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

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.

Health Mart Stomach Relief Tablets

Active ingredient (in each tablet)

Bismuth subsalicylate 262 mg (total salicylate 102 mg per tablet)

Purpose

Upset stomach reliever and anti-diarrheal

Uses

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.

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
- children under 12 years: ask a doctor
- drink plenty of fluids to help prevent dehydration which may accompany 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 missing.

Inactive ingredients

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

Principal Display Panel

Health Mart

NDC 62011-0140-1

Compare to Pepto-Bismol® Chewable Tablets Active Ingredient*

Stomach Relief

Bismuth Subsalicylate 262 mg

Upset Stomach Reliever/Anti-Diarrheal

Soothing Relief for

Upset Stomach, Nausea, Heartburn,

Indigestion & diarrhea

30 Chewable Tablets



HEALTH MART STOMACH RELIEF

bismuth subsalicylate tablet, chewable

| Product Information | | | |
|-------------------------|----------------|--------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:62011-0140 |
| 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 | 17mm |
| Flavor | | Imprint Code | GDC122 |
| Contains | | | |

| ı | Packaging | | | |
|---|----------------------|--|-------------------------|-----------------------|
| 7 | # Item Code | Package Description | Marketing Start Date | Marketing End Date |
| : | NDC:62011- 0140-1 | 5 in 1 CARTON | 10/17/2019 | |
| : | L | 6 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |

| Marketing In | arketing Information | | | |
|-----------------------|---|-------------------------|-----------------------|--|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| OTC monograph final | part335 | 10/17/2019 | | |
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Labeler - Strategic Sourcing Services LLC (116956644)

Registrant - Guardian Drug Company (119210276)

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