

LEADER STOMACH RELIEF ORIGINAL STRENGTH- bismuth subsalicylate tablet, chewable

Cardinal Health

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.

Cardinal Health Stomach Relief Chewables Drug Facts

Active ingredient (in each tablet)

Bismuth subsalicylate 262 mg

Purpose

Antidiarrheal/upset stomach reliever
(total salicylate 102 mg per tablet)

Uses

relieves

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

- 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 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 right away.

Directions

- chew or dissolve tablets in mouth
- drink plenty of clear fluids to help prevent dehydration caused by diarrhea
- **adults and children 12 years and older:** 2 tablets every ½ to 1 hour, or 4 tablets every hour as needed
- do not exceed 16 tablets in 24 hours
- use until diarrhea stops but not more than 2 days
- children under 12 years: ask a doctor

Other information

- **each tablet contains:** salicylate 102 mg
- **Do not use if individual blister compartments are torn or open**
- Store at room temperature 59°-86°F

Inactive ingredients

flavor, magnesium stearate, microcrystalline cellulose, red #27 aluminum lake, sorbitol, sucralose

Questions?

1-800-719-9260

Principal Display Panel

LEADER

NDC 37205-720-65

Compare to Pepto-Bismol® active ingredient*

Pink Bismuth

Chewable Tablets

Bismuth Subsalicylate 262 mg

Original Flavor

Provides Soothing Relief for:

- Indigestion
- Upset Stomach
- Nausea
- Diarrhea
- Heartburn

SATISFACTION GUARANTEED

30 CHEWABLE TABLETS

All Leader® Brand products are 100% satisfaction guaranteed or return to place of purchase for a full refund.

Distributed By: Cardinal Health

Dublin, Ohio 43017

www.myleader.com

CIN 2572691

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



Stomach Relief Chewables Carton

LEADER STOMACH RELIEF ORIGINAL STRENGTH

bismuth subsalicylate tablet, chewable

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:37205-720 |
| 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 |
|---|----------|
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U) | |
| D&C RED NO. 27 (UNII: 2LRS185U6K) | |
| SORBITOL (UNII: 506T60A25R) | |
| SUCRALOSE (UNII: 96K6UQ3ZD4) | |

Product Characteristics

| | | | |
|----------|-------|--------------|----------|
| Color | PINK | Score | no score |
| Shape | ROUND | Size | 17mm |
| Flavor | | Imprint Code | L469 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:37205-720-65 | 5 in 1 CARTON | 08/20/2019 | |
| 1 | | 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 | 08/20/2019 | |

Labeler - Cardinal Health (097537435)

Revised: 1/2021

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