

PINK-BISMUTH - bismuth subsalicylate liquid
Guardian Drug Company

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.

Pink-Bismuth Regular Strength

Active ingredient (in each 15 mL tbsp)

Bismuth subsalicylate 262 mg

Purpose

Upset stomach reliever and anti-diarrheal

Uses

relieves:

- diarrhea
- heartburn
- indigestion
- nausea
- upset stomach associated with these symptoms

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

- bloody or black stool
- an ulcer
- a bleeding problem

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

- 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

- 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 out of reach of children.

In case of overdose, get medical help 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 tbsp or 30 mL) every 1/2 to 1 hour as needed
- do not exceed 8 doses (16 tbsp or 240 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 Tbsp contains: sodium 5 mg, salicylate 130 mg, potassium 15 mg
- protect from freezing
- avoid excessive heat (over 104°F or 40°C)
- **TAMPER EVIDENT: Do not use if imprinted shrinkband is missing or broken.**

Inactive ingredients

benzoic acid, D and C red 22, D and C red 28, flavor, hydroxy ethyl cellulose, potassium hydroxide, purified water, saccharin sodium, salicylic acid, simethicone, xanthan gum.

Principal Display Panel

compare to the active ingredient in pepto-bismol®

Pink-Bismuth

Regular Strength

Protective coating

Bismuth subsalicylate

Anti-diarrheal/Upset stomach reliever

Soothing Relief For:

upset stomach

Indigestion

Nausea

Heartburn

Diarrhea

16 FL OZ (473 mL)

Drug Facts
Active ingredient (in each 15 mL tsp.) Purpose
Bismuth subsalicylate 262 mgUpset stomach reliever and anti-diarrheal

Uses relieves: ■ diarrhea ■ heartburn ■ indigestion ■ nausea ■ upset stomach associated with these symptoms

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Do not use if you have ■ bloody or black stool ■ an ulcer ■ a bleeding problem

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 ■ 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 ■ 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 out of reach of children. In case of overdose, get medical help or contact a Poison Control Center immediately.

Drug Facts continued

*Compare to the active ingredient of Pepto-Bismol®
NDC 53041-527-06

GUARDIAN

Pink-Bismuth

Regular Strength

Protective Coating

Bismuth Subsalicylate
Anti-diarrheal/Upset stomach reliever

Soothing Relief For:

- Upset stomach
- Indigestion
- Nausea
- Heartburn
- Diarrhea

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Drug Facts (continued)

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

Guardian Drug Company
2 Charles Court
Dayton, NJ 08810

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PINK-BISMUTH

bismuth subsalicylate liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53041-527
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BISMUTH SUBSALICYLATE (UNII: 62TEY51RR1) (BISMUTH CATION - UNII:ZS9CD1I8YE)	BISMUTH SUBSALICYLATE	262 mg in 15 mL

Inactive Ingredients

Ingredient Name	Strength
BENZOIC ACID (UNII: 8SKN0B0MIM)	
D&C RED NO. 22 (UNII: 1678RKX8RT)	
D&C RED NO. 28 (UNII: 767IP0Y5NH)	
HYDROXYETHYL CELLULOSE (2000 CPS AT 1%) (UNII: S38J6RZ N16)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
WATER (UNII: 059QF0K00R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SALICYLIC ACID (UNII: O414PZ4LPZ)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
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:53041-527-06	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/30/2008	
2	NDC:53041-527-05	354 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/30/2008	
3	NDC:53041-527-04	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/30/2008	
4	NDC:53041-527-03	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/30/2008	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part335	05/30/2008	

Labeler - Guardian Drug Company (119210276)