

BISMUTH CHEWABLE- bismuth subsalicylate 262 mg tablet, chewable
Marc Glassman, 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.

Bismuth

Active ingredient

Bismuth subsalicylate 262mg (each tablet contains 102mg salicylate)

Purpose

Antidiarrheal/Antacid

Uses

- controls diarrhea
- relieves heartburn, indigestion, nausea and upset stomach

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

- bloody or black stool
- an ulcer
- a bleeding problem

Ask a doctor before use if you have

- fever
- mucus in the stool

Ask a doctor or pharmacist before use if

you are taking a drug for

- anticoagulation (thinning of 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 for more than 2 days

Pregnancy/Breastfeeding

If pregnant or breast feeding, ask a health professional before use.

Keep out of reach of children

Keep out of reach of children. In case of accidental overdose, contact a doctor or Poison Control Center (1-800-222-1222) immediately.

Directions

- drink plenty of clear fluids to help prevent dehydration caused by diarrhea
- **Adults and children 12 years and over:** 2 tablets every ½ to 1 hour or 4 tablets every hour as needed
- do not exceed 16 tablets in 24 hours
- use until diarrhea stops but no more than 2 days
- **Children under 12 years of age:** ask a doctor

Other information

- Phenylketonurics: contains phenylalanine 1.1mg per tablet
- Calcium content per tablet: 73mg
- save carton for full directions and warnings
- store at room temperature 15°– 30°C (59°– 86°F)
- do not use if cellophane unit is torn

Inactive ingredients

acacia gum, aspartame, calcium carbonate, D&C red # 27 aluminum lake, dextrans, magnesium stearate, maltodextrin, microcrystalline cellulose, peppermint flavor, silicon dioxide

Principal Display Panel

Bismuth Subsalicylate 262 mg

NDC 68998-046-88 Compare to Pepto-Bismol®
Active Ingredients*



Bismuth

Bismuth Subsalicylate 262 mg

Sugar Free - Very Low Sodium

Soothing Relief for:

- Upset Stomach
- Indigestion
- Diarrhea
- Heartburn
- Nausea



30 Flavored
Chewable
Tablets

Bismuth Subsalicylate 262 mg

Drug Facts

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Inactive ingredients acacia gum, aspartame, calcium carbonate, D&C red # 27 aluminum lake, dextrates, magnesium stearate, maltodextrin, microcrystalline cellulose, peppermint flavor, silicon dioxide

*This product is not manufactured or distributed by Procter & Gamble, owner of the registered trademark Pepto-Bismol®.

Distributed by: Marc Glassman, Inc.
West 130th Street, Cleveland, OH 44130



Bismuth

BISMUTH CHEWABLE

bismuth subsalicylate 262 mg tablet, chewable

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68998-046
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BISMUTH SUBSALICYLATE (UNII: 62TEY51RR1) (SALICYLIC ACID - UNII:O414PZ4LPZ)	BISMUTH SUBSALICYLATE	262 mg

Inactive Ingredients

Ingredient Name	Strength
ASPARTAME (UNII: Z0H242BBR1)	
CALCIUM CARBONATE (UNII: H0G9379FGK)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
DEXTRATES (UNII: G263MI44RU)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTO DEXTRIN (UNII: 7CVR7L4A2D)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Product Characteristics

Color	PINK	Score	no score
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Shape	ROUND	Size	17mm
Flavor	PEPPERMINT	Imprint Code	RH;046
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68998-046-88	30 in 1 CARTON	04/28/2003	
1		1 in 1 CELLO 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	04/28/2003	

Labeler - Marc Glassman, Inc. (094487477)

Revised: 12/2016

Marc Glassman, Inc.