

SIGNATURE CARE UPSET STOMACH RELIEF - bismuth 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.

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

Compare 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

Route of Administration ORAL

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
CALCIUM CARBONATE (UNII: H0G9379FGK)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 3OWL53L36A)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21130-132-28	1 in 1 CARTON	10/24/2018	
1		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)