BISMUTH SUBSALICYLATE- sunmark stomach relief tablet, chewable
NuCare Pharmaceuticals,Inc.

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
- 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

BISMUTH SUBSALICYLATE

sunmark stomach relief tablet, chewable

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68071-4523(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 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:68071-4523-3	30 in 1 BOX; Type 0: Not a Combination Product	08/10/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part335	03/01/2011	

Labeler - NuCare Pharmaceuticals,Inc. (010632300)

Establishment

Name	Address	ID/FEI	Business Operations
NuCare Pharmaceuticals,Inc.		010632300	relabel(68071-4523)

Revised: 2/2022 NuCare Pharmaceuticals,Inc.