

PINK BISMUTH - bismuth subsalicylate liquid
Kareway Product, Inc.

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 15 ml Tablespoon)

Bismuth subsalicylate 262 mg

Purpose

Upset stomach reliever and antidiarrheal

Uses

relieves

- heartburn
- indigestion
- upset stomach
- nausea
- diarrhea

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 Reyes 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

- anticoagulation (thinning 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 right away.

Directions

- shake well before use
- for accurate dosing, use dose cup
- adults and children 12 years and over: 1 dose (2Tbsp 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 Tspb contains: sodium 9 mg
- salicylate 130 mg
- protect from freezing
- low sodium
- avoid excessive heat (over 104°F or 40°C)
- sugar free
- **TAMPER EVIDENT: Do not use if printed shrinkband is missing or broken.**

Inactive ingredients

propylene glycol, sodium benzoate, flavor, magnesium aluminum silicate, methylcellulose, red 40, saccharin sodium, salicylic acid, sodium salicylate, sorbic acid, water, sucrose, xanthan gum

Package label

Pink Bismuth

Drug Facts (continued)

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*This product is not manufactured by Procter & Gamble, owner of the registered trademark Pepto-Bismol®.



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KAREWAY
Exclusively distributed by:
Kareway Product Inc. Gardena, CA 90248
Made in Korea

Pure-Aid™

Compare to active ingredients in Pepto-Bismol

Pink Bismuth

BISMUTH SUBSALICYLATE UPSET STOMACH RELIEVER/ANTIDIARRHEAL

Soothing Relief for

- Heartburn
- Indigestion
- Upset Stomach
- Nausea
- Diarrhea

ORIGINAL

NET 6FL OZ(177mL)

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PINK BISMUTH

bismuth subsalicylate liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67510-0505
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
METHYLCELLULOSE (100 CPS) (UNII: 4GFU244C4J)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SALICYLIC ACID (UNII: O414PZ4LPZ)	
SODIUM SALICYLATE (UNII: WIQ1H85SYP)	
SORBIC ACID (UNII: X045WJ989B)	
WATER (UNII: 059QF0KO0R)	
SUCROSE (UNII: C151H8M554)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67510-0505-4	120 mL in 1 BOTTLE		
2	NDC:67510-0505-6	177 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part335	08/29/2011	

Labeler - Kareway Product, Inc. (121840057)

Revised: 8/2011

Kareway Product, Inc.