

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

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.

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 or 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[®] active ingredient*

5 Symptom Digestive Relief:

Diarrhea

Heartburn

Indigestion

Nausea

Upset stomach

30 CHEWABLE TABLETS



STOMACH RELIEF

bismuth subsalicylate tablet, chewable

Product Information

| | | | |
|-------------------------|----------------|--------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:70000-0591 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-----------------------|----------|
| BISMUTH SUBSALICYLATE (UNII: 62TEY51RR1) (SALICYLIC ACID - UNII:O414PZ4LPZ) | BISMUTH SUBSALICYLATE | 262 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| CALCIUM CARBONATE (UNII: H0G9379FGK) | |
| D&C RED NO. 27 (UNII: 2LRS185U6K) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |

| | | | | |
|--|------------------|--|-----------------------------|---------------------------|
| MANNITOL (UNII: 3OWL53L36A) | | | | |
| STARCH, CORN (UNII: O8232NY3SJ) | | | | |
| SACCHARIN SODIUM (UNII: SB8ZUX40TY) | | | | |
| | | | | |
| Product Characteristics | | | | |
| Color | PINK | Score | no score | |
| Shape | ROUND | Size | 16mm | |
| Flavor | | Imprint Code | G122 | |
| Contains | | | | |
| | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:70000-0591-1 | 5 in 1 BOX | 10/05/2021 | |
| 1 | | 6 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| 2 | NDC:70000-0591-2 | 8 in 1 BOX | 10/05/2021 | |
| 2 | | 6 in 1 BLISTER PACK; 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 | 10/05/2021 | |

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

Establishment

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

Revised: 11/2022

CARDINAL HEALTH 110, LLC. DBA LEADER