PEPTIC RELIEF- peptic relief tablet Rebel Distributors 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.

Peptic Relief Drug Facts

Active ingredient

Bismuth Subsalicytate 262mg

Purpose

Anti-diarrheal/Upset stomach reliever

Keep Out of Reach of Children

In case of overdose,, get medical help or contact a Poison Control Center right away.

Uses

* Controls diarrhea

* Relieves upset stomach due to overindulgence in food or drink

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: 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
- * if you have an ulcer or bleeding problem

Ask a doctor before use if you have

- * fever
- * mucus in the stool

Drug Facts

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.

Directions

- * drink plenty of clear fluids to help prevent dehydration caused by diarrhea
- * repeat dosage every 1/2 to 1 hour as needed
- * do not take more than 8 doses in 24 hours
- * use until diarrhea stops but not more than 2 days
- * adults and children 12 years and over:
- 2 tablets
- * children under 12 years: ask a doctor

Other information

* each tablet contains: calcium 77mg
salicylate 102mg
* store at 15°-30°C (59°-86°F)
* protect from moisture

Inactive ingredients

D&C red #27 (al-lake), dextrose, flavor (cherry), magnesium stearate, maltodextrin, silicon dioxide, sorbitol

Questions or comments?

call 1-800-645-2158, 9 am-5 pm EST, Monday-Friday.

Package/Label Principal Display Panel



PEPTIC RELIEF					
peptic relief tablet					
Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:21695-6	NDC:21695-639(NDC:0536-4301)	
Route of Administration	ORAL				
Active Ingredient/Active Mo	iety				
In	Basis of	Basis of Strength			
			BISMUTH SUBSALICYLATE		
	21E151KKI) (DI5MOTH 50	JBSALIC YLATE -		/LATE	262 mg
UNII:62TEY51RR1)	21E151KKI) (DI5MO1113)	JBSALICYLATE -		'LATE	262 mg
	2 TE 13 IKKI) (DISMOTI I S	JBSALICYLATE -		'LATE	262 mg
	2 TE 13 IKKI) (BISMOTH S	JBSALICYLATE -		/LATE	262 mg
UNII:62TEY51RR1)	Ingredient Name	JBSALICYLATE -		LATE Strei	
UNII:62TEY51RR1)	Ingredient Name	JBSALICYLATE -			
UNII:62TEY51RR1) Inactive Ingredients	Ingredient Name	JBSALICYLATE -			
UNII:62TEY51RR1) Inactive Ingredients D&C RED NO. 27 (UNII: 2LRS185U6K CALCIUM CARBONATE (UNII: H0G9	Ingredient Name	JBSALICYLATE -			
UNII:62TEY51RR1) Inactive Ingredients D&C RED NO.27 (UNII: 2LRS185U6K	Ingredient Name) 379 FGK)	JBSALICYLATE -			

so	SORBITOL (UNII: 506T60A25R)							
Product Characteristics								
C	olor	PINK	Score	Score		no score		
SI	nape	ROUND	Size	Size		18 mm		
Fl	avor		Imprint	Imprint Code		LOGO;045		
С	ontains							
Packaging								
#	Item Code	Package Descri	iption	Marketin	g Start Date	Μ	arketing End Date	
1	NDC:21695-639-30	30 in 1 BOTTLE						
Marketing Information								
N	larketing Category	Application Number or Monograph Citation		Marketing Start Date		Marketing End Date		
0	ГС monograph final	part335			12/30/2011			

Labeler - Rebel Distributors Corp (118802834)

Establishment

Name	Address	ID/FEI	Business Operations
Rebel Distributors Corp		118802834	RELABEL, REPACK

Revised: 12/2011

Rebel Distributors Corp