

PEPTO BISMOL- bismuth subsalicylate tablet, chewable
Navajo Manufacturing Company Inc.

Pepto Bismol

Drug Facts

Active ingredient (in each Chewable tablet)

Bismuth subsalicylate 262 mg

Purpose

Upset stomach reliever and antidiarrheal

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

- an ulcer
- a bleeding problem
- bloody or black stool

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 or last more than 2 days
- 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 right away.

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 exceed 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:
 - calcium 140 mg
 - magnesium 9 mg
 - salicylate 101 mg
 - very low sodium
 - protect from freezing
 - avoid excessive heat (over 104°F or 40°C)
- do not use if pouch is opened

Inactive ingredients

calcium carbonate, D&C red No. 27 aluminum lake, flavor, magnesium stearate, mannitol, povidone, saccharin sodium, talc

Questions?

1-800-717-3786

Package Labeling:



PEPTO BISMOL

bismuth subsalicylate tablet, chewable

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67751-155(NDC:58933-011)
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
CALCIUM CARBONATE (UNII: H0G9379FGK)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 3OWL53L36A)	
POVIDONE (UNII: FZ989GH94E)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics

Color	pink	Score	no score
Shape	ROUND	Size	16mm
Flavor	WINTERGREEN	Imprint Code	Pepto;Bismol
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67751-155-01	1 in 1 CARTON	09/20/2016	
1		2 in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:67751-155-02	1 in 1 CARTON	09/20/2016	
2		4 in 1 POUCH; 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	09/20/2016	

Labeler - Navajo Manufacturing Company Inc. (091917799)**Establishment**

Name	Address	ID/FEI	Business Operations
Navajo Manufacturing Company Inc.		136941411	repack(67751-155) , relabel(67751-155)

Revised: 4/2024

Navajo Manufacturing Company Inc.