

SUNMARK 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.

Sunmark Stomach relief tablets Regular Strength

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 stools
- 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
- 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 which 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

sunmark

COMPARE TO PEPTO-BISMOL® CHEWABLE TABLETS ACTIVE INGREDIENT*

NDC 49348-953-44

stomach relief tablets

Regular Strength

Antidiarrheal/Upset Stomach Reliever

Soothing relief for upset stomach, nausea

heartburn, indigestion and 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:49348-953

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BISMUTH SUBSALICYLATE (UNII: 62TEY51RR1) (SALICYLIC ACID - UNII:O414PZ4LPZ, BISMUTH CATION - UNII:ZS9CD1I8YE)	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	17mm
Flavor		Imprint Code	GDC122
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49348-953-44	5 in 1 CARTON	09/24/2019	
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	09/24/2019	

Labeler - Strategic Sourcing Services LLC (116956644)

Registrant - Guardian Drug Company (119210276)

Establishment

Name	Address	ID/FEI	Business Operations
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Guardian Drug Company

119210276

manufacture(49348-953)

Revised: 1/2022

Strategic Sourcing Services LLC