

PINK BISMUTH MAXIMUM STRENGTH- bismuth subsalicylate liquid
Rij Pharmaceutical Corporation

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 tablespoon= 15 mL)

Bismuth subsalicylate 525 mg

Purpose

Upset stomach reliever and anti-diarrheal

Uses

- relieves upset stomach due to overindulgence in food or drink
- controls 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 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
- if you have an ulcer or bleeding problem

Ask a doctor before use if you have

- fever
- mucus in the stool
- a magnesium-restricted diet
- a sodium-restricted diet

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 4 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

- drink plenty of clear fluids to help prevent dehydration caused by diarrhea
- shake well before using
- use pre-measured cup for accurate dosing
- repeat dosage every 1/2 to 1 hour as needed
- do not take more than 4 doses in 24 hours
- use until diarrhea stops but not more than 2 days
- **adults & children 12 years and over:** 2 tablespoons
- **children under 12 years:** ask a doctor

Inactive ingredients

Carboxymethylcellulose sodium, D&C Red #3, FD&C Red #40, flavor, glycerin, magnesium aluminum silicate, saccharin sodium, salicylic acid, sodium benzoate, sodium salicylate, sorbitol, water

Other information

- Store at room temperature. Protect from freezing and excessive heat (over 40°F or 104°C)
- **each tablespoon (15 mL) contains:** magnesium 32 mg
- **each tablespoon (15 mL) contains:** sodium 24 mg
- **each tablespoon (15 mL) contains:** total salicylate 262 mg
- **TAMPER EVIDENT: DO NOT USE IF PRINTED INNER CAP SEAL IS BROKEN OR MISSING.**

Principal Display Panel

Drug Facts

Active Ingredient (in each tablespoon=15mL) Purpose
Bismuth subsalicylate 525 mg { Upset stomach reliever
Anti-diarrheal

Uses • relieves upset stomach due to overindulgence in food or drink • controls 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 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 • if you have an ulcer or bleeding problem

Ask a doctor before use if you have • fever • mucus in the stool • a magnesium-restricted diet • a sodium-restricted diet

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



Pink Bismuth Liquid

Soothing Relief For:

- Upset Stomach
- Indigestion
- Diarrhea
- Heartburn
- Nausea

8 FL. OZ. (237mL)

TAMPER EVIDENT
DO NOT USE IF PRINTED INNER CAP SEAL IS BROKEN OR MISSING

NDC 53807-192-08

Compare to the Active Ingredient in Maximum Strength Pepto-Bismol®†

Special Coating Action



Drug Facts (continued)

Stop use and ask a doctor if • symptoms get worse • ringing in the ears or loss of hearing occurs • diarrhea lasts more than 4 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:

• drink plenty of clear fluids to help prevent dehydration caused by diarrhea • shake well before using • use pre-measured cup for accurate dosing • repeat dosage every 1/2 to 1 hour as needed • do not take more than 4 doses in 24 hours • use until diarrhea stops but not more than 2 days • adults & children 12 years and over: 2 tablespoons • children under 12 years: ask a doctor

Inactive ingredients:

Carboxymethylcellulose sodium, D&C Red #3, FD&C Red #40, flavor, glycerin, magnesium aluminum silicate, saccharin sodium, salicylic acid, sodium benzoate, sodium salicylate, sorbitol, water

Store at room temperature. Protect from freezing and excessive heat (over 40°C or 104°F) • each tablespoon (15 mL) contains: magnesium 32 mg • each tablespoon (15 mL) contains: sodium 24 mg • each tablespoon (15 mL) contains: total salicylate 262 mg

†This product is not manufactured or distributed by Procter & Gamble, Inc. owner of the registered trademark Pepto-Bismol® Maximum Strength Formula. All Preferred Plus Pharmacy products are satisfaction guaranteed or your money back from retailer where purchased.

Manufactured By:
P&P PHARMACEUTICAL CORP
40 COMMERCIAL AVENUE
MIDDLETOWN, NY 13841
Distributed By:
Kinray, Inc.
Whitehouse, NY 11357
Lfln 12/10



PINK BISMUTH MAXIMUM STRENGTH

bismuth subsalicylate liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53807-192
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BISMUTH SUBSALICYLATE (UNII: 62TEY51RR1) (BISMUTH CATION - UNII:ZS9CD118 YE)	BISMUTH SUBSALICYLATE	525 mg in 15 mL

Inactive Ingredients

Ingredient Name	Strength
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
FD&C RED NO. 3 (UNII: PN2ZH5LOQY)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SALICYLIC ACID (UNII: O414PZ4LPZ)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM SALICYLATE (UNII: WIQ1H85SYP)	
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0K00R)	

Product Characteristics

Color	PINK	Score	
Shape		Size	
Flavor	PEPPERMINT	Imprint Code	

Contains**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53807-192-08	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/16/1999	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part335	03/16/1999	

Labeler - Rij Pharmaceutical Corporation (144679156)**Establishment**

Name	Address	ID/FEI	Business Operations
Rij Pharmaceutical Corporation		144679156	manufacture(53807-192)

Revised: 5/2018

Rij Pharmaceutical Corporation