

TOPCARE STOMACH RELIEF CHERRY - bismuth subsalicylate liquid
Topco Associates, LLC

Topcare Stomach Relief Cherry Liquid

ACTIVE INGREDIENT(in each 30 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 (2 TBSP or 30 mL) every 1/2 to 1 hour as needed
- do not exceed 8 doses (16 TBSP or 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 or 2 TBSP contains:**
- potassium 25 mg
- salicylate 260 mg
- sodium 8 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

TOPCARE

COMPARE TO PEPTO-BISMOL® REGULAR STRENGTH ACTIVE INGREDIENT*
NDC 36800-769-04

REGULAR STRENGTH

Stomach Relief

BISMUTH SUBSALICYLATE 525 mg per 30 mL
UPSET STOMACH RELIEVER/ANTI-DIARRHEAL

5 SYMPTOM DIGESTIVE RELIEF

- Heartburn
- Indigestion
- Upset stomach
- Nausea
- Diarrhea

Cherry Flavor
8 FL OZ (236 mL)

Drug Facts DO NOT USE IF IMPRINTED SHRINKBAND IS MISSING OR BROKEN.

Active ingredient (in each 30 mL) **Purpose**
Bismuth subsalicylate 525 mgUpset 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

+TopCare
health

COMPARE TO PEPTO-BISMOL® REGULAR STRENGTH ACTIVE INGREDIENT*

REGULAR STRENGTH

Stomach Relief

BISMUTH SUBSALICYLATE 525 mg per 30 mL
UPSET STOMACH RELIEVER/ANTI-DIARRHEAL
5 SYMPTOM DIGESTIVE RELIEF

- Heartburn
- Indigestion
- Upset Stomach
- Nausea
- Diarrhea

CHERRY FLAVOR



8 FL OZ (236 mL)

Drug Facts (continued)

Directions ■ shake well before use
■ mL = milliliter ■ TBSP = tablespoon ■ adults and children 12 years and over: 1 dose (2 TBSP or 30 mL) every 1/2 to 1 hour as needed ■ do not exceed 8 doses (16 TBSP or 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 or 2 TBSP contains:
• potassium 25 mg • salicylate 260 mg • sodium 8 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.

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MFR# 53041
REV 10/21

TOPCARE STOMACH RELIEF CHERRY

bismuth subsalicylate liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-769
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 30 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: WZ H3C48M4T)	
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	CHERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-769-06	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/17/2021	
2	NDC:36800-769-04	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/17/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M008	12/17/2021	

Labeler - Topco Associates, LLC (006935977)

Establishment

Name	Address	ID/FEI	Business Operations
Guardian Drug Company		119210276	MANUFACTURE(36800-769)

Revised: 12/2024

Topco Associates, LLC