STOMACH RELIEF, MAXIMUM STRENGTH- bismuth subsalicylate suspension
AptaPharma Inc.

Stomach Relief - Maximum Strength

Drug Facts

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

Bismuth subsalicylate 1050 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

Slop 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 hour as needed
■ do not exceed 4 doses (120 mL or 8 TBSP) in 24 hours
■ use until diarrhea stops but not more than 2 days
■ children under 12 years: ask adoctor
■ drink plenty of clear fluids to help prevent dehydration caused by diarrhea

Other information
■ **each 30 mL dose cup contains**:
sodium 13 mg, salicylate 455 mg
■ protect from freezing ■ avoid excessive heat (over 104ºF or 40ºC) ■ Low sodium

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

Questions? 1-877-798-5944

Principal Display Panel

AP *SAFE*® NDC 76281-558-25

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

Stomach
Relief
Bismuth Subsalicylate
Antidiarrheal/Upset Stomach Reliever

Maximum Strength

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

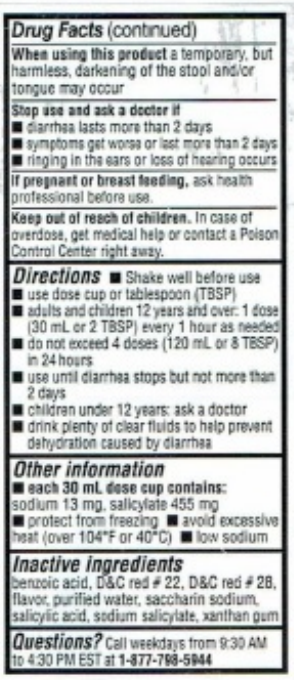
6 FL OZ (177 mL)

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™.

Manufactured by: AptaPharma Inc., Made in USA
1533 Union Ave. AP-LR-13
Pennsauken, NJ 081

LOT. **EXP.**



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STOMACH RELIEF, MAXIMUM STRENGTH

bismuth subsalicylate suspension

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:76281-558
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)	
WATER (UNII: 059QF0KO0R)	
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:76281-558-25	177 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/30/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M008	09/30/2020	

Labeler - AptaPharma Inc. (790523323)

Registrant - AptaPharma Inc. (790523323)

Establishment

Name	Address	ID/FEI	Business Operations
AptaPharma Inc.		790523323	manufacture(76281-558)

Revised: 12/2023 AptaPharma Inc.