CRANE SAFETY BISMUTH- bismuth subsalicylate tablet, chewable Crane Safety 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.

Crane Safety Bismuth

Drug Facts

Active ingredient (in each tablet)

Bismuth Subsalicylate 262 mg

(each tablet contains 102 mg salicylate)

Purpose

Upset stomach reliever/antidiarrheal

Uses

Temporarily relieves

- traveler's diarrhea
- diarrhea
- upset stomach due to overindulgence in food and drink, including:
- heartburn
- indigestion
- nausea
- gas
- belching
- 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 if you are taking any drug for

- anticoagulation (thinning of the blood)
- diabetes
- gout
- arthritis

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

When using this product

a temporary and harmless darkening of the tongue and/or stool may occur. Stool darkening should not be confused with melena.

If pregnant or breast-feeding,

ask a health professional before use.

Keep this and all drugs out of reach of children.

In case of accidental overdose, contact a physician or poison control center immediately.

Directions

- do not use more than directed
- chew or crush tablets completely befre swallowing
- do not swallow tablet whole
- use until diarrhea stops but not more than 2 days
- drink plenty of clear fluids to help prevent dehydration, which may accompany diarrhea
- do not exceed 16 tablets in 24 hours

Adults and children: (12 years and older) Chew 2 tablets every 1/2 to 1 hour or 4 tablets every hour as needed

Children under 12 years: Do not give to children under 12 years of age.

Other information

- phenylketonurics: contains phenylalanine 1.1mg per tablet
- each tablet contains 73mg elemental calcium
- store at room temperature 59°-86°F (15°-30°C)
- tamper-evident sealed packets
- do not use any opened or torn packets

Inactive ingredients

acacia gum, aspartame, calcium carbonate, D&C red #27, dextrates, flavoring, magnesium stearate, maltodextrin, microcrystalline cellulose, silicon dioxide

Questions or comments?

877.506.4291

Crane Safety Bismuth Label

Chewable

Bismuth Tabs

Upset Stomach/Diarrhea Relief

CRANE Safety®

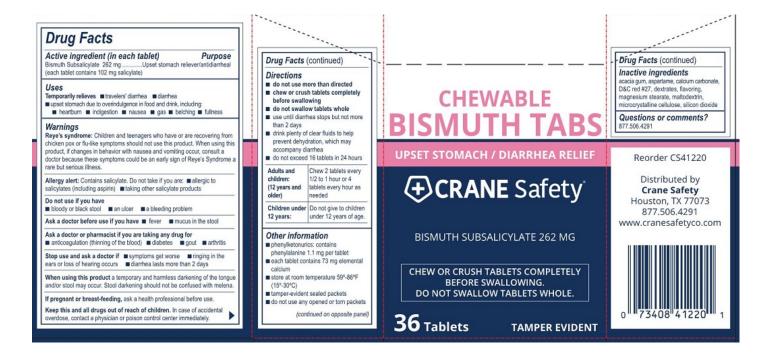
Bismuth Subsalicylate 262 MG

Chew or Crush Tablets Completely Before Swallowing.

Do Not Swallow Tablets Whole.

36 Tablets

Tamper Evident



CRANE SAFETY BISMUTH

bismuth subsalicylate tablet, chewable

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:73408-406

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name

BISMUTH SUBSALICYLATE (UNII: 62TEY51RR1) (SALICYLIC ACID - UNII:0414PZ4LPZ)

Basis of Strength

BISMUTH
SUBSALICYLATE

BISMUTH
SUBSALICYLATE

262 mg

Inactive Ingredients			
Ingredient Name	Strength		
D&C RED NO. 27 (UNII: 2LRS185U6K)			
CALCIUM CARBONATE (UNII: H0G9379FGK)			
DEXTRATES (UNII: G263MI44RU)			
MAGNESIUM STEARATE (UNII: 70097M6I30)			
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)			
ACACIA (UNII: 5C5403N26O)			
ASPARTAME (UNII: Z0H242BBR1)			
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)			
MALTODEXTRIN (UNII: 7CVR7L4A2D)			

Product Characteristics			
Color	pink	Score	no score
Shape	ROUND	Size	16mm

Flavor	Imprint Code	RH;046
Contains		

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73408-406- 20	6 in 1 BOX	01/17/2020	11/29/2024
1		6 in 1 CELLO 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	01/17/2020	11/29/2024

Labeler - Crane Safety LLC (080998015)

Registrant - Unifirst First Aid Corporation (832947092)

Revised: 6/2022 Crane Safety LLC