

TOPCARE STOMACH RELIEF CHERRY - 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 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.

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

NDC 36800-769-04



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 FINAL	part335	12/17/2021	

Labeler - Topco Associates, LLC (006935977)

Establishment

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

Revised: 11/2022

Topco Associates, LLC