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

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.

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

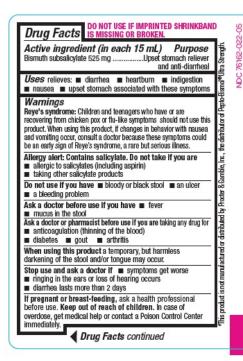
PRINCIPAL DISPLAY PANEL

NDC 76162-022-05
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

12 FL OZ (354 mL)





COMPARE TO PEPTO-BISMOL® ULTRA STRENGTH ACTIVE INGREDIENT*

ULTRA STRENGTH

Stomach Relief

BISMUTH SUBSALICYLATE 525 mg per 15 mL UPSET STOMACH RELIEVER/ANTIDIARRHEAL

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- Upset Stomach
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Drug Facts (continued)

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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 clear 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 oum.

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✓ QUALITY GUARANTEED

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3 6 8 0 0 1 3 5 8 5 7

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

BISMUTH SUBSALICYLATE (UNII: 62TEY51RR1) (SALICYLIC ACID - UNII:0414PZ4LPZ)

BISMUTH SUBSALICYLATE (UNII: 62TEY51RR1) (SALICYLIC ACID - SUBSALICYLATE in 15 mL

Ingredient Name Strength BENZOIC ACID (UNII: 85KN0B0MIM) D&C RED NO. 22 (UNII: 1678RKX8RT) D&C RED NO. 28 (UNII: 767IP0Y5NH) POTASSIUM HYDROXIDE (UNII: WZH3C48M4T) WATER (UNII: 059QF0K00R) SACCHARIN SODIUM (UNII: SB8ZUX40TY) SALICYLIC ACID (UNII: 0414PZ4LPZ) HYDROXYETHYL CELLULOSE (1500 MPA.S AT 1%) (UNII: L605B5892V)

DIMETHICONE (UNII: 92RU3N3Y10)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics					
Color	PINK	Score			
Shape		Size			
Flavor		Imprint Code			
Contains					

P	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 FINAL	part335	01/05/2022				

Labeler - Topco Associates, LLC (006935977)

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