REXALL BISMUTH- bismuth subsalicylate suspension
Dolgencorp, LLC

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.

Dolgencorp, LLC Bismuth Drug Facts

Active ingredient (in each 30 mL)

Bismuth subsalicylate 1050 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 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 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 the dose cup provided
- adults and children 12 years and over: 1 dose (30 mL) every hour as needed
- do not exceed 4 doses (120 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: magnesium 15 mg, potassium 5 mg and sodium 12 mg
- salicylate 461 mg
- low sodium
- store at 20-25°C (68-77°F). Avoid excessive heat over 104°F (40°C).
- protect from freezing
- does not meet USP requirements for pH
- for health information visit www.more-info.info

Inactive ingredients

D&C red #22, D&C red #28, magnesium aluminum silicate, methyl salicylate, methylcellulose, purified water, saccharin sodium, salicylic acid, sodium salicylate, sorbic acid, xanthan gum

Principal Display Panel

MAXIMUM STRENGTH

Bismuth

Bismuth subsalicylate 1050 mg per 30 mL

Upset stomach reliever / Antidiarrheal

Soothing relief for:

Indigestion

Upset stomach

Diarrhea

Heartburn

Nausea

GLUTEN FREE

12 FL OZ (355 mL)

REXALL BISMUTH

bismuth subsalicylate suspension

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:55910-337

Route of Administration	ORAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BISMUTH SUBSALICYLATE (UNII: 62TEY51RR1) (SALICYLIC ACID - UNII:O414PZ4LPZ, BISMUTH CATION - UNII:ZS9CD1I8YE)	BISMUTH SUBSALICYLATE	1050 mg in 30 mL

Inactive Ingredients	
Ingredient Name	**Strength**
D&C RED NO. 22 (UNII: 1678RKX8RT)	
D&C RED NO. 28 (UNII: 767IP0Y5NH)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SALICYLIC ACID (UNII: O414PZ4LPZ)	
SODIUM SALICYLATE (UNII: WIQ1H85SYP)	
SORBIC ACID (UNII: X045WJ989B)	
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:55910-337-40	355 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/06/2012	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part335	09/06/2012	

Labeler - Dolgencorp, LLC (068331990)

Revised: 7/2016 Dolgencorp, LLC