GNP STOMACH RELIEF - bismuth subsalicylate 525 mg liquid Amerisource Bergen

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.

GNP Stomach Relief Original Strength-527

ACTIVE INGREDIENT(in each 30 mL)

Bismuth subsalicylate 525 mg

PURPOSE

Upset stomach reliever and anti-diarrheal

USES

relieves:

- diarrhea
- heartburn
- indigestion
- nausea
- upset stomach associated with these symptoms

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

- bloody or black stool
- an ulcer

a bleeding problem

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 of 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 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 immediately.

DIRECTIONS

- shake well before use
- mL = milliliter
- TBSP = tablespoon
- adults and children 12 years and over: 1 dose (2 TBSP or 30 mL) every 1/2 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
- drink plenty of clear fluids to help prevent dehydration caused by diarrhea

OTHER INFORMATION

• each 30 mL or 2 TBSP contains:

- potassium 25 mg
- salicylate 260 mg
- sodium 8 mg
- protect from freezing
- avoid excessive heat (over 104°F or 40°C)
- dosage cup provided

INACTIVE INGREDIENTS

benzoic acid, D&C red 22, D&C red 28, flavor, hydroxyethyl cellulose, potassium hydroxide, purified water, saccharin sodium, salicylic acid, simethicone, xanthan gum.

PRINCIPAL DISPLAY PANEL GOOD NEIGHBOR PHARMACY®

NDC 46122-703-26

PROTECTIVE COATING ACTION

Stomach Relief

Original Strength Anti-diarrheal / Upset Stomach Reliever Bismuth subsalicylate (525mg/30mL) soothing relief for: indigestion, nausea, heartburn, upset stomach & diarrhea

4 FL. OZ. (118 mL)





GNP STOMACH RELIEF

bismuth subsalicylate 525 mg liquid

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:46122-703

Route of Administration ORAL

Active Ingredient/Active Moiety Ingredient Name Basis of Strength Strength Strength SALICYLATE (UNII: 62TEY51RR1) (BISMUTH CATION - UNII:ZS9CD118YE, SALICYLATE (UNII: 0414PZ4LPZ) BISMUTH SUBSALICYLATE (UNII: 0414PZ4LPZ) SUBSALICYLATE (UNII: 0414PZ4LPZ)

Inactive Ingredients		
Ingredient Name	Strength	
BENZOIC ACID (UNII: 85KN0B0MIM)		
D&C RED NO. 22 (UNII: 1678RKX8RT)		
D&C RED NO. 28 (UNII: 767IP0Y5NH)		
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)		
WATER (UNII: 059QF0KO0R)		
SACCHARIN SODIUM (UNII: SB8ZUX40TY)		
SALICYLIC ACID (UNII: O414PZ4LPZ)		
HYDROXYETHYL CELLULOSE (1500 MPA.S AT 1%) (UNII: L605B5892V)		
DIMETHICONE (UNII: 92RU3N3Y1O)		

XANTHAN	GUM	(UNII:	TTV12P4NEE)	١
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Product Characteristics			
Color	PINK	Score	
Shape		Size	
Flavor	WNTERGREEN	Imprint Code	
Contains			

l	P	Packaging			
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:46122-703- 26	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/30/2022	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part335	06/30/2022	

Labeler - Amerisource Bergen (007914906)

Revised: 6/2022 Amerisource Bergen