

BISMUTH- bismuth subsalicylate tablet
Safecor Health, LLC

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

Bismuth subsalicylate 262 mg (each tablet contains 102 mg 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 the blood)
- diabetes
- gout
- arthritis

Stop use and ask a doctor if

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

When using this product

a temporary, but harmless, darkening of the stool and/or tongue may occur

If pregnant or breast-feeding

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) 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 ½ 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 no 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 1.1 mg per tablet

Calcium content per tablet: 73 mg

- save carton for full directions and warnings
- store at room temperature 15°- 30°C (59°- 86°F)

Inactive Ingredients

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

BISMUTH SUBSALICYLATE

262 mg Chewable Tablet

Contains 100 Unit Dose Blisters NDC: 48433-127-01

3 48433 127 10 0

GTIN: 00348433127100

SN: 222202401

Exp: 2024-03-27

Lot: 22A0078

These unit dose packages meet USP specifications for light resistance.

The package design is not child resistant. For institutional use only.

Distributed by Safecor Health, LLC 317 New Boston St, Woburn MA 01801

06/2022 PN5728

Package/Label Principal Display Panel

Bismuth Subsalicylate

262 mg

Chewable Tablet

Mfg: Allegiant Health

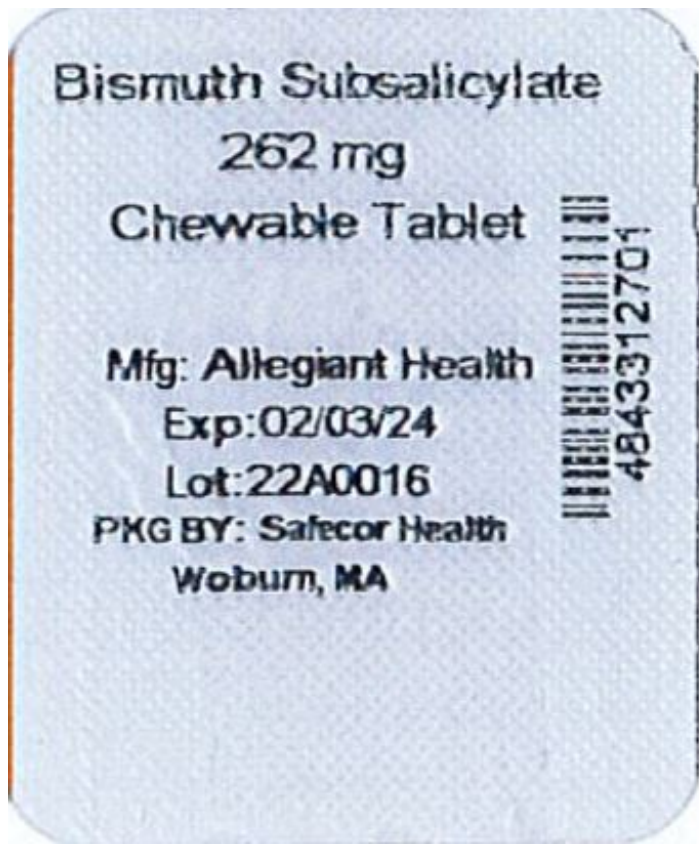
Exp:02/03/24

Lot22A0016

PKG BY: Safecor Health

Woburn, MA

4843312701



BISMUTH

bismuth subsalicylate tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:48433-127(NDC:69168-046)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BISMUTH SUBSALICYLATE (UNII: 62TEY51RR1) (BISMUTH CATION - UNII:ZS9CD1I8YE)	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)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
ACACIA (UNII: 5C5403N26O)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
PEPPERMINT (UNII: V95R5KMY2B)	

Product Characteristics

Color	pink	Score	no score
Shape	ROUND	Size	17mm
Flavor	PEPPERMINT	Imprint Code	RH046
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:48433-127-10	100 in 1 BOX, UNIT-DOSE	08/01/2020	
1	NDC:48433-127-01	1 in 1 BLISTER 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	08/01/2020	

Labeler - Safecor Health, LLC (828269675)

Establishment

Name	Address	ID/FEI	Business Operations
Safecor Health, LLC		828269675	repack(48433-127)

Establishment

Name	Address	ID/FEI	Business Operations
Allegiant Health		079501930	manufacture(48433-127)

Revised: 6/2022

Safecor Health, LLC