

## **STOMACH RELIEF- bismuth subsalicylate tablet CDMA- QC**

*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.*

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### **Stomach Relief**

#### **Active ingredient(s)**

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

#### **Purpose**

Antidiarrheal/Antacid

#### **Use(s)**

- 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**

- an ulcer
- a bleeding problem
- bloody or black stool

**Ask a doctor before use if**

- 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

**Pregnancy/Breastfeeding**

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 (1 dose) every ½ hour or 4 tablets (2 doses) every hour as needed for diarrhea
- 2 tablets (1 dose) every ½ hour as needed for overindulgence (upset stomach, heartburn, indigestion, nausea)
- do not exceed 8 doses (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

Do not use if cellophane unit is torn

## Storage

Store at room temperature 15°- 30°C (59°- 86°F)

## Inactive ingredients

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

## Principal Display Panel



## Stomach Relief

### STOMACH RELIEF

bismuth subsalicylate tablet

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:63868-622	
<b>Route of Administration</b>	ORAL			
<b>Active Ingredient/Active Moiety</b>				
	<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>	
	<b>BISMUTH SUBSALICYLATE</b> (UNII: 62TEY51RR1) (BISMUTH CATION - UNII:ZS9CD1I8YE)	BISMUTH SUBSALICYLATE	262 mg	
<b>Inactive Ingredients</b>				
	<b>Ingredient Name</b>	<b>Strength</b>		
	<b>ASPARTAME</b> (UNII: Z0H242BBR1)			
	<b>ACACIA</b> (UNII: 5C5403N26O)			
	<b>CALCIUM CARBONATE</b> (UNII: H0G9379FGK)			
	<b>D&amp;C RED NO. 27</b> (UNII: 2LRS185U6K)			
	<b>DEXTRATES</b> (UNII: G263MI44RU)			
	<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)			
	<b>MALTODEXTRIN</b> (UNII: 7CVR7L4A2D)			
	<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)			
	<b>PEPPERMINT</b> (UNII: V95R5KMY2B)			
	<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)			
<b>Product Characteristics</b>				
<b>Color</b>	pink	<b>Score</b>	no score	
<b>Shape</b>	ROUND	<b>Size</b>	17mm	
<b>Flavor</b>		<b>Imprint Code</b>	RH046	
<b>Contains</b>				
<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:63868-622-30	30 in 1 CELLO PACK; Type 0: Not a Combination Product	06/16/2021	
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
OTC monograph final	part335	12/23/2014		

**Labeler** - CDMA- QC (011920774)