

**PEPTO-BISMOL- bismuth subsalicylate tablet**  
**Savings Distributors LLC**

*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.*

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**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 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
- 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

**Package Label**



## PEPTO-BISMOL

bismuth subsalicylate tablet

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:73097-010(NDC:58933-477)
<b>Route of Administration</b>	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 (UNII: FZ989GH94E)	
D&C RED NO. 27 ALUMINUM LAKE (UNII: ZK64F7XSTX)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
TALC (UNII: 7SEV7J4R1U)	

### Product Characteristics

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

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73097-010-40	20 in 1 CARTON	07/15/2019	
1		2 in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:73097-010-02	2 in 1 POUCH; Type 0: Not a Combination Product	07/15/2019	
3	NDC:73097-010-50	25 in 1 CARTON	07/15/2019	
3		2 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 final	part335	07/15/2019	

**Labeler** - Savings Distributors LLC (010527359)

### Establishment

Name	Address	ID/FEI	Business Operations
Savings Distributors LLC		010527359	repack(73097-010)