

STOMACH RELIEF - REGULAR STRENGTH- bismuth subsalicylate liquid
AptaPharma Inc.

Stomach Relief - Regular Strength

Drug Facts

Active ingredient
(in each 30 mL dose cup or 2 tablespoons)

Bismuth subsalicylate 525 mg

Purposes

Bismuth subsalicylate 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 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 doctor
- drink plenty of clear fluids to help prevent dehydration caused by diarrhea

Other information ■ each 30 mL dose cup 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

AP SAFE

NDC 76281-537-28

***COMPARE TO
the active ingredient in
PEPTO-BISMOL™**

**Stomach
Relief
Bismuth Subsalicylate
Antidiarrheal / Upset Stomach Reliever**

Regular Strength

5 Symptom Relief of:
● Nausea ● Heartburn ● Indigestion
● Upset stomach ● Diarrhea

12 FL OZ (354 mL)

**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™.

Made in USA **AP-LR-11 REV01**
**Manufactured by: AptaPharma Inc.,
1533 Union Ave.
Pennsauken, NJ 08110**

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12 OZ

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

NDC 76281-537-25



*COMPARE TO the active ingredient in PEPTO-BISMOL™

Stomach Relief

Bismuth Subsalicylate
Antidiarrheal / Upset Stomach Reliever

Regular Strength

5 Symptom Relief of:

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Drug Facts (continued)

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Directions ■ Shake well before use ■ use dose cup or tablespoon (TBS) ■ adults and children 12 years and over: 1 dose (30 mL or 2 TBS) every 1/2 to 1 hour as needed ■ do not exceed 8 doses (240 mL or 16 TBS) 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

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Manufactured by: AptaPharma Inc., 1533 Union Ave., Pennsauken, NJ 08110



6 OZ

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

NDC 76281-537-25



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Stomach Relief

Bismuth Subsalicylate
Antidiarrheal / Upset Stomach Reliever

Regular Strength

5 Symptom Relief of:

- Nausea • Heartburn • Indigestion
- Upset stomach • Diarrhea

6 FL OZ (177 mL)

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Manufactured by:
AptaPharma Inc.,
1533 Union Ave.,
Pennsauken, NJ 08110

Made in USA AP-LR-06 REV01



EXP:

LOT:

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Peel Here

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Stomach Relief - Regular Strength by AptaPharma Inc.

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STOMACH RELIEF - REGULAR STRENGTH

bismuth subsalicylate liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76281-537
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: 767IP0Y5NH)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SALICYLIC ACID (UNII: O414PZ4LPZ)	
SODIUM SALICYLATE (UNII: WQ1H85SYP)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	pink (color suspension)	Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76281-537-28	354 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/01/2018	
2	NDC:76281-537-25	177 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/01/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M008	10/01/2018	

Labeler - Aptapharma Inc. (790523323)

Registrant - AptaPharma Inc. (790523323)**Establishment**

Name	Address	ID/FEI	Business Operations
AptaPharma Inc.		790523323	manufacture(76281-537)

Revised: 12/2023

AptaPharma Inc.