DIGESTIVE RELIEF REGULAR STRENGTH- bismuth subsalicylate liquid TARGET Corporation

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.

Drug Facts

Active ingredient (in each 30 mL)

Bismuth subsalicylate 525 mg

Purpose

Upset stomach reliever/Antidiarrheal

Uses

relieves

- travelers' diarrhea
- diarrhea
- upset stomach due to overindulgence in food and drink, including:
 - heartburn
 - indigestion
 - o nausea
 - o gas
 - fullness
 - belching

Warnings

Reye's syndrome: Children and teenagers who have or are recovering from chicken pox or flu-like symptoms ahould 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

- diabetes
- gout
- arthritis
- anticoagulation (thinning the blood)

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 childen.

In case of overdose, get medical help or contact a Posion Control Center right away. (1-800-222-1222)

Directions

- mL = milliliter
- shake well before using
- measure only with dosing cup provided. do not use any other dosng device.
- keep dosing cup with product
- adults and children 12 years and over
 - 30 mL (1 dose) every 1/2 or 60 mL (2 doses) every hour as needed for diarrhea/traveler's diarrhea
 - 30 mL (1 dose) every 1/2 as needed for overindulgence (upset stomach, heartburn, indigestion, nausea)
 - o do not exceed 8 doses (240 mL) in 24 hours
 - use until diarrhea stops but not more than 2 days
- children under 12 years of age: ask a doctor
- drink plenty of clear fluids to help prevent dehydration caused by diarrhea

Other information

- each 30 mL contains: potassium 8 mg sodium 6 mg
- each 30 mL contains: salicylate 206 mg
- low sodium
- keep tightly closed
- protect from freezing
- avoid excessive heat (over 104°F or 40°C)

Inactive ingredients

benzoic acid, D&C red #22, D&C red #28, flavor, glycerin, purified water, sucralose, xanthan gum

Questions or comments?

Call 1-800-910-6874

Principal Display Panel

Compare to the active ingredient in Pepto-Bismol®*

5-symptom

digestive relief

Bismuth subsalicylate 525 mg per 30 mL

upset stomach reliever/antidiarrheal

helps relieve upset stomach, nausea, heartburn, indigestion diarrhea

FL OZ (mL)

*This product is not manufactured or distributed by The Procter & Gamble Company. Pepto-Bismol® is a registered trademark of The Procter & Gamble Company.

TAMPER EVIDENT; DO NOT USE IF PRINTED SAFETY SEAL AROUND DOSAGE CUP OR UNDER CAP IS BROKEN OR MISSING.

Dist. by Target Corp., Mpls., MN 55403

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Package Label



TARGET Digestive Relief

DIGESTIVE RELIEF REGULAR STRENGTH bismuth subsalicylate liquid Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:11673-372 Route of Administration ORAL Active Ingredient/Active Moiety Ingredient Name Basis of Strength Strength

BISMUTH

525 mg

BISMUTH SUBSALICYLATE (UNII: 62TEY51RR1) (BISMUTH CATION - UNII:ZS9CD118YE,

Inactive Ingredients				
Ingredient Name	Strength			
BENZOIC ACID (UNII: 8 SKN0 B0 MIM)				
D&C RED NO. 22 (UNII: 1678 RKX8 RT)				
D&C RED NO. 28 (UNII: 767IP0 Y5NH)				
GLYCERIN (UNII: PDC6A3C0OX)				
WATER (UNII: 059QF0KO0R)				
SUCRALOSE (UNII: 96K6UQ3ZD4)				
XANTHAN GUM (UNII: TTV12P4NEE)				

Packaging					
# Item Code	Package Description	Marketing Start Date	Marketing End Date		
1 NDC:11673-372- 32	2 in 1 PACKAGE	09/30/2019			
1	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product				

Marketing Inform			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part335	09/30/2019	

Labeler - TARGET Corporation (006961700)

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