

GASTROBIZ- bismuth subsalicylate tablet, chewable

Allegiant Health

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.

Gastrobiz Bismuth Subsalsicylate 262mg

Active ingredient

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

Purpose

Antidiarrheal/Antacid

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 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 or last more than 2 days
- ringing in the ears or loss of hearing occurs
- diarrhea lasts more than 2 days

Pregnancy/Breastfeeding

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

Keep out of reach of children

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

Directions

- chew or dissolve in mouth
- **Adults and children 12 years and over:** 2 tablets (1 dose) every ½ hour or 4 tablets (2 doses) every hour as needed for diarrhea
- 2 tablets (1 dose) every 1/2 hour as needed for overindulgence (upset stomach, heartburn, indigestion, nausea)
- do not exceed 8 doses (16 tablets) in 24 hours
- use until diarrhea stops but not more than 2 days
- **Children under 12 years of age:** ask a doctor
- drink plenty of clear fluids to help prevent dehydration caused by diarrhea

Other information

- **Phenylketonurics:** contains phenylalanine 1.1mg per tablet
- **Each tablet contains:** calcium 73mg
- save carton for full directions and warnings
- store at room temperature 15°– 30°C (59°– 86°F)
- avoid excessive heat (over 40°C or 104°F)

- do not use if cellophane unit is torn
- you may report side effects to 1888-952-0050

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

SUMMR®

Compare to Pepto Bismol® Active Ingredient

Gastrobiz

Bismuth Subsalicylate 262 mg

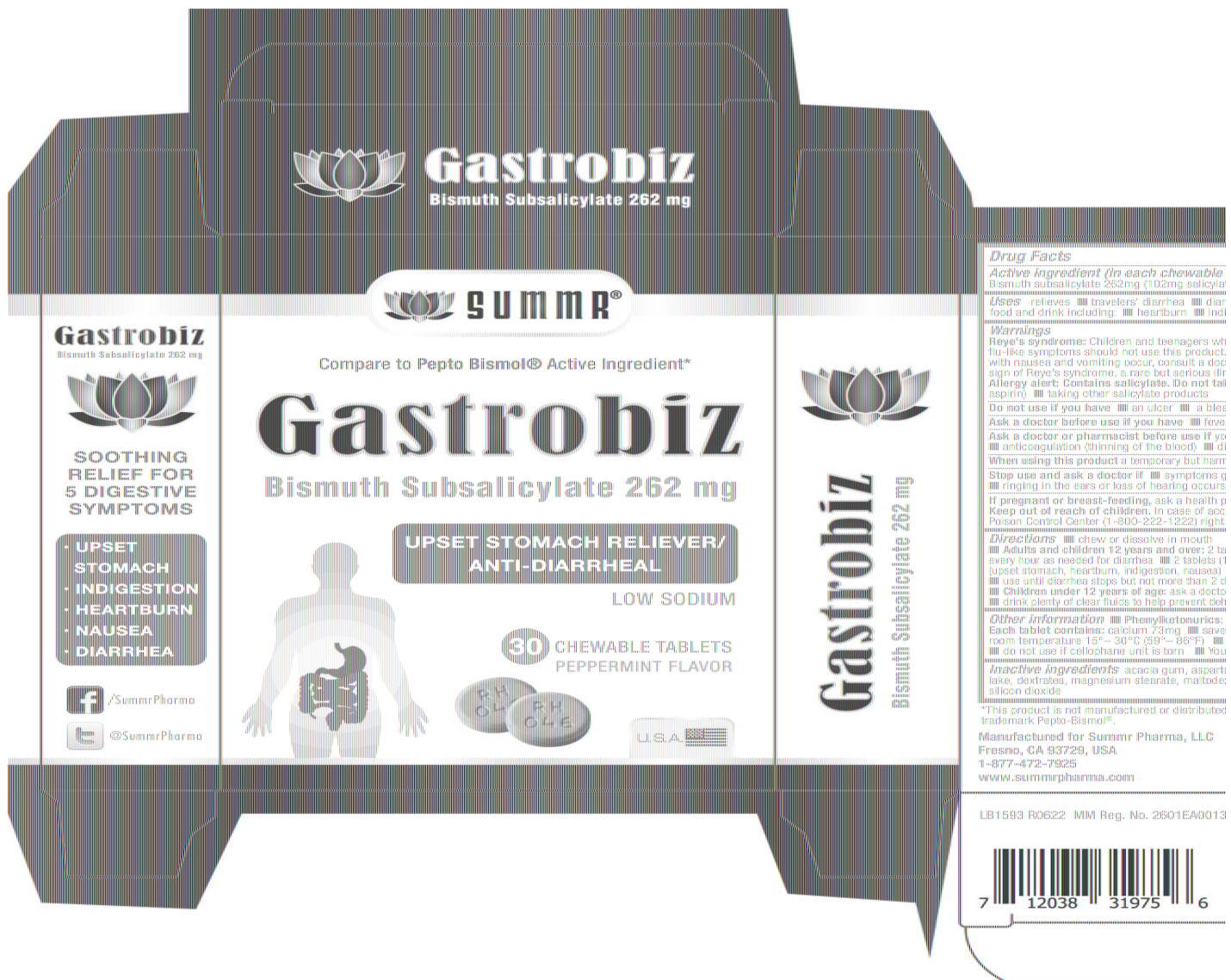
UPSET STOMACH RELIEVER/ANTI-DIARRHEAL

PROTECTIVE COATING ACTION

LOW SODIUM

30 CHEWABLE TABLETS

PEPPERMINT FLAVOR



Gastrobiz

GASTROBIZ

bismuth subsalicylate tablet, chewable

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69168-999
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
ACACIA (UNII: 5C5403N26O)	
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)	
PEPPERMINT (UNII: V95R5KMY2B)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69168-999-98	30 in 1 CARTON	07/04/2014	
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	07/04/2014	

Labeler - Allegiant Health (079501930)

Registrant - Allegiant Health (079501930)

Revised: 9/2018

Allegiant Health