

BISMUTINA- bismuth subsalicylate liquid
Menper Distributors, 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.

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 or 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
- 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 the reach of children.

Directions:

Shake well before use

Adult and children 12 years and over: 1 dose (2tbsp or 30 mL) every 1/2 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 water or clear fluids to help prevent dehydration caused by diarrhea.

Other Information

Each tablespoon contains: Sodium 6 mg, Low sodium, Sugar free, Salicylate 130 mg. Protect from freezing. Avoid excessive heat (more than 140°F or 40°C)

Tamper-Evident: Do not use if imprinted shrinkband is missing or broken

Inactive ingredients

BENZOIC ACID, MAGNESIUM ALUMINUM SILICATE, METHYLCELLULOSE (100 CPS), FD&C YELLOW #5, SALICYLIC ACID, SODIUM SALICYLATE, SORBIC ACID, SUCRALOSE, WATER, XANTHAN GUM, KAOLIN, SODIUM SACCHARIN



Drug Facts

Active ingredient (in each 15 mL tbsp) Bismuth subsalicylate 262 mg.....**Purposes** Upset Stomach Reliever and Antidiarrheal

Uses Relieves ■ diarrhea
 ■ upset stomach due to over indulgence in food and drink, including:
 ■ heartburn ■ 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
 ■ 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 the reach of children. In case of accidental 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 (2 tbsp or 30 mL) every ½ hour 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: consult a doctor
 ■ Drink plenty of water or clear fluids to help prevent dehydration caused by diarrhea

Drug Facts (continued)

Other information
 ■ Each tablespoon contains: sodium 6 mg ■ Low sodium ■ Sugar free ■ Salicylate 130 mg ■ Protect from freezing ■ Avoid excessive heat (more than 104° F or 40° C) ■ Tamper-Evident: Do not use if printed cello-band is torn, broken or missing.

Inactive ingredients
 benzoic acid, FD&C yellow #5, flavor, kaolin, magnesium aluminum silicate, salicylic acid, sodium saccharin, sodium salicylate, sorbic acid, sucralose, sucrose, water, xanthan gum

Questions? call 1-800-560-5223 M-F 9 AM to 5 PM Eastern Time

Distributed by:
MENPER DISTRIBUTORS, INC.
 6500 N.W. 35th Avenue Miami, FL 33147



BISMUTINA			
bismuth subsalicylate liquid			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53145-055
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
BISMUTH SUBSALICYLATE (UNII: 62TEY51RR1) (SALICYLIC ACID - UNII:O414PZ4LPZ)		BISMUTH SUBSALICYLATE	262 mg in 15 mL
Inactive Ingredients			
Ingredient Name			Strength
BENZOIC ACID (UNII: 8SKN0B0MIM)			
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)			
KAOLIN (UNII: 24H4NWX5CO)			
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)			
XANTHAN GUM (UNII: TTV12P4NEE)			
SODIUM SALICYLATE (UNII: WIQ1H85SYP)			
SORBIC ACID (UNII: X045WJ989B)			
SUCRALOSE (UNII: 96K6UQ3ZD4)			
SALICYLIC ACID (UNII: O414PZ4LPZ)			
WATER (UNII: 059QF0K00R)			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53145-055-08	1 in 1 CARTON		
1		240 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part335	02/21/2012	

Labeler - Menper Distributors, Inc. (101947166)

Revised: 9/2013

Menper Distributors, Inc.