hour as needed for diarrhea/traveler's diarrhea
- 30 mL (1 dose) every 1/2 hour as needed for overindulgence (upset stomach, heartburn, indigestion, nausea)
- do not exceed 8 doses (240 mL) in 24 hours
- use until diarrhea stop but not more than 2 days

- children under 12 years of age: ask a doctor
- drink plenty of clear fluids to help prevent dehydration cause by diarrhea

Other information

- **each 30 mL contains**: potassium 8 mg, sodium 9 mg
- **each 30 mL contains**: salicylate 206 mg

- low sodium
- protect from freezing
- avoid excessive heat (over 104ºF or 40ºC)
- supplied in the following oral dosage forms

NDC 0121-0910-30: 30 mL unit dose cup, in a tray of ten cups.

Inactive ingredients

benzoic acid, D&C red #22, D&C red #28, flavor, glycerin, purified water, sucralose, xanthan gum

Questions or comments?

Call 1-800-845-8210.

PACKAGED BY:

Pharmaceutical Associates, Inc.

Greenville, SC 29605

www.paipharma.com

R11/20

Principal Display Panel

Delivers 30 mL

NDC 0121-0910-30

Bismuth Subsalicylate

525 mg/30 mL

Upset stomach reliever/Antidiarrheal

Package Not Child-Resistant

Pkg by: Pharmaceutical Associates, Inc.

Greenville, SC 29605

SEE INSERT

STOMACH RELIEF

bismuth subsalicylate liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0121-0910
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BISMUTH SUBSALICYLATE (UNII: 62TEY51RR1) (BISMUTH CATION - UNII:ZS9CD1I8YE, SALICYLIC ACID - UNII:O414PZ4LPZ)	BISMUTH SUBSALICYLATE	525 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)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics			
Color	pink	**Score**	
Shape		**Size**	
Flavor	WINTERGREEN	**Imprint Code**	

Contains	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0121-0910-40	4 in 1 CASE	07/17/2020	
1		10 in 1 TRAY		
1	NDC:0121-0910-30	30 mL in 1 CUP, UNIT-DOSE; 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	07/17/2020	

Labeler - PAI Holdings, LLC (044940096)

Establishment

Name	Address	ID/FEI	Business Operations
PAI Holdings, LLC dba Pharmaceutical Associates, Inc. and dba PAI Pharma		097630693	label(0121-0910) , manufacture(0121-0910)

Revised: 7/2023 PAI Holdings, LLC