

# **ULTRA STRENGTH DIGESTIVE RELIEF- bismuth subsalicylate tablet** **THE KROGER CO.**

*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.*

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## **Ultra Strength Digestive Relief 24 Caplets**

### **Drug Facts**

#### **Active ingredient (in each caplet)**

Bismuth Subsalicylate 525 mg

#### **Purpose**

Upset stomach reliever and antidiarrheal

#### **Uses**

relieves

- travelers' diarrhea
- diarrhea
- upset stomach due to overindulgence in food and drink, including:
  - heartburn
  - indigestion
  - nausea
  - gas
  - belching
  - fullness

#### **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
- a bleeding problem
- bloody or black stool

**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 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 or last more than 2 days
- 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 right away.

**Directions**

- swallow with water, do not chew
- **adults and children 12 years and over:** 1 caplet (1 dose) every ½ hour or 2 caplets (2 doses) every hour as needed for diarrhea
- 1 caplet (1 dose) every ½ hour as needed for overindulgence (upset stomach, heartburn, indigestion, nausea)
- do not exceed 8 doses (8 caplets) 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 caplet contains:** calcium 54 mg
- salicylate 199 mg
- store at room temperature

## **Inactive ingredients**

calcium carbonate, crospovidone, FD&C Red No. 27 Lake, magnesium stearate, microcrystalline cellulose, polysorbate 80.

## **Questions?**

**1-866-467-2748**

## **PRINCIPAL DISPLAY PANEL - 24 Caplet Carton**

**NDC 30142-138-24**

Ultra Strength

Bismuth Subsalicylate

Upset Stomach Reliever/Antidiarrheal

Symptom Digestive Relief

- **Heartburn**
- **Indigestion**
- **Nausea**
- **Upset Stomach**
- **Diarrhea**

**24 Caplets**

**2X STRENGTH per caplet\***

**Drug Facts (continued)**

Ask a doctor or pharmacist before use if you are taking any drug for  
■ anticoagulation (thinning 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 or last more than 2 days ■ 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 at 1-800-222-1222.

**Directions** ■ swallow with water, do not chew ■ adults and children 12 years and over: 1 caplet (1 dose) every ½ hour or 2 caplets (2 doses) every hour as needed for diarrhea ■ 1 caplet (1 dose) every ½ hour as needed for overindulgence (upset stomach, heartburn, indigestion, nausea) ■ do not exceed 8 doses (8 caplets) 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 caplet contains: calcium 54 mg ■ salicylate 199 mg ■ store at room temperature

COMPARE TO the active ingredient in PEPTO-BISMOL® ULTRA \*\*See side panel



NDC 30142-138-24



Ultra Strength

**Stomach Relief**

Bismuth Subsalicylate  
Upset Stomach  
Reliever/  
Antidiarrheal

actual size

2x STRENGTH per caplet

5 SYMPTOM RELIEF:

Heartburn,  
Indigestion, Nausea,  
Upset Stomach, Diarrhea

24 CAPLETS

COMPARE TO the active ingredient in PEPTO-BISMOL® ULTRA \*\*See side panel

NDC 30142-138-24



Ultra Strength

**Stomach Relief**

Bismuth Subsalicylate  
Upset Stomach Reliever/  
Antidiarrheal

2x STRENGTH per caplet

actual size



5 SYMPTOM RELIEF:  
Heartburn,  
Indigestion, Nausea,  
Upset Stomach, Diarrhea

24 CAPLETS

**Drug Facts**

DO NOT USE IF PRINTED INNER SEAL UNDER CAP IS BROKEN OR MISSING

**Active ingredient (in each caplet)**

Bismuth subsalicylate 525 mg.....Upset stomach reliever and anti-diarrheal

**Purposes**

**Uses** relieves ■ travelers' diarrhea ■ diarrhea  
■ upset stomach due to overindulgence in food and drink, including:  
■ heartburn ■ indigestion ■ nausea ■ gas ■ belching ■ fullness

**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 ■ a bleeding problem ■ bloody or black stool

**Ask a doctor before use if you have** ■ fever ■ mucus in the stool

**Drug Facts (continued)**

**Inactive ingredients** calcium carbonate, croscarmellose, FD&C Red No. 27 Lake, magnesium stearate, microcrystalline cellulose, polysorbate 80.

**Questions? 1-800-632-5900**

\*vs Original Caplet



PLEASE RECYCLE  
DISTR. BY THE KROGER CO.,  
CINCINNATI, OHIO 45202  
QUALITY GUARANTEE  
800-632-6900 | www.kroger.com

**IMPORTANT: Keep this carton for future reference on full labeling.**

EXP: 13024KROFC

LOT: 0 41260100854 2



**ULTRA STRENGTH DIGESTIVE RELIEF**

bismuth subsalicylate tablet

**Product Information**

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:30142-138 |
| <b>Route of Administration</b> | ORAL           |                           |               |

**Active Ingredient/Active Moiety**

| Ingredient Name  | Basis of Strength     | Strength |
|--|-----------------------|----------|
| <b>BISMUTH SUBSALICYLATE</b> (UNII: 62TEY51RR1) (SALICYLIC ACID - UNII:O414PZ4LPZ) | BISMUTH SUBSALICYLATE | 525 mg   |

**Inactive Ingredients**

| Ingredient Name                                      | Strength |
|--|----------|
| <b>CALCIUM CARBONATE</b> (UNII: H0G9379FGK)          |          |
| <b>CROSPROVIDONE (120 .MU.M)</b> (UNII: 68401960MK)  |          |
| <b>D&amp;C RED NO. 27</b> (UNII: 2LRS185U6K)         |          |
| <b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)         |          |
| <b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U) |          |
| <b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)             |          |

**Product Characteristics**

|                 |               |                     |          |
|-----------------|---------------|---------------------|----------|
| <b>Color</b>    | PINK          | <b>Score</b>        | no score |
| <b>Shape</b>    | OVAL (Caplet) | <b>Size</b>         | 18mm     |
| <b>Flavor</b>   |               | <b>Imprint Code</b> | RP130    |
| <b>Contains</b> |               |                     |          |

**Packaging**

| # | Item Code        | Package Description                               | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:30142-138-24 | 1 in 1 CARTON                                     | 11/18/2019           |                    |
| 1 |                  | 24 in 1 BOTTLE; Type 0: Not a Combination Product |                      |                    |

**Marketing Information**

| Marketing Category  | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part335                                  | 11/18/2019           |                    |

**Labeler** - THE KROGER CO. (006999528)