GUARDIAN PINK-BISMUTH CHERRY - bismuth subsalicylate tablet, chewable Guardian Drug Company

Guardian Pink bismuth Stomach Relief Cherry 122CHR

ACTIVE INGREDIENT(in each tablet)

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

PURPOSE

Upset stomach reliever and anti-diarrheal

USE(S)

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 behaviour 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

- 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 caused by diarrhea

OTHER INFORMATION

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

INACTIVE INGREDIENTS

adipic acid, calcium carbonate, D&C red 27 aluminum lake, FD&C red 40 aluminum lake, flavors, magnesium stearate, mannitol, povidone, pregelatinized starch, saccharin sodium

PRINCIPAL DISPLAY PANEL

*Compare to the active ingredient of Pepto-Bismol® NDC 53041-022-49

GAURDIAN®

Pink-Bismuth Tablets

Cherry Flavor

Bismuth Subsalicylate

Anti-diarrheal/Upset Stomach Reliever

Soothing Relief For:

- Upset stomach
- Indigestion
- Nausea
- Heartburn
- Diarrhea

30 CHEWABLE TABLETS



GUARDIAN PINK-BISMUTH CHERRY

bismuth subsalicylate tablet, chewable

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53041-022
Route of Administration	ORAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
BISMUTH SUBSALICYLATE (UNII: 62TEY51RR1) (SALICYLIC ACID - UNII: 0414PZ 4LPZ)	BISMUTH SUBSALICYLATE	262 mg		

Inactive Ingredients			
Strength	Ingredient Name		
	CALCIUM CARBONATE (UNII: H0G9379FGK)		
D&C RED NO. 27 (UNII: 2LRS185U6K)			

MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 30WL53L36A)	
STARCH, CORN (UNII: O8232NY3SJ)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
ADIPIC ACID (UNII: 76A0JE0FKJ)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
POVIDONE, UNSPECIFIED (UNII: FZ 989GH94E)	

Product Characteristics			
Color	PINK	Score	no score
Shape	ROUND	Size	16mm
Flavor	CHERRY	Imprint Code	GDC122
Contains			

F	Packaging				
#	tem Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:53041-022- 49	5 in 1 BOX	12/04/2023		
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 Drug	part335	12/04/2023	

Labeler - Guardian Drug Company (119210276)

Establishment				
Name	Address	ID/FEI	Business Operations	
Guardian Drug Company		119210276	MANUFACTURE(53041-022)	

Revised: 12/2023 Guardian Drug Company