REGULAR STRENGTH PINK BISMUTH- bismuth subsalicylate suspension
Raritan Pharmaceuticals 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.

DRx Choice Regular Strength Bismuth Subsalicylate 525 mg Drug Facts

Active ingredient (in each 30 mL dose)

Bismuth subsalicylate 525 mg

Purposes

Upset stomach reliever and antidiarrheal

Uses

relieves

- travelers' diarrhea
- diarrhea
- upset stomach due to overindulgence in food and drink, including:
- heartburn
- indigestion
- nausea
- gas
- belching
- fullness

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 or last more than 2 days
- 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 (1-800-222-1222).

Directions

- shake well before use
- only use dose cup provided
- **adults and children 12 years and over:** (30 mL) 1 dose every 1/2 or 60 mL (2 doses) every hour as needed for diarrhea/traveler's diarrhea
- 30 mL (1 dose) every ½ hour as needed for overindulgence (upset stomach, heartburn, indigestion, nausea)
- do not exceed 8 doses (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 30 mL contains:** sodium 10 mg
- **salicylate 261 mg**
- low sodium

- sugar free
- store at room temperature
- protect from freezing
- avoid excessive heat (over 104°F 40°C)

Inactive ingredients

carboxymethylcellulose sodium, D&C Red No. 22, D&C Red No. 28, flavor, microcrystalline cellulose, potassium hydroxide, potassium sorbate, purified water, salicylic acid, simethicone emulsion, sodium benzoate, sucralose, xanthan gum

Questions or comments?

1-866-467-2748

Do not use if imprinted shrink band is missing or broken.

Principal Display Panel

DRx CHOICE®

NDC# **68163-706-04**

***Compare to the active ingredient Pepto-Bismol® Regular Strength**

Regular Strength

Pink Bismuth

Bismuth Subsalicylate

Upset Stomach Reliever/Antidiarrheal

Relieves nausea, heartburn, indigestion, upset stomach, diarrhea

ORIGINAL FLAVOR

4 FL. OZ. (118 mL)

Manufactured by:

Raritan Pharmaceuticals

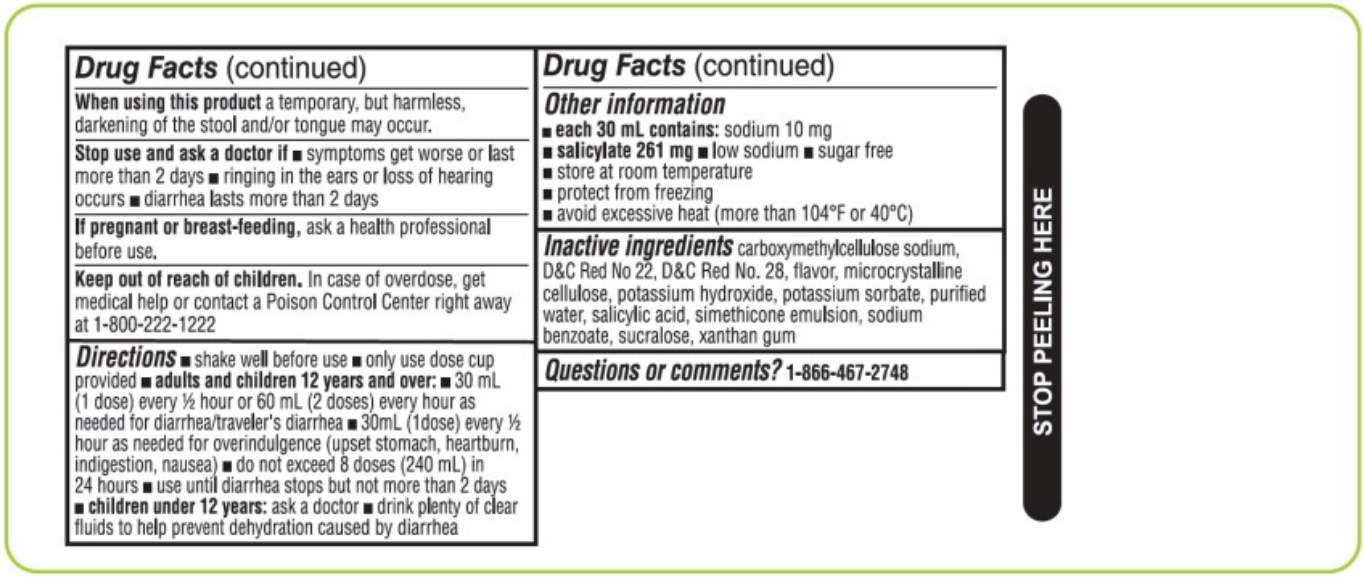
8 Joanna Court

East Brunswick, NJ 08816

DO NOT USE IF IMPRINTED SHRINK BAND IS MISSING OR BROKEN.

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

Package Label for 118 mL



Package Label for 354 mL

REGULAR STRENGTH PINK BISMUTH

bismuth subsalicylate suspension

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68163-706
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BISMUTH SUBSALICYLATE (UNII: 62TEY51RR1) (BISMUTH CATION - UNII:ZS9CD1I8YE, SALICYLIC ACID - UNII:O414PZ4LPZ)	BISMUTH SUBSALICYLATE	525 mg in 30 mL

Inactive Ingredients

Ingredient Name	Strength
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K679OBS311)	
D&C RED NO. 22 (UNII: 1678RKX8RT)	
D&C RED NO. 28 (UNII: 767IP0Y5NH)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
WATER (UNII: 059QF0KO0R)	
SALICYLIC ACID (UNII: O414PZ4LPZ)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics			
Color	PINK (viscous)	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68163-706-04	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/13/2019	
2	NDC:68163-706-12	354 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/13/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part335	05/13/2019	

Labeler - Raritan Pharmaceuticals Inc (127602287)

Revised: 9/2023 Raritan Pharmaceuticals Inc