

FOSTER AND THRIVE REGULAR STRENGTH STOMACH RELIEF 527 - bismuth subsalicylate 525 mg liquid
Strategic Sourcing Services 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.

Foster and Thrive Regular Strength Stomach Relief -527

ACTIVE INGREDIENT(in each 30 mL)

Bismuth subsalicylate 525 mg

PURPOSE

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 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(1-800-222-1222).

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.

QUESTIONS OR COMMENTS?

Call 833-358-6431 Monday to Friday 9:00 am to 7:00 pm EST

PRINCIPAL DISPLAY PANEL

NDC 70677-1191-1

COMPARE TO PEPTO-BIMOL® ACTIVE INGREDIENT*

Foster and Thrive™

REGULAR STRENGTH

Stomach Relief

Bismuth Subsalicylate 525mg

ANTIDIARRHEAL UPSET STOMACH RELIEVER

Relieves:

- Upset Stomach
- Nausea
- Heartburn
- Indigestion
- Diarrhea

8 FL. OZ. (236 mL)

| | | |
|--|---|---|
| <p>Drug Facts <small>DO NOT USE IF IMPRINTED SHRINKBAND IS MISSING OR BROKEN.</small></p> <p>Active ingredient (in each 30 mL) Purpose Bismuth subsalicylate 525 mg Upset stomach reliever and anti-diarrheal</p> <p>Uses relieves: ■ diarrhea ■ heartburn ■ indigestion ■ nausea ■ upset stomach associated with these symptoms</p> <p>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 salicylates. 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 (1-800-222-1222). Drug Facts continued</p> | <p>NDC 70677-1191-1</p> <p>COMPARE TO PEPTO-BIMOL® ACTIVE INGREDIENT*</p> <p>Foster & Thrive™ REGULAR STRENGTH Stomach Relief Bismuth Subsalicylate 525 mg ANTIDIARRHEAL UPSET STOMACH RELIEVER</p> <p>Relieves:</p> <ul style="list-style-type: none">• Upset Stomach• Nausea• Heartburn• Indigestion• Diarrhea <p>8 FL OZ (236 mL)</p> | <p>Drug Facts (continued)</p> <p>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</p> <p>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</p> <p>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.</p> <p>Questions or comments? Call 833-358-6431 Monday to Friday 9:00 am to 7:00 pm EST</p> <p><small>*This product is not manufactured or distributed by Procter & Gamble Inc., the distributor of Pepto-Bismol®</small></p> <p>©2023 McKesson Corporation NPI# 53041 REI 0523</p> <p>Distributed by: McKesson Corp., via SSLL Hempstead, NY 11549 Money Back Guarantee www.fosterandthrive.com</p>  |
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FOSTER AND THRIVE REGULAR STRENGTH STOMACH RELIEF 527

bismuth subsalicylate 525 mg liquid

Product Information

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|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:70677-1191 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-----------------------|--------------------|
| BISMUTH SUBSALICYLATE (UNII: 62TEY51RR1) (BISMUTH CATION - UNII:ZS9CD1I8YE) | 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: 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 | WINTERGREEN | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:70677-1191-1 | 236 mL in 1 BOTTLE; Type 0: Not a Combination Product | 08/02/2023 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC MONOGRAPH FINAL | part335 | 08/02/2023 | |

Labeler - Strategic Sourcing Services LLC (116956644)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-----------------------|---------|-----------|-------------------------|
| Guardian Drug Company | | 119210276 | MANUFACTURE(70677-1191) |

Revised: 8/2023

Strategic Sourcing Services LLC