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

046 - 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

ask a health professional before use.

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 revent deydration caused by diarrhea
- \blacksquare Adults and children 12 years and over: 2 tablets every $\frac{1}{2}$ 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, dextrates, magnesium stearate, maltodextrin, microcrystalline cellulose, peppermint flavor, silicon dioxide

Principal Display Panel



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

Product

Ingredient Name	Basis of Strength	Strength
BISMUTH SUBSALICYLATE (UNII: 62TEY51RR1) (SALICYLIC ACID - UNII: 0414PZ4LPZ)	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)			
MALTODEXTRIN (UNII: 7CVR7L4A2D)			
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)			
SILICON DIOXIDE (UNII: FTI776XBU4)			

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

Packaging Marketing Start Marketing End Package Description # Item Code Date 1 NDC:68998-046-88 30 in 1 CARTON 04/28/2003 1 in 1 CELLO PACK; Type 0: Not a Combination 1

Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC Monograph Drug	M008	04/28/2003				

Labeler - Marc Glassman, Inc. (094487477)

Revised: 12/2016 Marc Glassman, Inc.