

STOMACH RELIEF REGULAR STRENGTH- bismuth subsalicylate suspension
Pharmacy Value Alliance, LLC

Premier Value STOMACH RELIEF

Drug Facts

Active ingredient

(in each 30 mL dose cup or 2 tablespoons)

Bismuth subsalicylate 525 mg

Purposes

Upset stomach reliever
and antidiarrheal

Uses • relieves. travelers' diarrhea • diarrhea • upset stomach due to overindulgence of food and drink including:
• heart burn • indigestion • nausea • gas • 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

- black or bloody 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 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 a doctor if

- diarrhea lasts more than 2 days
- symptoms get worse or last more than 2 days
- 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
- use dose cup or tablespoon (TBSP)
- adults and children 12 years and over: 1 dose (30 mL or 2 TBSP) every 1/2 to 1 hour as needed
- do not exceed 8 doses (240 mL or 16 TBSP) 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 contains: sodium 13 mg, salicylate 256 mg

- protect from freezing
- avoid excessive heat (over 104° F or 40° C)
- Low sodium

Inactive ingredients benzoic acid, D&C red #22, D&C red # 28, flavor, purified water, saccharin sodium, salicylic acid, sodium salicylate, xanthan gum

Questions? 1-877-798-5944.

Principal Display Panel

Premier

Value®

COMPARE TO THE ACTIVE
INGREDIENTS IN
PEPTO BISMOL™*

STOMACH RELIEF

Bismuth Subsalicylate
Antidiarrheal / Upset Stomach Reliever

Regular Strength

5 Symptom Relief of:

- Nausea
- Heartburn
- Indigestion
- Upset stomach
- Diarrhea

8 FL OZ (237 mL)

INDEPENDENTLY TESTED

PV

SATISFACTION GUARANTEED

**TAMPER EVIDENT: Do not use if imprinted
shrinkband is missing or broken**

*This product is not manufactured or distributed by Procter & Gamble, Inc., the distributor of Pepto-Bismol™.

Distributed By:
Pharmacy Value Alliance, LLC
407 East Lancaster Avenue,
Wayne, PA 19087

Made in USA
LR-121

8 40986 03581 4

→DRUG FACTS CONTINUED ON BACK →

8 fl oz pkg.

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Drug Facts (continued)

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Peel Here

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12 fl oz pkg.

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12 FL OZ (354 mL)



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STOMACH RELIEF REGULAR STRENGTH			
bismuth subsalicylate suspension			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68016-557
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
	BISMUTH SUBSALICYLATE (UNII: 62TEY51RR1) (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: 7671P0Y5NH)		
	WATER (UNII: 059QF0KOOR)		
	SACCHARIN SODIUM (UNII: SB8ZUX40TY)		
	SALICYLIC ACID (UNII: O414PZ4LPZ)		
	SODIUM SALICYLATE (UNII: WQ1H85SYP)		
	XANTHAN GUM (UNII: TTV12P4NEE)		

Product Characteristics

Color	pink	Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68016-557-08	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/17/2019	
2	NDC:68016-557-12	354 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/17/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M008	12/17/2019	

Labeler - Pharmacy Value Alliance, LLC (101668460)

Registrant - AptaPharma Inc. (790523323)

Establishment

Name	Address	ID/FEI	Business Operations
AptaPharma Inc.		790523323	manufacture(68016-557)

Revised: 12/2023

Pharmacy Value Alliance, LLC