## PEPTIC RELIEF- peptic relief tablet <br> 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 102 mg
- sodium less than 1 mg
- very low sodium
- avoid excessive heat (over $104^{\circ} \mathrm{F}$ or $40^{\circ} \mathrm{C}$ )


## 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 ${ }^{\circledR}$ *
Rugby ${ }^{\circledR}$
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

## Active Ingredient/Active Moiety

|  | Ingredient Name | Basis of Strength | Strength |
| :--- | :--- | :--- | :--- |
| BISMUTH SUBSALICYLATE (UNII: 62TEY51RR1) (SALICYLIC ACID - UNII:O414PZ4LPZ, <br> BISMUTH CATION - UNII:ZS9CD1I8 YE) | BISMUTH | 262 mg |  |

## Inactive Ingredients

## Ingredient Name <br> Strength

D\& C RED NO. 27 (UNII: 2LRS185U6K)
CALCIUM CARBO NATE (UNII: H0 G9379 FGK)
MAGNESIUM STEARATE (UNII: 7009 7M6 I30)
MANNITOL (UNII: 3OWL53L36 A)
STARCH, CORN (UNII: O8232NY3SJ)
SACCHARIN SO DIUM (UNII: SB8ZUX40TY)

## Product Characteristics

| Color | PINK | Score | no score |
| :--- | :--- | :--- | :--- |
| Shape | ROUND | Size | 18 mm |
| Flavor |  | Imprint Code | GDC; 122 |
| Contains |  |  |  |

## Packaging

| \# | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| :--- | :---: | :---: | :---: | :---: |
| 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) |

