STOMACH RELIEF- bismuth subsalicylate capsule, liquid filled Shield Pharmaceuticals Corp

Stomach Relief

Drug Facts

Active ingredient (in each softgel)

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
- qas
- 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

- 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) right away. Quick medical attention is critical for adults & for children even if you do not notice any signs or symptoms.

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 $\frac{1}{2}$ 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 99 mg
- very low sodium
- store between 20-25° C (68-77° F)

Questions or comments?

1-800-373-6981 (toll-free)

Inactive ingredients

FD&C red #33, gelatin, glycerin, lecithin, polyethylene glycol-400, polysorbate 80, povidone, sorbitan, titanium dioxide

Distributed by:

Shield Pharmaceuticals Corp.

Hauppauge, NY 11788

PRINCIPAL DISPLAY PANEL

ValuRx

Compare to the active ingredient in Pepto-Bismol® LiquicapsTM†

Stomach Relief Bismuth Subsalicylate Upset Stomach Reliever/Antidiarrheal Soothing Relieves of 5 Symptoms:

- Nausea
- Heartburn
- Indigestion
- Upset Stomach
- Diarrhea

Carton



STOMACH RELIEF

bismuth subsalicylate capsule, liquid filled

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:83059-0026 Route of Administration ORAL

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
BISMUTH (UNII: U015TT5I8H) (BISMUTH - UNII:U015TT5I8H)	BISMUTH	262 mg

Inactive Ingredients		
Ingredient Name	Strength	
FD&C RED NO. 3 (UNII: PN2ZH5LOQY)		
GELATIN (UNII: 2G86QN327L)		
GLYCERIN (UNII: PDC6A3C0OX)		
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)		
POLYSORBATE 80 (UNII: 6OZP39ZG8H)		
POVIDONE (UNII: FZ 989GH94E)		
SORBITOL (UNII: 506T60A25R)		
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)		

Product Characteristics				
Color	pink	Score	no score	
Shape	CAPSULE	Size	14mm	
Flavor		Imprint Code	SD30	
Contains				

P	Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date			
1	NDC:83059- 0026-8	1 in 1 CARTON	04/07/2024				
1		8 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 Drug	M008	04/07/2024		

Labeler - Shield Pharmaceuticals Corp (118724924)

Revised: 4/2024 Shield Pharmaceuticals Corp