

DG HEALTH STOMACH RELIEF MAXIMUM STRENGTH- bismuth subsalicylate suspension
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 Stomach Relief 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
- diarrhea lasts more than 2 days
- ringing in the ears or loss of hearing occurs

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

Questions or comments?

1-888-309-9030

Principal Display Panel

Compare to active ingredient of Pepto-Bismol® Max Strength

Maximum Strength

Stomach Relief

Bismuth Subsalicylate 1050 mg per 30 mL

Upset Stomach Reliever/Antidiarrheal

Relieves:

Heartburn

Indigestion

Nausea

Upset stomach

Diarrhea

8 FL OZ (237 mL)

Drug Facts (continued)

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

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Compare to the active ingredient of Pepto-Bismol® Max Strength*

Drug Facts **DO NOT USE IF PRINTED NECKBAND IS BROKEN OR MISSING**

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DG HEALTH STOMACH RELIEF MAXIMUM STRENGTH

bismuth subsalicylate suspension

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55910-800
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:ZS9CD118YE)	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: 059QF0K00R)	
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	WINTERGREEN	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55910-800-34	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/09/2012	

Marketing Information

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

Labeler - Dolgencorp Inc (068331990)