# GERI-PECTATE PEPPERMINT FLAVOR- 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.

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## geri-pectate

## Active ingredient (in each 15 mL tablespoon=Tbsp)

Bismuth subsalicylate 262 mg

## Purposes

antidiarrheal and upset stomach reliever

## Uses

- relieves diarrhea
- relieves upset stomach and nausea associated with it

## 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

## adults and children 12 years and over

- take 30 mL = 2 tablespoonfuls (Tbsp)
- repeat dose every 1/2 hour to 1 hour as needed
- do not exceed 8 doses (16 Tbsp or 240 mL) in 24 hours
- use until diarrhea stops but not more than 2 days

## children under 12 years:

ask a doctor

## Other information

- each 15 mL tables poon contains: salicylate 130 mg, sodium 10 mg
- protect from freezing
- avoid excessive heat (over 104F or 40C)
- TAMPER-EVIDENT: Do not use this product if foil seal under cap is missing or broken.
- visit www.info-xtra.com for health information

## **Inactive ingredients**

caramel, carboxymethylcellulose sodium, FD and C red no. 40, flavor, microcrystalline cellulose, purified water, sodium salicylate, sorbic acid, sucrose, titanium dioxide, xanthan gum

package Label



#### GERI-PECTATE PEPPERMINT FLAVOR bismuth subsalicylate liquid **Product Information Product** Type HUMAN OTC DRUG Item Code (Source) NDC:57896-396 **Route of Administration** ORAL **Active Ingredient/Active Moiety Ingredient** Name Basis of Strength Strength BISMUTH SUBSALICYLATE (UNII: 62TEY51RR1) (SALICYLIC ACID - UNII:O414PZ4LPZ, BISMUTH 262 mg **BISMUTH CATION - UNII: ZS9CD118 YE)** SUBSALICYLATE in 15 mL **Inactive Ingredients Ingredient Name** Strength

CARAMEL (UNII: T9D99G2B1R)						
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)						
FD&C RED NO. 40 (UNII: WZB9127XOA)						
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)						
WATER (UNII: 059QF0KO0R)						
SODIUM SALICYLATE (UNII: WIQ 1H8 5S YP)						
SORBIC ACID (UNII: X045)	SORBIC ACID (UNII: X045WJ989B)					
SUCROSE (UNII: C151H8M554)						
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)						
XANTHAN GUM (UNII: TTV12P4NEE)						
PEPPERMINT OIL (UNII: AV092KU4JH)						
Product Characteristics						
Color	red (brownish-red)		Score			

Shape		Size				
Flavor	PEPPERMINT	Imprint Code				
Contains						
Packaging						
# Item Code	Package Description	Marketing Start Date	Marketing End Date			
1 NDC:57896-396-12	355 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2011				
Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC monograph final	part335	01/01/2000				

Labeler - Geri-Care Pharmaceuticals, Corp (611196254)

**Registrant -** GCP Laboratories (965480861)

## Establishment

Name	Address	ID/FEI	Business Operations
GCP LABORATORIES		965480861	manufacture(57896-396)

Revised: 12/2018

Geri-Care Pharmaceuticals, Corp