

STOMACH RELIEF- bismuth subsalicylate tablet, chewable
PuraCap Pharmaceutical LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Stomach Relief

Drug Facts

Active Ingredient (in each tablet)

Bismuth subsalicylate 262 mg

Purposes

Upset stomach reliever and antidiarrheal

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

- chew or dissolve in mouth
- adults and children 12 years and over: 2 tablets every 1/2 to 1 hour as needed
- do not exceed 8 doses (16 tablets) 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 tablet contains:** calcium 77 mg, salicylate 102 mg
- store at 15°-30°C (59°-86°F)
- protect from moisture

Inactive ingredients

calcium carbonate, D&C red # 27 (Al-lake), dextrose, flavor (cherry), magnesium stearate, maltodextrin, silicon dioxide, sorbitol

Questions or comments

Call toll free: **1-855-215-8180**

PRINCIPAL DISPLAY PANEL

Stomach Relief

30 Tablets 15 Pouches (2 Tablets per Pouch)

NDC: 51013-321-54

DO NOT USE IF PACKET IS TORN OR DAMAGED

Stomach Relief

Bismuth Subsalicylate Digestive Relief

Upset Stomach Reliever | Antidiarrheal

Distributed By:
COMPANY NAME
ADDRESS
Made in India

2 Tablets

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Allergy alert: Contains salicylate.

Do not take if you are ■ allergic to salicylates (including aspirin) ■ taking other salicylate product

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

CVSF34-00 ▶

Ask a doctor or pharmacist before use if you are taking any drug for

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Inactive ingredients Calcium Carbonate, Dextrose, Sorbitol, Silicon Dioxide, D&C Red #27, Cherry Flavor, Magnesium Stearate

Questions or comments? Call toll free: 1-855-215-8180

Important: Read all product information before using.
Keep the box for important information.

CVSB34-00

STOMACH RELIEF

bismuth subsalicylate tablet, chewable

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:510 13-321
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BISMUTH SUBSALICYLATE (UNII: 62TEY51RR1) (BISMUTH CATION - UNII:ZS9CD1I8YE)	BISMUTH SUBSALICYLATE	262 mg

Inactive Ingredients

Ingredient Name	Strength
CALCIUM CARBONATE (UNII: H0G9379FGK)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
DEXTROSE (UNII: IY9XDZ35W2)	
CHERRY (UNII: BUC5I9595W)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTO DEXTRIN (UNII: 7CVR7L4A2D)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color	PINK (light)	Score	no score
Shape	ROUND	Size	16mm
Flavor	CHERRY	Imprint Code	AP;045
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:510 13-321-54	15 in 1 CARTON	11/28/2017	
1		2 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part335	11/28/2017	

Labeler - PuraCap Pharmaceutical LLC (962106329)

Establishment

Name	Address	ID/FEI	Business Operations
Advance Pharmaceutical Inc.		078301063	MANUFACTURE(51013-321)

Revised: 11/2017

PuraCap Pharmaceutical LLC