KROGER REGULAR STRENGTH PINK BISMUTH- bismuth subsalicylate suspension KROGER COMPANY

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.

Kroger Regular Strength Pink Bismuth Subsalicylate 525 mg Drug Facts

Active ingredient (in each 30 mL dose)

Bismuth subsalicylate 525 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
- qas
- 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 or 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 at (1-800-222-1222).

Directions

- shake well before use
- only use dose cup provided
- adults and children 12 years and over: 30 mL 1 (dose) every 1/2 hour or 60 mL (2 doses) every hour as needed for diarrhea/traveler's diarrhea
- 30 mL (1 dose) every ½ hour as needed for overindulgence (upset stomach, heartburn, indigestion, nausea)
- do not exceed 8 doses (240 mL) 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 30 mL contains: sodium 10 mg

- salicylate 261 mg
- low sodium
- sugar free
- store at room temperature
- protect from freezing
- avoid excessive heat (over 104°F or 40°C)

Inactive ingredients

carboxymethylcellulose sodium, D&C Red No. 22, D&C Red No. 28, flavor, microcrystalline cellulose, potassium hydroxide, potassium sorbate, purified water, salicylic acid, simethicone emulsion, sodium benzoate, sucralose, xanthan gum

Questions or comments?

1-866-467-2748

DO NOT USE IF IMPRINTED SHRINK BAND IS MISSING OR BROKEN.

Principal Display Panel

*COMPARE TO the active ingredient in PEPTO-BISMOL® REGULAR STRENGTH *See side panel

Regular Strength

Stomach Relief

Bismuth Subsalicylate 525 mg

Upset Stomach Reliever/Antidiarrheal

Original Flavor

5 SYMPTOM RELIEF

RELIEF:

- Heartburn
- Indigestion
- Nausea
- Upset Stomach
- Diarrhea

*This product is not manufactured or distributed by Procter & Gamble, distributor of Pepto-Bismol® Regular Strength.

Package Label 236 mL



Package Label 354 mL



KROGER REGULAR STRENGTH PINK BISMUTH

bismuth subsalicylate suspension

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:30142-608

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
BISMUTH SUBSALICYLATE (UNII: 62TEY51RR1) (BISMUTH CATION - UNII:ZS9CD1I8YE, SALICYLIC ACID - UNII:O414PZ4LPZ)	BISMUTH SUBSALICYLATE	525 mg in 30 mL	

Inactive Ingredients	
Ingredient Name	Strength
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K6790BS311)	
D&C RED NO. 22 (UNII: 1678RKX8RT)	
D&C RED NO. 28 (UNII: 767IP0Y5NH)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
WATER (UNII: 059QF0KO0R)	
SALICYLIC ACID (UNII: O414PZ4LPZ)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics			
Color	PINK (viscous)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

ı	Packaging				
4	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
]	NDC:30142-608- 08	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020		
2	NDC:30142-608- 12	354 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part335	03/30/2020	

Revised: 8/2023 KROGER COMPANY