GNP PINK BISMUTH- bismuth subsalicylate tablet, chewable 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 Pink Bis muth Tablets

Active ingredient (in each tablet)

Bismuth subsalicylate 262 mg (total salicylate 102 mg per tablet)

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 stools
- 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 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 immediately.

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 take more than 8 doses (16 tablets) in 24 hours
- children under 12 years: ask a doctor
- drink plenty of fluids to help prevent dehydration which may accompany diarrhea.

Other information

- each tablet contains:sodium less than 1 mg
- salicylate 102 mg
- calcium 140 mg
- very low sodium
- avoid excessive heat (over 104°F or 40°C)
- TAMPER EVIDENT: Do not use if individual compartments are torn or missing.

Inactive ingredients

calcium carbonate, D&C red 27 aluminum lake, flavor, magnesium stearate, mannitol, pregelatinized starch, saccharin sodium.

PDP

Good Neighbor Pharmacy

Compare to pepto-bismol chewable active ingredient

protective coating

Pink Bismuth

Anti-Diarrheal

Soothing relief for:

upset stomach, indigestion, heartburn, diarrhea & neausea

30 chewable tablets



GNP PINK BISMUTH

bismuth subsalicylate tablet, chewable

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:24385-024

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength

BISMUTH SUBSALICYLATE (UNII: 62TEY51RR1) (SALICYLIC ACID - UNII:O414PZ4LPZ) BISMUTH SUBSALICYLATE 262 mg

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Ingredient Name	Strength	
CALCIUM CARBONATE (UNII: H0 G9 379 FGK)		
D&C RED NO. 27 (UNII: 2LRS185U6K)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		
MANNITOL (UNII: 3OWL53L36A)		

STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)

SACCHARIN SODIUM (UNII: SB8ZUX40TY)

Product Characteristics			
Color	pink	Score	no score
Shape	ROUND	Size	17mm
Flavor		Imprint Code	GDC122
Contains			

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:24385-024-65	5 in 1 CARTON	07/07/2011	
1	6 in 1 BLISTER PACK; 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	07/07/2011		

Labeler - Amerisource Bergen (007914906)

Registrant - Guardian Drug Company (119210276)

Establishment				
Name	Address	ID/FEI	Business Operations	
Guardian Drug Company		119210276	manufacture(24385-024)	

Revised: 4/2016 Amerisource Bergen