

PEPTO-BISMOL ULTRA- bismuth subsalicylate tablet
Procter & Gamble Manufactura, S. de R.L. de C.V.

Pepto[®] BISMOL[™] ULTRA

Drug Facts

Active ingredient (in each caplet)

Bismuth subsalicylate 525 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

- swallow with water, do not chew
- adults and children 12 years and over:
 - 1 caplet (1 dose) every ½ hour or 2 caplets (2 doses) every hour as needed for diarrhea
 - 1 caplet (1 dose) every ½ hour as needed for overindulgence (upset stomach, heartburn, indigestion, nausea)
- do not exceed 8 doses (8 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 54 mg

- salicylate 199 mg
- very 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.

MADE IN MEXICO

DIST. BY PROCTER & GAMBLE,

CINCINNATI OH 45202

PRINCIPAL DISPLAY PANEL - 12 Caplet Carton

Pepto

Bismol® ULTRA

Bismuth Subsalicylate

Upset Stomach Reliever/

Antidiarrheal

2x CONCENTRATED FORMULA*

5 SYMPTOM RELIEF

NAUSEA

HEARTBURN

INDIGESTION

UPSET STOMACH

DIARRHEA

12 CAPLETS



PEPTO-BISMOL ULTRA

bismuth subsalicylate tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58933-478
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BISMUTH SUBSALICYLATE (UNII: 62TEY51RR1) (SALICYLIC ACID - UNII:O414PZ4LPZ)	BISMUTH SUBSALICYLATE	525 mg

Inactive Ingredients

Ingredient Name	Strength
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 3OWL53L36A)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
CALCIUM CARBONATE (UNII: H0G9379FGK)	
POVIDONE (UNII: FZ989GH94E)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Product Characteristics

Color	pink	Score	no score
Shape	OVAL (Caplet)	Size	18mm
Flavor		Imprint Code	Pepto
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58933-478-24	1 in 1 CARTON	02/01/2018	
1		24 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:58933-478-12	1 in 1 CARTON	02/01/2018	
2		12 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	02/01/2018	

Labeler - Procter & Gamble Manufactura, S. de R.L. de C.V. (812807550)

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Procter & Gamble Manufactura, S. de R.L. de C.V.