

REXALL BISMUTH- bismuth subsalicylate tablet, chewable
Dolgenercorp 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.

Dolgenercorp, LLC Bismuth Tabs Drug Facts

Active ingredient (in each tablet)

Bismuth subsalicylate 262 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

- chew or dissolve in mouth
- adults and children 12 years and over: 2 tablets every ½ to 1 hour as needed
- do not exceed 8 doses (16 tablets) 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 tablet contains: calcium 190 mg
- salicylate 104 mg
- very low sodium
- store at 20-25°C (68-77°F). Avoid excessive heat over 104°F (40°C).

Inactive Ingredients

calcium carbonate, D&C red #27 aluminum lake, flavor, magnesium stearate, mannitol, saccharin sodium, stearic acid

Principal Display Panel

Bismuth Tabs

Bismuth subsalicylate 262 mg

Upset stomach reliever / Antidiarrheal

Soothing relief for:

Indigestion

Upset stomach

Diarrhea

Heartburn

Nausea

actual size

30 Chewable Tablets



REXALL BISMUTH

bismuth subsalicylate tablet, chewable

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:559 10-469

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:ZS9CD18YE)	BISMUTH SUBSALICYLATE	262 mg

Inactive Ingredients

Ingredient Name	Strength
CALCIUM CARBONATE (UNII: H0G9379FGK)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 3OWL53L36A)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	

Product Characteristics

Color	PINK	Score	no score
Shape	ROUND	Size	17mm
Flavor		Imprint Code	L469
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55910-469-65	15 in 1 CARTON	09/28/2012	
1		2 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part335	09/28/2012	

Labeler - Dolgencorp Inc (068331990)

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Dolgencorp Inc