# STOMACH RELIEF - bismuth subsalicylate tablet, chewable CARDINAL HEALTH 110, LLC. DBA LEADER

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#### Leader Stomach Relief

#### ACTIVE INGREDIENT(in each tablet)

Bismuth subsalicylate 262 mg

(total salicylate 102 mg per tablet)

#### 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

- bloody or black stool
- an ulcer
- 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).

#### DIRECTIONS

- chew or dissolve in mouth
- adults and children 12 years and over: 2 tablets every 1/2 to 1 hour as needed
- do not take more than 8 doses (16 tablets) 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 tablet contains:
- sodium less than 1 mg
- salicylate 102 mg
- very low sodium
- avoid excessive heat (over 104°F or 40°C)

• TAMPER EVIDENT: Do not use if individual compartments are torn on open.

#### **INACTIVE INGREDIENTS**

calcium carbonate, D&C red 27 aluminum lake, flavor, magnesium stearate, mannitol, pregelatinized starch, saccharin sodium

#### PRINCIPAL DISPLAY PANEL

LEADER

NDC 70000-0591-1 Stomach Relief

Bismuth Subsalicylate, 262 mg Upset Stomach Reliever / Anti-Diarrheal

COMPARE TO PEPTO-BISMOL<sup>®</sup> active ingredient\*

5 Symptom Digestive Relief:

Diarrhea

Heartburn

Indigestion

Nausea

Upset stomach

30 CHEWABLE TABLETS



#### LEADER

NDC 70000-0591-2 Stomach Relief

Bismuth Subsalicylate, 262 mg Upset Stomach Reliever / Anti-Diarrheal

COMPARE TO PEPTO-BISMOL® active ingredient\*

5 Symptom Digestive Relief:

Diarrhea

Heartburn

Indigestion

Nausea

#### 48 CHEWABLE TABLETS

| Prove For da                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                                                                                                                                                                                                                                                                                                                                                                          | Relief                                                                                                                                           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
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| Drug Facts     Active ingredient (in each tablet)   Purpose     Bismuth subsalicytate 262 mg   Upset stomach reliever<br>(total salicytate 102 mp per tablet)   Upset stomach reliever<br>and and-damheal     Uses relieves:   diartheal   heartburn   indigestion   nausea                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | 412 mg<br>EMT. Do act use if<br>Magnesium stoarsie,                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                                  | NF88 53041                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| Warnings   Reprise synchrone: Children and theragens who have or are recovering from children govor of "while synchrone, sine but settings product, the synchrone is the synchrone synchrone are but settings product.   Marcings In behavior with nueses and vomiling occur, consult a doctor because these synchrone, are but settings index of the synchrone, are but settings lines.   Altergy alert: Contains sativity of Reyck's synchrone, are but settings lines.   Altergy alert: Contains sativity from the two of the sativity synchrone, are but settings lines.   Dent use If you have bitoody or black stool if an ulcer   a bitooling problem In ulcer   As a doctor or pharmacids before use if you are taking any drug for Antergy alert: Contains sativity, but harm issis darkening of the alter to rupe may occur.   Step ased ask a doctor if the symptoms get worse Antergy and set a doctor if a symptoms get worse   Anter asing hit product a temporary, but harmiess darkening of the or control canter to rose of hearing occurs.   Step ase and set a doctor if a symptoms get worse.   and one the sate fooding , ask a health production before use.   Keep out of mach of ehildren. In case of overdose, get medical help or control canter a Poison Control Canter immediately (1-800-222-1222).   Directions _ thew or dissolve in much _ adults and children 18 years and exer: 2 bible every 16 yo here as needed _ do not tisk more than 2 days or they are used if dorts use than 2 days and were areat of ehildren. | Drug Facts (continued)<br>Other information = exchasint certains: • sodim less than 1 mg = subjetie 302 mg<br>= way low sodium = are tann er open.<br>Infordual cempartments are tann er open.<br>Inactive infordiations are tann er open.<br>Inactive infordiations starth, accloim cationale, D&C not 27 aluminum late, flavor, magnesium stoara<br>mentiol, progradiations starth, accloim cationale. | <section-header><section-header><text><text><text><text><text><text></text></text></text></text></text></text></section-header></section-header> | Thermatics is the mandenergic distance from the formula.<br>The many of the segment handwards from the formula<br>Coll Control and Coll and the formula of the manual<br>coll of the manufacture of the manual<br>coll of the manufacture of the manufact |

| STOMACH RELIEF<br>bismuth subsalicylate tablet, chewable                           |                |                |                        |           |          |
|------------------------------------------------------------------------------------|----------------|----------------|------------------------|-----------|----------|
| Product Information                                                                |                |                |                        |           |          |
| Product Type                                                                       | HUMAN OTC DRUG | ltem Code (Sou | rce)                   | NDC:70000 | -0591    |
| Route of Administration                                                            | ORAL           |                |                        |           |          |
|                                                                                    |                |                |                        |           |          |
| Active Ingredient/Active Moiety                                                    |                |                |                        |           |          |
| Ingredient Name                                                                    |                |                | Basis of S             | Strength  | Strength |
| <b>BISMUTH SUBSALICYLATE</b> (UNII: 62TEY51RR1) (SALICYLIC ACID - UNII:0414PZ4LPZ) |                |                | BISMUTH<br>SUBSALICYL/ | ATE       | 262 mg   |

| Inactive Ingredients                  |          |  |  |  |
|---------------------------------------|----------|--|--|--|
| Ingredient Name                       | Strength |  |  |  |
| CALCIUM CARBONATE (UNII: H0G9379FGK)  |          |  |  |  |
| D&C RED NO. 27 (UNII: 2LRS185U6K)     |          |  |  |  |
| MAGNESIUM STEARATE (UNII: 70097M6I30) |          |  |  |  |
| MANNITOL (UNII: 30WL53L36A)           |          |  |  |  |
| STARCH, CORN (UNII: 08232NY3SJ)       |          |  |  |  |
| SACCHARIN SODIUM (UNII: SB8ZUX40TY)   |          |  |  |  |

| Product Characteristics |       |              |          |  |
|-------------------------|-------|--------------|----------|--|
| Color                   | PINK  | Score        | no score |  |
| Shape                   | ROUND | Size         | 16mm     |  |
| Flavor                  |       | Imprint Code | G122     |  |
| Contains                |       |              |          |  |

### Packaging

| # | ltem Code                            | Package Description                                       | Marketing Start<br>Date | Marketing End<br>Date |
|---|--------------------------------------|-----------------------------------------------------------|-------------------------|-----------------------|
| 1 | NDC:70000-<br>0591-1                 | 5 in 1 BOX                                                | 10/05/2021              |                       |
| 1 |                                      | 5 in 1 BLISTER PACK; Type 0: Not a Combination<br>Product |                         |                       |
| 2 | NDC:70000-<br>0591-2                 | 3 in 1 BOX                                                | 10/05/2021              |                       |
| 2 |                                      | 5 in 1 BLISTER PACK; Type 0: Not a Combination<br>Product |                         |                       |
|   |                                      |                                                           |                         |                       |
|   |                                      |                                                           |                         |                       |
| M | larketing l                          | nformation                                                |                         |                       |
| M | larketing I<br>Marketing<br>Category | nformation<br>Application Number or Monograph<br>Citation | Marketing Start<br>Date | Marketing End<br>Date |

## Labeler - CARDINAL HEALTH 110, LLC. DBA LEADER (063997360)

| Establishment         |         |           |                            |  |  |
|-----------------------|---------|-----------|----------------------------|--|--|
| Name                  | Address | ID/FEI    | <b>Business Operations</b> |  |  |
| Guardian Drug Company |         | 119210276 | MANUFACTURE(70000-0591)    |  |  |

Revised: 1/2025

CARDINAL HEALTH 110, LLC. DBA LEADER