# PEPTO-BISMOL- bismuth subsalicylate tablet ASCLEMED USA INC.

-----

# Pepto BISMOL ® Caplets

**Drug Facts** 

#### **Active ingredient (in each caplet)**

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
  - o 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**

- swallow with water, do not chew
- adults and children 12 years and over:
- 2 caplets (1 dose) every ½ hour or 4 caplets (2 doses) every hour as needed for diarrhea
- 2 caplets (1 dose) every ½ hour as needed for overindulgence (upset stomach, heartburn, indigestion, nausea)
- do not exceed 8 doses (16 caplets) 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 caplet contains: calcium 27 mg
- salicylate 99 mg
- low sodium
- avoid excessive heat (over 104°F or 40°C)

# **Inactive ingredients**

calcium carbonate, D&C red No. 27 aluminum lake, magnesium stearate, mannitol, microcrystalline cellulose, polysorbate 80, povidone, silicon dioxide, sodium starch glycolate

#### **Questions?**

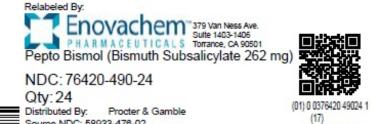
1-800-717-3786

TAMPER EVIDENT: Do not use if inner printed seal on bottle is broken or missing.

#### Relabeled by:

**Enovachem PHARMACEUTICALS** Torrance, CA 90501

#### PRINCIPAL DISPLAY PANEL



Source NDC: 58933-476-02 Description: pink; capsule shaped tablets/Pepto Bismol

Lot #: 00000000 Exp: Batch #: 00000000

CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION, SEE PACKAGE INSERT. KEEP OUT OF REACH OF CHILDREN. STORE AT 20-25C (68-77F) [SEE USP CONTROLLED ROOM TEMP]. Pepto Bismol (Bismuth Subsalicylate 262 mg)

NDC: 76420-490-24

S/N: Qty: 24

Pepto Bismoi (Bismuth Subsalicylate 262 mg)

NDC: 76420-490-24

S/N: Qty: 24

Pepto Bismoi (Bismuth Subsalicylate 262 mg)

NDC: 76420-490-24

S/N: Qty: 24

#### **PEPTO-BISMOL**

bismuth subsalicylate tablet

Drug Status: OTC

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76420-490(NDC:58933-476)
Route of Administration	ORAL		

(10) 00000000

(21)

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	Strength	
BISMUTH SUBSALICYLATE (UNII: 62TEY51RR1) (SALICYLIC ACID - UNII: O414PZ4LPZ)	BISMUTH SUBSALICYLATE	262 mg	

Inactive Ingredients		
Ingredient Name	Strength	
D&C RED NO. 27 ALUMINUM LAKE (UNII: ZK64F7XSTX)		
CALCIUM CARBONATE (UNII: H0G9379FGK)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		
MANNITOL (UNII: 30WL53L36A)		
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)		
POLYSORBATE 80 (UNII: 6OZP39ZG8H)		

SILICON DIOXIDE (UNII: ETJ7Z6XBU4)

**SODIUM STARCH GLYCOLATE TYPE A POTATO** (UNII: 5856J3G2A2)

Product Characteristics			
Color	pink	Score	no score
Shape	OVAL (Caplet)	Size	16mm
Flavor		Imprint Code	PeptoBismol
Contains			

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76420-490- 24	1 in 1 CARTON	10/15/2025	
1		24 in 1 BOTTLE; 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	06/30/2004	

# Labeler - ASCLEMED USA INC. (059888437)

Revised: 10/2025 ASCLEMED USA INC.