GERI-PECTATE VANILLA 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.

geri-pectate vanil

Active ingredient (in each 15 mL Tbsp)

Bismuth subsalicylate 262 mg

Purposes

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

adults and children 12 years and over

- take 2 tablespoonfuls (30 mL)
- 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)
- visit www.info-xtra.com for health information

Inactive ingredients

caramel, carboxymethylcellulose sodium, flavor, microcrystalline cellulose, purified water, sodium salicylate, sorbic acid, sucrose, titanium dioxide, xanthan gum

package Label



GERI-PECTATE VANILLA FLAVOR bismuth subsalicylate liquid Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:57896-391 Route of Administration ORAL Active Ingredient/Active Moiety Ingredient Name Basis of Strength BISMUTH SUBSALICYLATE (UNII: 62TEY51RR1) (SALICYLIC ACID - UNI:0414PZ4LPZ, BISMUTH CATION - UNII:2S9CD118YE) BISMUTH 262 mg in 15 mL						
Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:57896-391 Route of Administration ORAL V V Active Ingredient/Active Moiety Ingredient Name Basis of Strength Strength BISMUTH SUBSALICYLATE (UNII: 62TEY51RR1) (SALICYLIC ACID - UNII:O414PZ4LPZ, BISMUTH 262 mg	GERI-PECTATE VANIL	LA FLAVOR				
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						0

Inactive Ingredient	ts						
	Ingredient Na	me		Strei	ngth		
CARAMEL (UNII: T9D99G2B1R)							
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)							
CELLULOSE, MICROCI	RYSTALLINE (UNII: OP1R32D61U)						
WATER (UNII: 059QF0KO0R)							
SODIUM SALICYLATE	(UNII: WIQ 1H8 5S YP)						
SORBIC ACID (UNII: X0	45WJ989B)						
SUCROSE (UNII: C151H8	M554)						
TITANIUM DIO XIDE (UI	NII: 15FIX9V2JP)						
XANTHAN GUM (UNII: T	TV12P4NEE)						
	• •						
Product Character							
Color	white (light tan)	Sc	ore				
Shape		Siz	ze				
Flavor	VANILLA	Im	print Code				
Contains							
Packaging							
# Item Code	Package Descriptio	n	Marketing Start Date	Marketing E	nd Date		
1 NDC:57896-391-12 35	55 mL in 1 BOTTLE; Type 0: Not a Cor	nbination Product	12/0 1/20 10				
Marketing Information							
Marketing Category	Application Number or Monog	raph Citation	Marketing Start Date	Marketing E	nd Date		
OTC monograph final	part335	_	0 1/0 1/20 0 0	5			
5 1	-						

Labeler - Geri-Care Pharmaceuticals, Corp (611196254)

Registrant - GCP Laboratories (965480861)

Establishment						
Name	Address	ID/FEI	Business Operations			
GCP LABORATORIES		965480861	manufacture(57896-391)			

Revised: 12/2018

Geri-Care Pharmaceuticals, Corp