PINK BISMUTH- bismuth subsalicylate liquid Geri-Care Pharmaceuticals, Corp

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.

GC PEPTO

Active ingredient (in each 15 mL Tablespoon = TBSP)

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

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
- 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

- shake well before using
- drink plenty of clear fluids to help prevent dehydration caused by diarrhea
- for accurate dosing, use dose cup

adults and children 12 years and over

- take 2 TBSP every 1/2 hour to 1 hour as needed
- do not exceed 16 TBSP in 24 hours
- use until diarrhea stops but not more than 2 days

children under 12 years:ask a doctor

Other information

- each TBSP contains: sodium 6 mg. salicylate 130 mg
- low sodium
- sugar free
- protect from freezing
- avoid excessive heat (over 104F or 40C)
- store at room temperature
- TAMPER-EVIDENT: Do not use if imprinted neckband is missing or broken.
- for health information visit www.info-xtra.com for health information

Inactive ingredients

benzoic acid, D and C red no. 22, D and C red no. 28, flavor, magnesium aluminum silicate, methylcellulose, purified water, saccharin sodium, salicyclic acid, simethicone emulsion, sodium salicylate, sorbic acid, xanthan gum

package Label

GERICARE

NDC 57896-392-16

pink bismuth regular strength bismuth subsalicylate 262mg/15mL upset stomach reliever/antidiarrheal soothing relief for 5 symptoms heartburn indigestion upset stomach nausea diarrhea compare to the active ingredient of Pepto-Bismol 16 FL OZ (1 PT) (473 mL)



PINK BISMUTH

bismuth subsalicylate liquid

Product Information			
Product Type	HUMAN OTC DRUG Item Code (Source)		NDC:57896-392
Route of Administration	ORAL		

Active Ingredient/Active Moiety Ingredient Name Bismuth subsalicylate (UNII: 62TEY51RR1) (SALICYLIC ACID - UNII:0414PZ4LPZ, BISMUTH SUBSALICYLATE (UNII: 262 mg in 15 mL

Inactive Ingredients		
Ingredient Name	Strength	
BENZOIC ACID (UNII: 8 SKN0 B0 MIM)		
D&C RED NO. 22 (UNII: 1678 RKX8 RT)		
D&C RED NO. 28 (UNII: 767IP0 Y5NH)		
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)		
METHYLCELLULOSE (100 CPS) (UNII: 4GFU244C4J)		
WATER (UNII: 059QF0KO0R)		

SACCHARIN SO DIUM (UNII: SB8 ZUX40 TY)	
SALICYLIC ACID (UNII: O414PZ4LPZ)	
DIMETHICO NE (UNII: 92RU3N3Y1O)	
SODIUM SALICYLATE (UNII: WIQ 1H8 5 S YP)	
SORBIC ACID (UNII: X045WJ989B)	
XANTHAN GUM (UNII: TTV12P4NEE)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	

Product Characteristics			
Color	pink	Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

	Packaging			
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 NDC:57896-392-08	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2012	11/0 1/20 19
ı	2 NDC:57896-392-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2012	09/01/2019

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part335	0 1/0 1/20 0 0	11/0 1/20 19

Labeler - Geri-Care Pharmaceuticals, Corp (611196254)

Registrant - GCP Laboratories (965480861)

Establishment				
Name	Address	ID/FEI	Business Operations	
GCP LABORATORIES		965480861	manufacture(57896-392), pack(57896-392)	

Revised: 3/2020 Geri-Care Pharmaceuticals, Corp