ULTRA BISMUTH- bis muth subsalicylate liquid Dolgencorp, Inc. (DOLLAR GENERAL & REXALL)

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 15 mL)

Bismuth subsalicylate 525 mg

Purpose

Upset stomach reliever/Antidiarrheal

Uses

relieves

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

Warnings

Reye's syndrome: Children and teenagers who have or are recovering from chicken pox or flu-like symptoms ahould 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

- diabetes
- gout
- arthritis
- anticoagulation (thinning the blood)

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 childen.

In case of overdose, get medical help or contact a Posion Control Center (1-800-222-1222) right away.

Directions

- do not take more than 8 doses (120 mL) in 24 hours
- use until diarrhea stops but not more than 2 days
- drink plenty of clear fluids to help prevent dehydration cause by diarrhea
- mL = mililiter
- shake well before using
- measure only with dosing cup provided. Do not use any other dosing device
- keep dosing cup with product
- adults and children12 years and over:
 - 15 mL (1 dose) every 1/2 hour or 30 mL (2 doses) every hour as needed for diarrhea/traveler's diarrhea
 - 15 mL (1 dose) every 1/2 hour as needed for overindulgence (upset stomach, heartburn, indigestion,nausea)
- children under 12 years of age: ask a doctor

Other information

• each 15 mL contains: sodium 6 mg

- each 15 mL contains: salicylate 227 mg
- low sodium
- keep tightly closed
- protect from freezing
- avoid excessive heat (over 104°F or 40°C)

Inactive ingredients

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

Questions or comments?

Call 1-888-309-9030

Principal Display Panel

ULTRA

Bismuth

Bismuth subsalicylate 525 mg per 15 mL

Upset stomach reliever / antidiarrheal

Soothing relief for:

- Indigestion
- Upset stomach
- Diarrhea
- Heartburn
- Nausea

2x Strength per ounce[†]

Alcohol free • Sugar free

GLUTEN FREE

FL OZ (mL)

TAMPER EVIDENT; DO NOT USE IF PRINTED SAFETY SEAL AROUND DOSAGE CUP OR UNDER CAP IS BROKEN OR MISSING.

MANUFACTURED FOR DOLGENCORP, LLC

100 MISSION RIDGE

GOODLETTSVILLE, TN 37072 USA

Package Label



REXALL Ultra Bismuth

ULTRA BISMUTH

bismuth subsalicylate liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55910-843
Route of Administration	ORAL		

Active Ingredient/Active Moiety					
Ingredient Name	Basis of Strength	Strength			
BISMUTH SUBSALICYLATE (UNII: 62TEY51RR1) (BISMUTH CATION - UNII:ZS9CD118 YE, SALICYLIC ACID - UNII:O414PZ4LPZ)	BISMUTH SUBSALICYLATE	525 mg in 15 mL			

Ingredient Name	Strength
BENZOIC ACID (UNII: 8 SKN0 B0 MIM)	
D&C RED NO. 22 (UNII: 1678 RKX8 RT)	
D&C RED NO. 28 (UNII: 767IP0 Y5NH)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SO DIUM (UNII: SB8 ZUX40 TY)	
SALICYLIC ACID (UNII: O414PZ4LPZ)	
SODIUM SALICYLATE (UNII: WIQ 1H8 5SYP)	
SORBIC ACID (UNII: X045WJ989B)	
METHYLCELLULOSE (1500 CPS) (UNII: P0NTE48364)	

Packaging					
# Item Code	Package Description	Marketing Start Date	Marketing End Date		
1 NDC:55910-843- 12	$355~\mathrm{mL}$ in $1~\mathrm{BOTTLE},$ PLASTIC; Type 0: Not a Combination Product	09/30/2018			
Marketing Information					
Marketing Cates	gory Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC MONOGRAPH F	INAL part335	09/30/2018			

Labeler - Dolgencorp, Inc. (DOLLAR GENERAL & REXALL) (068331990)

Revised: 12/2019 Dolgencorp, Inc. (DOLLAR GENERAL & REXALL)