

SOOTHE- bismuth subsalicylate tablet
Walgreen Company

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.

Walgreens 44-346

Active ingredient (in each caplet)

Bismuth subsalicylate 262 mg

Purpose

Upset stomach reliever/antidiarrheal

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 the blood)
- gout
- diabetes
- 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

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 (1-800-222-1222) right away.

Directions

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

Other information

- **each caplet contains:** calcium 20 mg, salicylate 103 mg
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- avoid excessive heat
- see end flap for expiration date and lot number

Inactive ingredients

calcium carbonate, corn starch, D&C red #27 aluminum lake, D&C red #30 aluminum lake, magnesium stearate, mannitol, microcrystalline cellulose, povidone, silicon dioxide, sodium starch glycolate, stearic acid

Questions or comments?

1-800-426-9391

Principal Display Panel

Well at

Walgreens

WALGREENS PHARMACIST RECOMMENDED

NDC 0363-0346-10

Soothe[®]

Bismuth Subsalicylate 262 mg

Upset Stomach Reliever / Antidiarrheal

Multi-symptom relief of:

- Nausea • Heartburn
- Indigestion
- Upset stomach
- Diarrhea

40 CAPLETS

Actual Size

Compare to Pepto-Bismol[®] active ingredient^{□□}[□]Walgreens Pharmacist Survey Study, November 2014.^{□□}This product is not manufactured or distributed by Procter & Gamble, owner of the registered trademark Pepto-Bismol[®].

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200 WILMOT RD., DEERFIELD, IL 60015

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BROKEN OR MISSING**



Walgreens 44-346

SOOTHE

bismuth subsalicylate tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0363-0346
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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BISMUTH SUBSALICYLATE (UNII: 62TEY51RR1) (SALICYLIC ACID - UNII:O414PZ4LPZ)	BISMUTH SUBSALICYLATE	262 mg
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Inactive Ingredients	
Ingredient Name	Strength
D&C RED NO. 27 (UNII: 2LRS185U6K)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
CALCIUM CARBONATE (UNII: H0G9379FGK)	
MANNITOL (UNII: 3OWL53L36A)	

Product Characteristics			
Color	PINK	Score	no score
Shape	OVAL	Size	16 mm
Flavor		Imprint Code	44;346
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-0346-10	1 in 1 CARTON	05/06/2011	
1		40 in 1 BOTTLE, PLASTIC; 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	05/06/2011	

Labeler - Walgreen Company (008965063)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	MANUFACTURE(0363-0346)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(0363-0346)