## EQUATE STOMACH RELIEF - bismuth subsalicylate tablet, chewable Wal-Mart Stores, 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.

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#### **Equate Stomach Relief**

#### ACTIVE INGREDIENT (in each tablet)

Bismuth subsalicylate 262 mg (total salicylate 102 mg per tablet)

#### **PURPOSE**

Upset stomach reliever and anti-diarrheal

#### USE(S)

relieves:

- diarrhea
- heartburn
- indigestion
- nausea
- upset stomach associated with these symptoms

#### **WARNINGS**

**Allergy alert:** Contains salicylate. Do not take if you are

- allergic to salicylates (including aspirin)
- taking other salicylate products

**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 behaviour 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.

#### 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 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 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 right away.

#### **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)

#### INACTIVE INGREDIENTS

calcium carbonate, D&C red 27 aluminum lake, flavor, magnesium stearate, mannitol, pregelatinized starch, saccharin sodium

#### PRINCIPAL DISPLAY PANEL

NDC 49035-122-49
equate
Compate to Pepto-Bismol Chewable Active Ingredient\*
Stomach Relief

#### Pink Bismuth Subsalicylate 262 mg Antidiarrheal/Upset Stomach Reliever

#### 5 Symptom Relief of:

- Nausea
- Heartburn
- Indigestion
- Upset stomach
- Diarrhea

#### 30 CHEWABLE TABLETS



# bismuth subsalicylate tablet, chewable Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:49035-122

ORAL

**Route of Administration** 

# Active Ingredient/Active Moiety Ingredient Name Basis of Strength BISMUTH SUBSALICYLATE (UNII: 62TEY51RR1) (SALICYLIC ACID - UNII:O414PZ4LPZ) BISMUTH SUBSALICYLATE (262 mg

Inactive Ingredients			
Ingredient Name	Strength		
CALCIUM CARBONATE (UNII: H0 G9 379 FGK)			
<b>D&amp;C RED NO. 27</b> (UNII: 2LRS185U6K)			
MAGNESIUM STEARATE (UNII: 70097M6I30)			
MANNITOL (UNII: 3OWL53L36A)			
STARCH, CORN (UNII: O8232NY3SJ)			
SACCHARIN SO DIUM (UNII: SB8 ZUX40 TY)			

Product Characteristics					
Color	PINK	Score	no score		
Shape	ROUND	Size	17mm		
Flavor		Imprint Code	GDC122		
Contains					

Packaging					
# Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>		
1 NDC:49035-122-49	5 in 1 BOX	05/01/2011			
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	05/01/2011				

### Labeler - Wal-Mart Stores, Inc. (051957769)

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