

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

Stomach Relief Softgels

Drug Facts

Active ingredient (in each softgel)

Purpose

Bismuth subsalicylate 262 mgUpset 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?

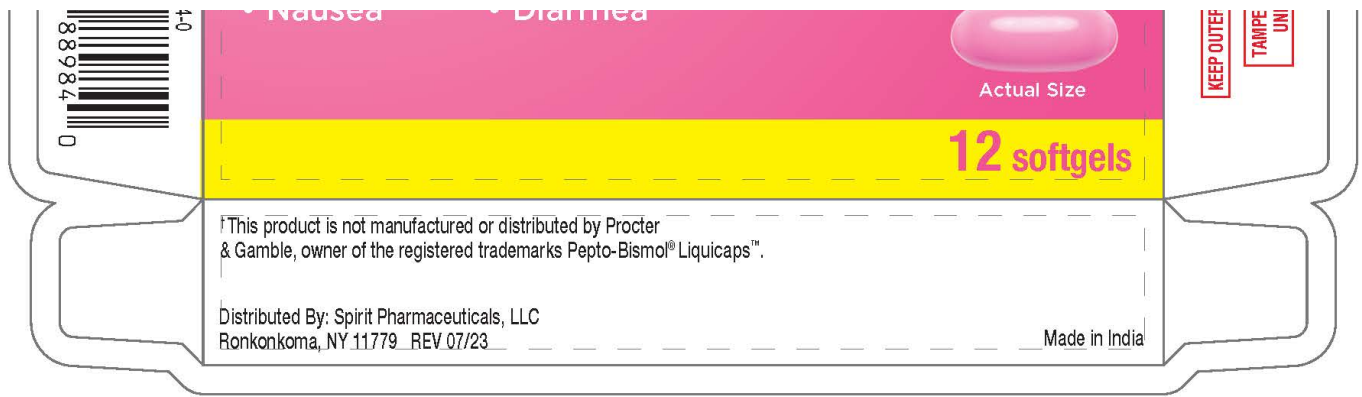
1-888-333-9792

PRINCIPAL DISPLAY PANEL

Stomach relief

12 Softgels

[illegible]



BISMUTH SUBSALICYLATE

bismuth subsalicylate capsule, gelatin coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68210-5018
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
WATER (UNII: 059QF0KO0R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
POVIDONE (UNII: FZ989GH94E)	
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

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

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: 12/2024

Spirit Pharmaceuticals LLC