STOMACH RELIEF- bismuth subsalicylate capsule, liquid filled Spirit Pharmaceuticals LLC

Stomach Relief

Drug Facts

Active ingredient Purpose

(in each softgel)

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 (1 dose) every 1/2 hour or 4 softgels (2 doses) every hour as needed for diarrhea
- 2 softgels (1 dose) every 1/2 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

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Other information

- each softgel contains:
- salicylate 99 mg n very low sodium
- store between 15-30°C (59-86°F)

Inactive ingredients

aerosil, beeswax, FD&C Red#33. FD&C Yellow#6, gelatin, glycerin, light liquid paraffin, purified water, soya lecithin, sodium carboxy methyl cellulose, sorbitol solution, titanium dioxide

Ouestions or comments?

1-888-333-9792

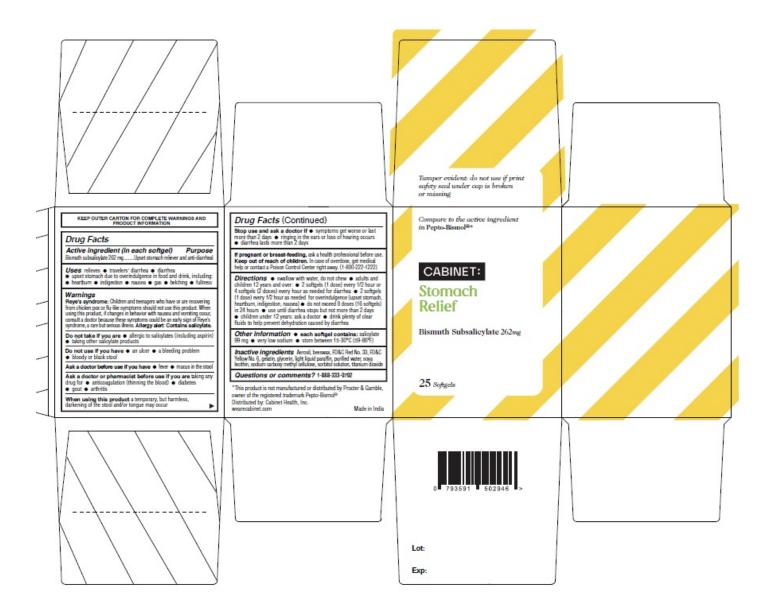
PRINCIPAL DISPLAY PANEL

Stomach Relief

BISMUTH SUBSALICYLATE
UPSET STOMACH RELIEVER / ANTIDIARRHEAL

25 CT / 75 CT





STOMACH RELIEF

bismuth subsalicylate capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68210-4092
Route of Administration	ORAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
BISMUTH SUBSALICYLATE (UNII: 62TEY51RR1) (SALICYLIC ACID - UNII: 0414PZ4LPZ)	BISMUTH SUBSALICYLATE	262 mg		

Inactive Ingredients		
Ingredient Name	Strength	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)		
YELLOW WAX (UNII: 2ZA36H0S2V)		

D&C RED NO. 33 (UNII: 9DBA0SBB0L)

FD&C YELLOW NO. 6 (UNII: H77VEI93A8)

GELATIN (UNII: 2G86QN327L)

GLYCERIN (UNII: PDC6A3C0OX)

PARAFFIN (UNII: 1900E3H2ZE)

WATER (UNII: 059QF0KO0R)

LECITHIN, SOYBEAN (UNII: 1DI56QDM62)

CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K6790BS311)

SORBITOL (UNII: 506T60A25R)

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

Product Characteristics				
Color	pink	Score	no score	
Shape	CAPSULE	Size	18mm	
Flavor		Imprint Code	854	
Contains				

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68210- 4092-2	1 in 1 CARTON	07/02/2020	
1		25 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:68210- 4092-1	75 in 1 BOTTLE; Type 0: Not a Combination Product	07/02/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M008	07/02/2020	

Labeler - Spirit Pharmaceuticals LLC (179621011)

Revised: 1/2024 Spirit Pharmaceuticals LLC