

**BISMUTH SUBSALICYLATE- bismuth subsalicylate capsule, gelatin coated**  
**Spirit Pharmaceuticals LLC**

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**Stomach Relief Softgels**

**Drug Facts**

**Active ingredient ( in each softgel)**

**Purpose**

Bismuth subsalicylate 262 mg .....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

**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

**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 right away.

**Directions**

- swallow with water, do not chew
- adults and children 12 years and over:
  - 2 softgels every ½ hour or 4 softgels every hour as needed for diarrhea
  - 2 softgels every ½ hour to 1 hour as needed for overindulgence (upset stomach, heartburn, indigestion, nausea)
- do not exceed 8 doses (16 softgels) 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 softgel contains: salicylate 102 mg
- very low sodium
- do not exceed 25°C

**Inactive ingredients**

beeswax, colloidal silicon dioxide, FD&C Red#33, FD&C Yellow#6, gelatin, glycerin, light liquid paraffin, povidone, purified water, soya lecithin, sodium carboxymethyl cellulose, sorbitol sorbitan solution, titanium dioxide

**Questions or comments?**

**1-888-333-9792**

**PRINCIPAL DISPLAY PANEL**

Stomach relief

**Bismuth Subsalicylate 262 mg  
Upset Stomach Reliever/Antidiarrheal**

Soothing relief for 5 symptoms:

- Heartburn • Indigestion • Upset stomach
- Nausea • Diarrhea

12 Softgels

<b>Drug Facts (continued)</b>	
<b>Purpose</b> Bismuth Upset stomach reliever subsalicylate 262 mg ..... and anti-diarrheal	<b>Active ingredient (in each softgel)</b>
<b>Uses</b> relieves travellers' diarrhea ■ diarrhea upset stomach due to overindulgence in food and drink, including: ■ heartburn ■ indigestion ■ nausea ■ gas ■ belching ■ fullness	
<b>Warnings</b> 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, it 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. <b>Allergy alert:</b> Contains salicylate. Do not take if you are allergic to salicylates (including aspirin) ■ taking other salicylate products <b>Do not use if you have</b> an ulcer ■ a bleeding problem ■ bloody or black stool	
<b>Ask a doctor before use if you have</b> ■ fever ■ mucus in the stool <b>Ask a doctor or pharmacist before use if you are taking any drug for</b> anticoagulation (thinning the blood) ■ diabetes ■ gout ■ arthritis	
<b>When using this product</b> a temporary, but harmless, darkening of the stool and/or tongue may occur <b>Stop use and ask a doctor if</b> ■ symptoms get worse or last more than 2 days	
<b>Questions or comments?</b> 1-888-333-9792	
<b>Inactive ingredients</b> beeswax, colloidal silicon dioxide, FD&C Red#33, FD&C Yellow#6, gelatin, glycerin, light liquid paraffin, povidone, purified water, soya lecithin, sodium carboxymethyl cellulose, sorbitol sorbitan solution, titanium dioxide	
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**stomach relief**

Bismuth Subsalicylate 262 mg  
Upset Stomach Reliever/Antidiarrheal



12 softgels



Compare to the active ingredient in Pepto-Bismol® LiquiCaps™†

**stomach relief**

Bismuth Subsalicylate 262 mg  
Upset Stomach Reliever/Antidiarrheal

Soothing relief for 5 symptoms:

- Heartburn • Indigestion • Upset stomach
- Nausea • Diarrhea

LOT:  
EXP:

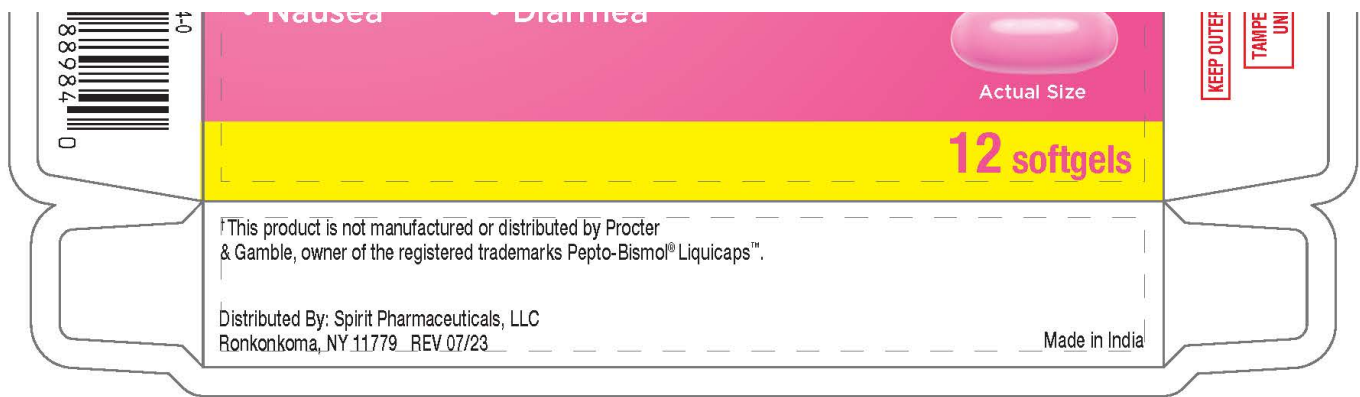
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† CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

† EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF BLISTER IT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING



## BISMUTH SUBSALICYLATE

bismuth subsalicylate capsule, gelatin coated

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68210-5018
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>LECITHIN, SOYBEAN</b> (UNII: 1DI56QDM62)	
<b>YELLOW WAX</b> (UNII: 2ZA36H0S2V)	
<b>CARBOXYMETHYLCELLULOSE SODIUM</b> (UNII: K679OBS311)	
<b>LIGHT MINERAL OIL</b> (UNII: N6K5787QVP)	
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>D&amp;C RED NO. 33</b> (UNII: 9DBA0SBB0L)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

### Product Characteristics

<b>Color</b>	pink	<b>Score</b>	no score
<b>Shape</b>	OVAL (Oblong shaped)	<b>Size</b>	21mm
<b>Flavor</b>		<b>Imprint Code</b>	262
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68210-5018-1	1 in 1 CARTON	07/19/2023	
1		12 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 Drug	M008	07/19/2023	

**Labeler** - Spirit Pharmaceuticals LLC (179621011)

Revised: 12/2023

Spirit Pharmaceuticals LLC