# SIGNATURE CARE UPSET STOMACH RELIEF - bis muth subsalicylate tablet Safeway

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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# Signature care Upset Stomach Relief

# **ACTIVE INGREDIENT (in each caplet)**

Bismuth subsalicylate 262 mg

#### **PURPOSE**

Upset stomach reliever and anti-diarrheal

# USE(S)

relieves:

- indigestion
- nausea
- heartburn
- diarrhea
- 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 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.

# 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 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**

- swallow caplet(s) with water, do not chew
- adults and children 12 years and over: 2 caplets every 1/2 to 1 hour as needed
- do not take more than 8 doses (16 tablets) in 24 hours
- use until diarrhea stops but not more than 2 days
- children under 12 years: ask a doctor
- drink plenty of clear fluids to help prevent dehydration caused by diarrhea

# OTHER INFORMATION

- each caplet contains: calcium 27mg, salicylate 102 mg and sodium 2 mg
- very low sodium
- TAMPER EVIDENT: do not use if printed seal under cap is torn or missing
- store at room temperature, in a dry place

# INACTIVE INGREDIENTS

calcium carbonate, colloidal silicon dioxide, D&C red 27 aluminum lake, magnesium stearate, mannitol, microcrystalline cellulose, polysorbate 80, sodium starch glycolate

# PRINCIPAL DISPLAY PANEL

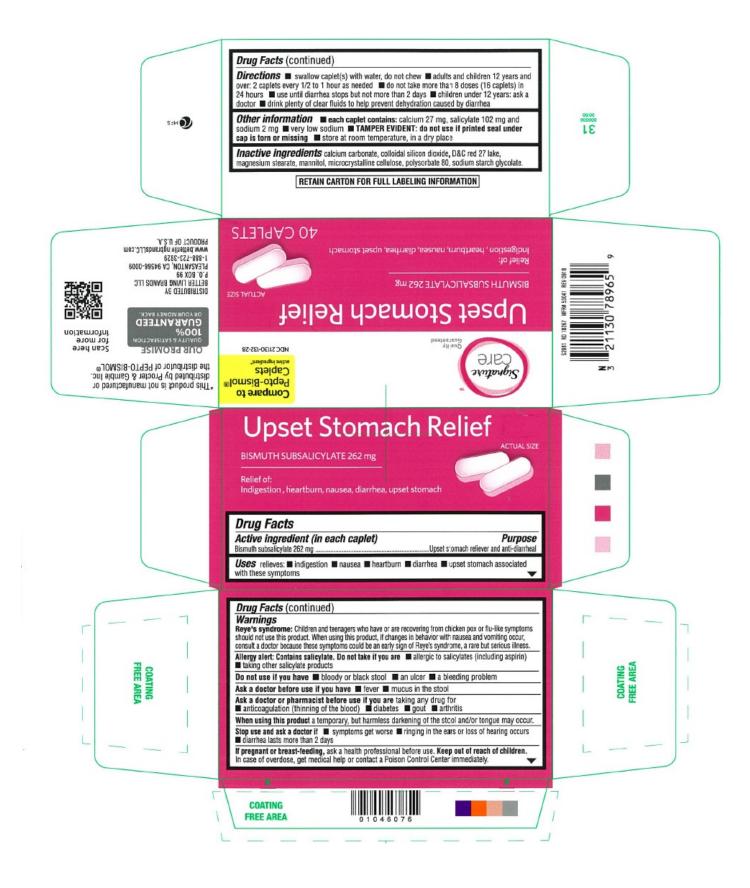
Compate to Pepto-Bismol® caplets active ingredient\* NDC 21130-132-28
Signature care
Upset Stomach Relief

# BISMUTH SUBSALICYLATE 262 mg

Relief of::

indigestion, heartburn, nausea, diarrhea, upset stomach

40 CAPLETS



# SIGNATURE CARE UPSET STOMACH RELIEF

bismuth subsalicylate tablet

#### **Product Information**

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:21130-132
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
<b>BISMUTH SUBSALICYLATE</b> (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: 30WL53L36A)		
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)		
CELLULOSE, MICRO CRYSTALLINE (UNII: OP1R32D61U)		
POLYSORBATE 80 (UNII: 6OZP39ZG8H)		
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)		

Product Characteristics			
Color	PINK	Score	no score
Shape	CAPSULE	Size	16 mm
Flavor		Imprint Code	GDC172
Contains			

]	Packaging			
7	# Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date
:	NDC:21130-132-28	1 in 1 CARTON	10/24/2018	
		40 in 1 BOTTLE; 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	10/24/2018	

# **Labeler -** Safeway (009137209)

Revised: 10/2018 Safeway