

PEP TUM- bismuth subsalicylate tablet, chewable
First Aid Direct

Drug Facts

Active ingredient (in each tablet)

Bismuth subsalicylate 262 mg (each tablet contains 102 mg salicylate)

Purpose

Antidiarrheal/Antacid

Uses

relieves

- travelers' diarrhea
- diarrhea
- upset stomach due to overindulgence in food and drink including:
- heartburn
- indigestion
- nausea
- gas
- belching
- fullness

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 stool
- an ulcer
- a bleeding problem

Ask a doctor or pharmacist before use if you

- are taking any drug for anticoagulation (thinning the blood)
- diabetes
- gout
- arthritis

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

When using this product

a temporary, but harmless, darkening of the stool and/or tongue may occur.

If pregnant or breast-feeding,

ask a health professional before use.

Keep Out of Reach of Children.

In case of accidental overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Directions

- chew or dissolve in mouth
- **Adults and children 12 years and over:** 2 tablets (1 dose) every ½ hour or 4 tablets (2 doses) every hour as needed for diarrhea
- 2 tablets (1 dose) every 1/2 hour as needed for overindulgence (upset stomach, heartburn, indigestion, nausea)
- do not exceed 8 doses (16 tablets) in 24 hours
- use until diarrhea stops but not more than 2 days
- **Children under 12 years of age:** ask a doctor
- drink plenty of clear fluids to help prevent dehydration caused by diarrhea

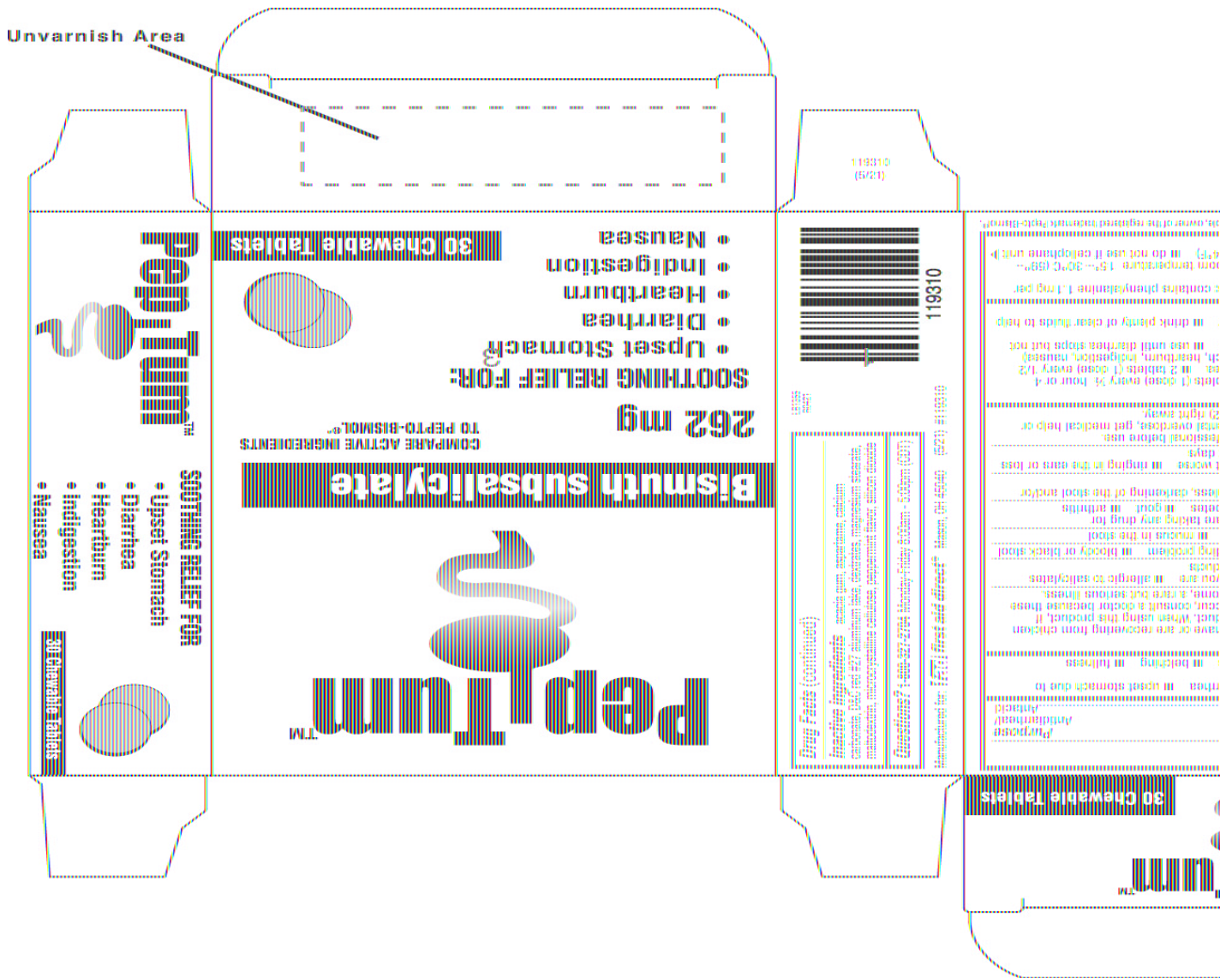
Inactive Ingredients

acacia gum, aspartame, calcium carbonate, D&C red #27 aluminum lake, dextrates, magnesium stearate, maltodextrin, microcrystalline cellulose, peppermint flavor, silicon dioxide

Other Information

- Phenylketonurics: contains phenylalanine 1.1mg per tablet
Calcium content per tablet: 73mg
- store at room temperature 15°– 30°C (59°– 86°F)
- avoid excessive heat (over 40°C or 104°F)
- do not use if cellophane unit is torn

Package/Label Principal Display Panel



Pep Tum

PEP TUM

bismuth subsalicylate tablet, chewable

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53117-046
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

Inactive Ingredients

Ingredient Name	Strength
ASPARTAME (UNII: Z0H242BBR1)	
CALCIUM CARBONATE (UNII: H0G9379FGK)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
DEXTRATES (UNII: G263MI44RU)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Product Characteristics

Color	pink	Score	no score
Shape	ROUND	Size	17mm
Flavor		Imprint Code	RH046
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53117-046-85	30 in 1 CARTON	12/23/2014	
1		1 in 1 CELLO 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	M008	12/23/2014	

Labeler - First Aid Direct (962283128)

Revised: 12/2017

First Aid Direct