SUNMARK STOMACH RELIEF- bismuth subsalicylate tablet, chewable Strategic Sourcing Services LLC

Sunmark Stomach Relief

ACTIVE INGREDIENT(in each tablet)

Bismuth subsalicylate 262 mg

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 behaviour 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 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 fluids to help prevent dehydration caused 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

sunmark

NDC 70677-0138-1

COMPARE TO PEPTO-BISMOL® CHEWABLE TABLETS ACTIVE INGREDIENT*

stomach relief

Regular Strength

Antidiarrheal / Upset Stomach Reliever Soothing Relief For Upset stomach, Nausea,

Heartburn, Indigestion & Diarrhea

BISMUTH SUBSALICYLATE 262 mg

CHEWABLE 30 TABLETS



SUNMARK STOMACH RELIEF

bismuth subsalicylate tablet, chewable

| Product Information | | | |
|-------------------------|----------------|--------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:70677-0138 |
| Route of Administration | ORAL | | |

| Active Ingredient/Active Moiety | | | |
|---------------------------------|--------------------------|----------|--|
| Ingredient Name | Basis of Strength | Strength | |
| | 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: 30WL53L36A) | |
|-------------------------------------|--|
| STARCH, CORN (UNII: O8232NY3SJ) | |
| SACCHARIN SODIUM (UNII: SB8ZUX40TY) | |

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

| F | Packaging | | | | |
|---|----------------------|--|-------------------------|-----------------------|--|
| # | tem Code | Package Description | Marketing Start Date | Marketing End Date | |
| 1 | NDC:70677- 0138-1 | 5 in 1 BOX | 09/08/2021 | | |
| 1 | L | 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 Drug | M008 | 09/08/2021 | 12/13/2024 |
| | | | |

Labeler - Strategic Sourcing Services LLC (116956644)

| Establishment | | | | |
|-----------------------|---------|-----------|----------------------------|--|
| Name | Address | ID/FEI | Business Operations | |
| Guardian Drug Company | | 119210276 | MANUFACTURE(70677-0138) | |

Revised: 12/2024 Strategic Sourcing Services LLC