

**TOPCARE STOMACH RELIEF ORIGINAL STRENGTH- bismuth
subsalicylate tablet
TopCo Associates, LLC**

Drug Facts

Active ingredient

Bismuth subsalicylate 262 mg (each tablet contains 102 mg salicylate)

Purpose

Antidiarrheal/Antacid

Uses

relieves

- travelers' 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

- an ulcer
- a bleeding problem

- bloody or black stool

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

Stop use and ask a doctor if

- symptoms get worse or last more than 2 days
- ringing in the ears or loss of hearing occurs
- diarrhea lasts more than 2 days

When using this product

a temporary, but harmless, darkening of the stool and/or tongue may occur

If pregnant or breast-feeding

ask a health professional before use.

Keep out of reach of children

In case of accidental overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Directions

- chew or dissolve in mouth

Adults and children 12 years and over: 2 tablets every ½ to 1 hour as needed

- do not exceed 16 tablets in 24 hours
- use until diarrhea stops but not more than 2 days

Children under 12 years of age: ask a doctor

- drink plenty of clear fluids to help prevent dehydration caused by diarrhea

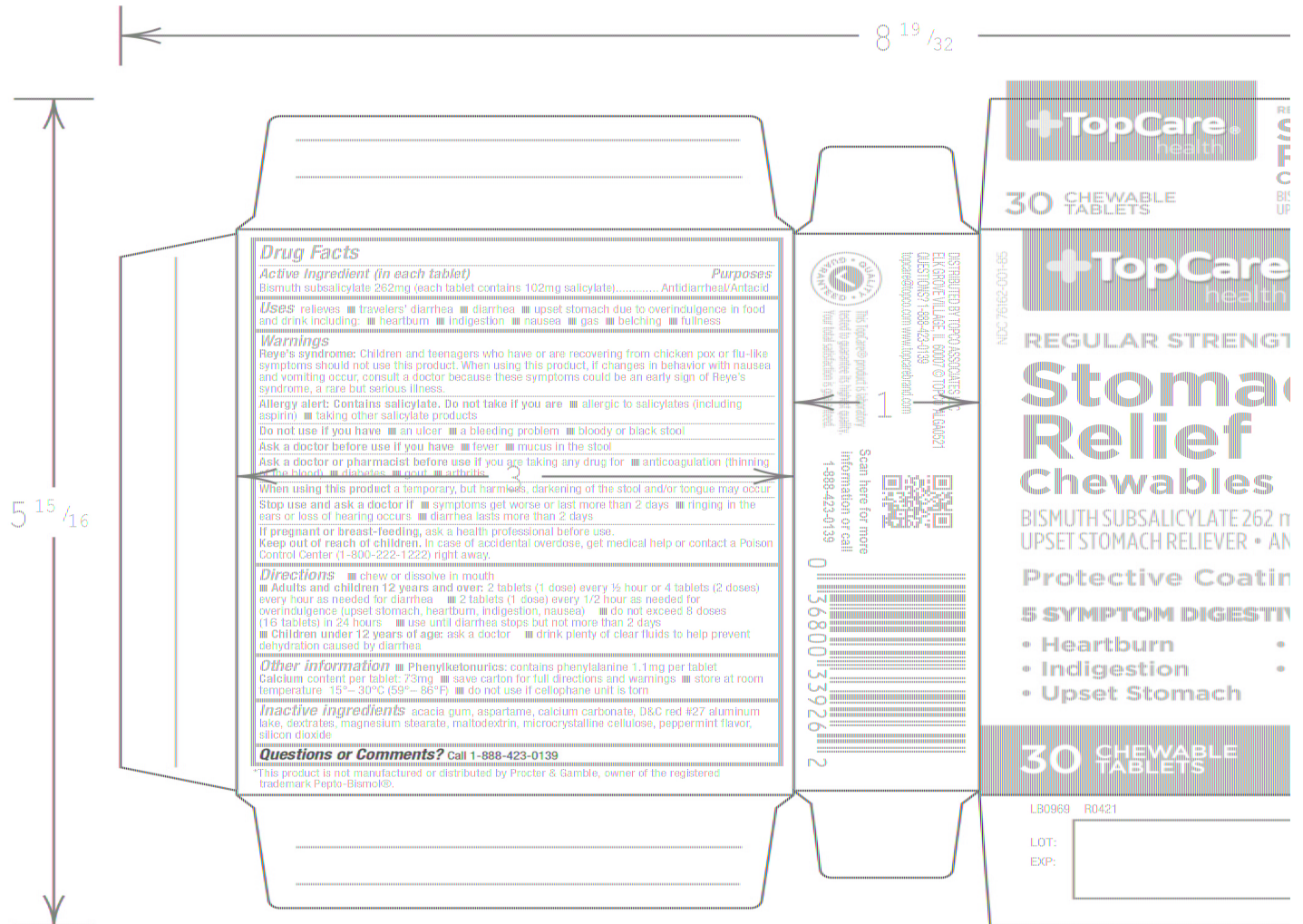
Other information

- **Phenylketonurics:** contains phenylalanine 1.1mg per tablet
- **Calcium content per tablet:** 73mg
- save carton for full directions and warnings
- store at room temperature 15°- 30°C (59°- 86°F)
- do not use if cellophane unit is torn

Inactive ingredients

acacia gum, aspartame, calcium carbonate, D&C red #27 aluminum lake, dextrans, magnesium stearate, maltodextrin, microcrystalline cellulose, peppermint flavor, silicon dioxide

Package/Label Principal Display Panel



Stomach Relief

TOPCARE STOMACH RELIEF ORIGINAL STRENGTH

bismuth subsalicylate tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76162-001
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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BISMUTH SUBSALICYLATE (UNII: 62TEY51RR1) (BISMUTH CATION - UNII:ZS9CD1I8YE)	BISMUTH SUBSALICYLATE	262 mg
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Inactive Ingredients

Ingredient Name	Strength
ACACIA (UNII: 5C5403N26O)	
ASPARTAME (UNII: Z0H242BBR1)	
CALCIUM CARBONATE (UNII: H0G9379FGK)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
DEXTRATES (UNII: G263MI44RU)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
PEPPERMINT (UNII: V95R5KMY2B)	

Product Characteristics

Color	pink	Score	no score
Shape	ROUND	Size	17mm
Flavor		Imprint Code	RH046
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76162-001-85	6 in 1 CARTON	12/23/2014	
1		5 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	12/23/2014	

Labeler - TopCo Associates, LLC (006935977)