

PEPTO-BISMOL- bismuth subsalicylate tablet

A-S Medication Solutions

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

Purposes

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 (1 dose) every ½ 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 101 mg
- low sodium
- avoid excessive heat (over 104°F or 40°C)

Inactive ingredients

calcium carbonate, D&C Red No. 27 aluminum lake, flavor, magnesium stearate,

mannitol, povidone, saccharin sodium, talc

Questions?

1-800-717-3786

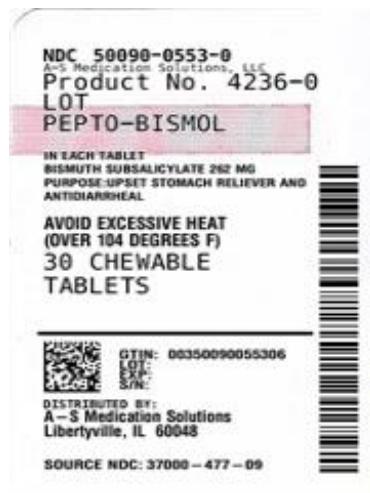
Dist. by Procter & Gamble, Cincinnati OH 45202

HOW SUPPLIED

Product: 50090-0553

NDC: 50090-0553-0 6 TABLET in a CELLO PACK / 5 in a CARTON

Bismuth subsalicylate



PEPTO-BISMOL

bismuth subsalicylate tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50090-0553(NDC:37000-477)
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)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 3OWL53L36A)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
D&C RED NO. 27 ALUMINUM LAKE (UNII: ZK64F7XSTX)	
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:50090-0553-0	5 in 1 CARTON	11/28/2014	
1		6 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	M008	06/30/2004	

Labeler - A-S Medication Solutions (830016429)

Establishment

Name	Address	ID/FEI	Business Operations
A-S Medication Solutions		830016429	RELABEL(50090-0553)

Revised: 2/2023

A-S Medication Solutions