

TOPCARE ULTRA STRENGTH STOMACH RELIEF- bismuth subsalicylate liquid
Topco Associates, LLC

Topcare Ultra Strength Stomach Relief Liquid

ACTIVE INGREDIENT(in each 15 mL)

Bismuth subsalicylate 525 mg

PURPOSE

Upset stomach reliever and anti-diarrheal

USE(S)

relieves:

- diarrhea
- heartburn
- indigestion
- nausea
- upset stomach associated with these symptoms

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
- bloody or black stool
- a bleeding problem

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 of 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 DOCTOR IF

- symptoms get worse
- 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 immediately.

DIRECTIONS

- **shake well before use**
- mL = milliliter
- TBSP = tablespoon
- adults and children 12 years and over: 1 dose (1 TBSP or 15 mL) every 1/2 hour as needed
- do not exceed 8 doses (120 mL) in 24 hours
- use until diarrhea stops but not more than 2 days
- children under 12 years: ask a doctor
- drink plenty of fluids to help prevent dehydration caused by diarrhea

OTHER INFORMATION

- **each 15 mL or 1 TBSP contains:**
- potassium 15 mg
- salicylate 236 mg
- sodium 5 mg
- protect from freezing

- avoid excessive heat (over 104°F or 40°C)
- dosage cup provided

INACTIVE INGREDIENTS

benzoic acid, D&C red # 22, D&C red # 28, flavor, hydroxyethyl cellulose, potassium hydroxide, purified water, saccharin sodium, salicylic acid, simethicone, xanthan gum

PRINCIPAL DISPLAY PANEL

NDC 76162-022-04

COMPARE TO PEPTO-BISMOL® ULTRA STRENGTH ACTIVE INGREDIENT*

TopCare

ULTRA STRENGTH

Stomach Relief

BISMUTH SUBSALICYLATE 525 mg per 15 mL

UPSET STOMACH RELIEVER/ANTIDIARRHEAL

5 SYMPTOM DIGESTIVE RELIEF

- Heartburn
- Indigestion
- Nausea
- Upset stomach
- Diarrhea

8 FL OZ (236 mL)

Drug Facts		DO NOT USE IF IMPRINTED SHRINKBAND IS MISSING OR BROKEN.
Active ingredient (per 15 mL)	Purpose	
Bismuth subsalicylate 525 mg	Upset stomach reliever and anti-diarrheal	
Uses relieves: ■ diarrhea ■ heartburn ■ indigestion ■ nausea ■ upset stomach associated with these symptoms		
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 ■ bloody or black stool ■ a bleeding problem		
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 of 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 ■ 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 immediately.		
Drug Facts continued		

NDC 76162-022-04



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ULTRA STRENGTH

Stomach Relief

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MFR# 53041 REV 1021

NDC 76162-022-05

COMPARE TO PEPTO-BISMOL® ULTRA STRENGTH ACTIVE INGREDIENT*

TopCare

ULTRA STRENGTH

Stomach Relief

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12 FL OZ (354 mL)

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Do not use if you have ■ bloody or black stool ■ an ulcer ■ a bleeding problem

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
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■ 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 ■ 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 immediately.

Drug Facts continued

TopCare
health

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ULTRA STRENGTH

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Inactive ingredients benzoic acid, D&C red # 22, D&C red # 28, flavor, hydroxyethyl cellulose, potassium hydroxide, purified water, saccharin sodium, salicylic acid, simethicone, xanthan gum.

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QUALITY GUARANTEED



TOPCARE ULTRA STRENGTH STOMACH RELIEF			
bismuth subsalicylate liquid			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76162-022
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 in 15 mL
Inactive Ingredients			
Ingredient Name			Strength
BENZOIC ACID (UNII: 8SKN0B0MIM)			

D&C RED NO. 22 (UNII: 1678RKX8RT)	
D&C RED NO. 28 (UNII: 767IP0Y5NH)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SALICYLIC ACID (UNII: O414PZ4LPZ)	
HYDROXYETHYL CELLULOSE (1500 MPA.S AT 1%) (UNII: L605B5892V)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	PINK	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76162-022-05	354 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/05/2022	
2	NDC:76162-022-04	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/05/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M008	01/05/2022	

Labeler - Topco Associates, LLC (006935977)

Revised: 12/2024

Topco Associates, LLC