STOMACH RELIEF- bismuth subsalicylate capsule, liquid filled TOP CARE (Topco Associates LLC)

TopCare health Stomach Relief - Bismuth Subsalicylate 262mg

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
 - 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 ifyou 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

Other information

each softgel contains:

- salicylate 99 mg 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

Questions or comments?

PRINCIPAL DISPLAY PANEL

TopCare health ™

Stomach Relief

BISMUTH SUBSALICYLATE
UPSET STOMACH RELIEVER / ANTIDIARRHEAL

5 SYMPTOM Digestive Relief

heartburn indigestion nausea upset stomach diarrhea 30 Softgels



COMPARE TO PEPTO-BISMOL® ACTIVE INGREDIENT*

Stomach Relief

BISMUTH SUBSALICYLATE 262 mg
UPSET STOMACH RELIEVER • ANTIDIARRHEAL

5 SYMPTOM DIGESTIVE RELIEF

- Heartburn Indigestion Upset Stomach
- Nausea Diarrhea

30 SOFTGELS

actual size



STOMACH RELIEF

bismuth subsalicylate capsule, liquid filled

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:36800-134

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BISMUTH SUBSALICYLATE (UNII: 62TEY51RR1) (SALICYLIC ACID - UNII: 0414PZ 4LPZ)	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 (UNII: 05JZ17B19X)			
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:36800-134- 66	1 in 1 CARTON	06/28/2019		
1		30 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	06/28/2019	

Labeler - TOP CARE (Topco Associates LLC) (006935977)