

BISMUTH SUBSALICYLATE- bismuth subsalicylate tablet, film coated **Cardinal 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.

5346 - Cardinal

Drug Facts

Active ingredient (in each caplet)

Bismuth subsalicylate 262 mg

Purpose

Upset stomach reliever and anti-diarrheal

Uses

relieves: ■ travelers' diarrhea ■ diarrhea
■ upset stomach due to overindulgence in food and drink, including: ■ heartburn ■ indigestion ■ nausea ■ gas ■ belching ■ fullness

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

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 (1-800-222-1222) immediately.

Directions

- swallow caplets with water, do not chew

adults and children 12 years and over:

- 2 caplets (1 dose) every 1/2 hour or 4 caplets (2 doses) every hour as needed for diarrhea
- 2 caplets (1 dose) every 1/2 hour as needed for overindulgence (upset stomach, heartburn, indigestion, nausea)
- do not exceed 8 doses (16 caplets) 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 caplet contains:** salicylate 102 mg
- Store in a dry place at 15° – 30°C (59° – 86°F)
- **TAMPER EVIDENT:** do not use if printed seal under cap is torn or missing

croscarmellose sodium, crospovidone, hypromellose, magnesium stearate, microcrystalline cellulose, mineral oil, povidone, silica, sodium lauryl sulfate, stearic acid, talc, titanium dioxide, triacetin.

Questions or comments?

1-800-200-6313

RETAIN THIS CARTON FOR FULL LABELING INFORMATION

WARNING: This product can expose you to chemicals including lead, which is known to the State of California to cause cancer and birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov.

COMPARE TO PEPTO-BISMOL active ingredient*

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

DISTRIBUTED BY CARDINAL HEALTH

DUBLIN, OHIO 43017
 www.myleader.com
 1-800-200-6313
 Essential to Care™ since 1979
 Product of Mexico



BISMUTH SUBSALICYLATE

bismuth subsalicylate tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0594
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
CROSPROVIDONE (UNII: 2S7830E561)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
TALC (UNII: 7SEV7J4R1U)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
POVIDONE K30 (UNII: U725QWY32X)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
TRIACETIN (UNII: XHX3C3X673)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

Product Characteristics

Color	white	Score	no score
Shape	OVAL	Size	17mm
Flavor		Imprint Code	V
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0594-1	1 in 1 CARTON	01/03/2022	
1		24 in 1 BOTTLE; 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	01/03/2022	

Labeler - Cardinal Health (063997360)