PEPTIC RELIEF- peptic relief tablet Rugby Laboratories

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.

Peptic Relief

Active ingredient (in each tablet)

Bismuth Subsalicytate 262mg

Purpose

Upset stomach reliever / anti-diarrheal

Uses

relieves:

- diarrhea
- hearbrun
- indigesttion
- 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

- 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 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
- 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 tablet contains: salicylate 102mg
- sodium less than 1 mg
- very low sodium
- avoid excessive heat (over 104°F or 40°C)

Inactive ingredients

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

Questions or comments?

1-800-645-2158

PDP

COMPARE TO THE ACTIVE INGREDINET IN PEPTO-BISMOL®*

Rugby®

NDC 0536-1021-07

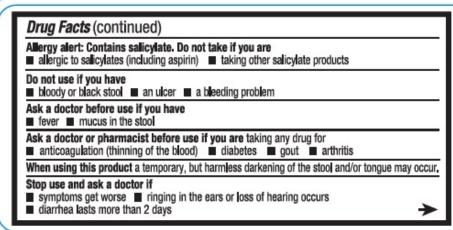
Peptic Relief

Bismuth Subsalicylate 262 mg

FOR UPSET STOMACH, INDIGESTION, SIMPLE DIARRHEA AND NAUSEA

30 CHEWABLE TABLETS





Drug Facts (continued)

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PEPTIC RELIEF

peptic relief tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0536-1021
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
BISMUTH SUBSALICYLATE (UNII: 62TEY51RR1) (SALICYLIC ACID - UNII:O414PZ4LPZ, BISMUTH CATION - UNII:ZS9CD118YE)	BISMUTH SUBSALICYLATE	262 mg	

Inactive Ingredients			
Ingredient Name	Strength		
D&C RED NO. 27 (UNII: 2LRS185U6K)			
CALCIUM CARBO NATE (UNII: H0 G9 379 FGK)			
MAGNESIUM STEARATE (UNII: 70097M6I30)			
MANNITOL (UNII: 3OWL53L36A)			
STARCH, CORN (UNII: O8232NY3SJ)			
SACCHARIN SO DIUM (UNII: SB8 ZUX40 TY)			

Product Characteristics				
Color	PINK	Score	no score	
Shape	ROUND	Size	18 mm	
Flavor		Imprint Code	GDC;122	
Contains				

ı	Packaging			
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 NDC:0536-1021-07	30 in 1 BOTTLE; Type 0: Not a Combination Product	02/20/2014	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part335	02/20/2014	

Labeler - Rugby Laboratories (079246066)

Establishment				
Name	Address	ID/FEI	Business Operations	
Guardian Drug Company		119210276	manufacture(0536-1021)	

Revised: 9/2019 Rugby Laboratories