

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

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**5346 - Cardinal**

***Drug Facts***

***Active ingredient (in each caplet)***

Bismuth subsalicylate 262 mg

***Purpose***

Upset stomach reliever and antidiarrheal

***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?**

1-800-231-4670

**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](http://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®.


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DUBLIN, OHIO 43017

[www.myleader.com](http://www.myleader.com)

1-800-200-6313

Essential to Care™ since 1979

	<p><b>Drug Facts (continued)</b></p> <p>Ask a doctor or pharmacist before use if you are taking any drug for</p> <ul style="list-style-type: none"> <li>■ anticoagulation (thinning the blood) ■ diabetes ■ gout ■ arthritis</li> </ul> <p>When using this product a temporary but harmless darkening of the stool and/or tongue may occur.</p> <p>Stop use and ask a doctor if ■ symptoms get worse or last more than 2 days</p> <ul style="list-style-type: none"> <li>■ ringing in the ears or loss of hearing occurs ■ diarrhea lasts more than 2 days</li> </ul> <p>If pregnant or breast-feeding, ask a health professional before use. <b>Keep out of reach of children.</b> In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) immediately.</p> <p><b>Directions</b> ■ swallow caplets with water, do not chew ■ <b>adults and children 12 years and over:</b> ■ 2 caplets 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 overindigestion (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 ■ <b>children under 12 years:</b> ask a doctor ■ drink plenty of clear fluids to help prevent dehydration caused by diarrhea ▲</p>	
<p>R51368</p>	<p><b>Drug Facts</b></p> <p><b>Active ingredient (in each caplet)</b> Bismuth subsalicylate 262 mg</p> <p><b>Uses</b> relieves: ■ travelers' diarrhea ■ diarrhea ■ upset stomach due to overindigestion in food and drink, including: ■ heartburn ■ indigestion ■ nausea ■ gas ■ belching ■ fullness</p> <p><b>Warnings</b> 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.</p> <p><b>Allergy alert: Contains salicylate. Do not take if you are</b> ■ allergic to salicylates (including aspirin) ■ taking other salicylate products.</p> <p><b>Do not use if you have</b> ■ an ulcer ■ a bleeding problem ■ bloody or black stool</p> <p>Ask a doctor before use if you have ■ fever ■ mucus in the stool ▲</p>	
<p><b>CardinalHealth™</b></p> <p>DISTRIBUTED BY CARDINAL HEALTH DUBLIN, OHIO 43017 www.myleader.com 1-800-200-6335 <b>Essential to Care™ since 1979</b></p> <p>Product of Mexico</p> <p>*This product is not manufactured or distributed by The Procter &amp; Gamble Company, the distributor of Pepto-Bismol®.</p> <p>©2022 Cardinal Health. CARDINAL HEALTH, the Cardinal Health LOGO, ESSENTIAL TO CARE, LEADER, and the Leader LOGO are trademarks or registered trademarks of Cardinal Health. All other marks are the property of their respective owners.</p> <p><b>100% Money Back Guarantee</b> Return to place of purchase if not satisfied.</p>	<p><b>LEADER™</b></p> <p><b>Stomach Relief</b></p> <p>Bismuth Subsalicylate, 262 mg Upset Stomach Reliever   Antidiarrheal</p> <p>NDC 70000-0594-1</p> <p><b>COMPARE TO PEPTO-BIS-MOL®</b> active ingredient*</p> <p>100% Money Back guarantee</p> <p>Actual Size</p> <p><b>24 CAPLETS</b></p>	<p>CIN 5745799 REV. 7/22</p>  <p>0 96295 14 137 5</p>
	<p><b>Drug Facts (continued)</b></p> <p><b>Other information</b> ■ each caplet contains: salicylate 102 mg ■ Store in a dry place at 15° - 30°C (59° - 86°F) ■ <b>TAMPER EVIDENT: do not use if printed seal under caplet is torn or missing</b></p> <p><b>Inactive ingredients</b> croscarmellose sodium, crospovidone, hypromellose, magnesium stearate, microcrystalline cellulose, mineral oil, povidone, silica, sodium lauryl sulfate, stearic acid, talc, titanium dioxide, triacetin.</p> <p><b>Questions or comments?</b> 1-800-231-4670</p> <p><b>RETAIN THIS CARTON FOR FULL LABELING INFORMATION</b></p> <p><b>WARNING:</b> 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.</p>	

**BISMUTH SUBSALICYLATE**  
bismuth subsalicylate tablet, film coated

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70000-0594
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>CROSPROVIDONE</b> (UNII: 2S7830E561)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	
<b>CROSCARMELLOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>TRIACETIN</b> (UNII: XHX3C3X673)	
<b>LIGHT MINERAL OIL</b> (UNII: N6K5787QVP)	
<b>POVIDONE K30</b> (UNII: U725QWY32X)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	

## Product Characteristics

<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	17mm
<b>Flavor</b>		<b>Imprint Code</b>	V
<b>Contains</b>			

## 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

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC Monograph Drug	M008	01/03/2022	

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**Labeler** - Cardinal Health (063997360)

Revised: 1/2024

Cardinal Health