PEPTO BISMOL- bismuth subsalicylate tablet, chewable Lil' Drug Store Products, Inc.

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.

Pepto Bismol

Drug Facts

Active Ingredient(in each 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

- o 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
- 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 (1 dose) every 1/2 hour or 4 tablets (2 doses) every hour as needed for diarrhea
- 2 tablets (1 dose) every ½ 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: 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 99 mg
- low sodium

• avoid excessive heat (over 104°F or 40°C)

Inactive Ingredients

adipic acid, calcium carbonate, D&C Red No. 27 aluminum lake, FD&C Red No. 40 aluminum lake, flavor, magnesium stearate, mannitol, povidone, saccharin sodium, talc

Questions?

1-800-717-3786

PRODUCT REPACKAGED AND DISTRIBUTED WITH PERMISSION OF MANUFACTURER BY:

Convenience Valet® Glendale Heights, IL 60139 1-800-351-2000 (8:30 AM - 5:00 PM CST)

Pepto Bismol

Bismuth Subsalicylate Upset Stomach Reliever/Antidiarrheal

CHEWABLES

5 SYMPTOM RELIEF

NAUSEA

HEARTBURN

INDIGESTION

UPSET STOMACH

DIARRHEA

4 CHEWABLE TABLETS



Pepto Bismol

Bismuth Subsalicylate Upset Stomach Reliever/Antidiarrheal

CHEWABLES

5 SYMPTOM RELIEF

NAUSEA

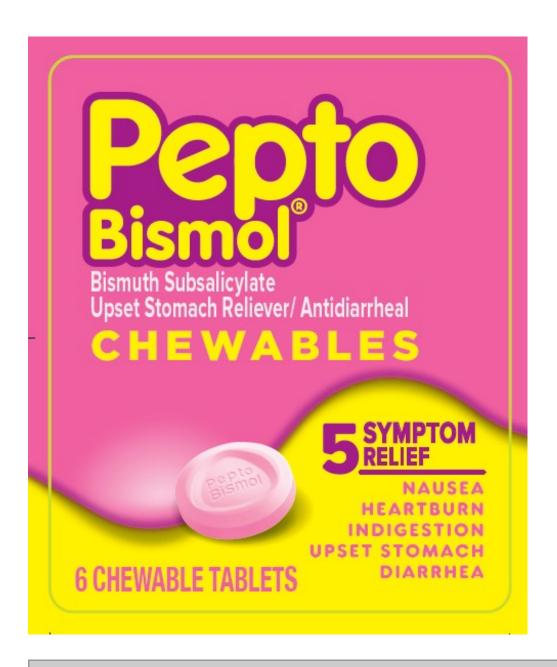
HEARTBURN

INDIGESTION

UPSET STOMACH

DIARRHEA

6 CHEWABLE TABLETS



PEPTO BISMOL

bismuth subsalicylate tablet, chewable

Product	Intorm	ation

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:29485-1531
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Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength

BISMUTH SUBSALICYLATE (UNII: 62TEY51RR1) (SALICYLIC ACID - UNII: 0414PZ4LPZ)

BISMUTH SUBSALICYLATE 262 mg

Inactive Ingredients

Ingredient Name

Strength

MANNITOL (UNII: 30WL53L36A)

TALC (UNII: 75EV7J4R1U)

CALCIUM CARBONATE (UNII: H0G9379FGK)

MAGNESIUM STEARATE (UNII: 70097M6I30)

POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)

D&C RED NO. 27 ALUMINUM LAKE (UNII: ZK64F7XSTX)

SACCHARIN SODIUM (UNII: SB8ZUX40TY)

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

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:29485- 1531-4	2 in 1 BLISTER PACK	04/30/2002	11/03/2025
1		2 in 1 CELLO PACK; Type 0: Not a Combination Product		

Marketing Information				
Marketing Application Number or Monograph Marketing Start Marketing End Category Citation Date Date				
OTC monograph final	M001	04/30/2002	11/03/2025	

PEPTO BISMOL

bismuth subsalicylate tablet, chewable

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:29485-6754
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
	BISMUTH SUBSALICYLATE	262 mg

Inactive Ingredients	
Ingredient Name	Strength
MANNITOL (UNII: 30WL53L36A)	

POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
TALC (UNII: 7SEV7J4R1U)	
CALCIUM CARBONATE (UNII: H0G9379FGK)	
D&C RED NO. 27 ALUMINUM LAKE (UNII: ZK64F7XSTX)	

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

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:29485- 6754-6	3 in 1 BLISTER PACK	02/06/2017	10/13/2025
1	2 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 final	M001	02/06/2017	10/13/2025

Labeler - Lil' Drug Store Products, Inc. (093103646)

Revised: 7/2023 Lil' Drug Store Products, Inc.