STOMACH RELIEF- bismuth subsalicylate tablet 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.

Equate 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:
 - belching
 - indigestion
 - gas
 - fullness
 - heartburn
 - nausea

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)
- 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

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 ½ 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?

1-888-287-1915

Principal display panel

equate™

NDC 49035-346-10

Compare to

Pepto-Bismol® active ingredient*

Stomach Relief Bismuth Subsalicylate 262 mg

Upset Stomach Reliever/ Antidiarrheal

Relieves:

- Nausea
- Heartburn
- Indigestion
- Upset Stomach
- Diarrhea

262 mg EACH

40 CAPLETS

Actual Size

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

Satisfaction guaranteed - Or we'll replace it or give you your money back. For questions or comments please call **1-888-287-1915.**

DISTRIBUTED BY: Walmart Inc., Bentonville, AR 72716

PRODUCT OF GERMANY AND MEXICO

*This product is not manufactured or distributed by Procter & Gamble, owner of the registered trademark Pepto-Bismol®. 50844 ORG101634610



Equate 44-346

STOMACH RELIEF					
bismuth subsalicylate tablet					
Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Source)		NDC:49035-3	46
Route of Administration	ORAL				
Active Ingredient/Active Moi	ety				
1	ngredient Name		Basis	of Strength	Strength

Inactive Ingredients

Ingredient Name	Strength
D&C RED NO. 27 ALUMINUM LAKE (UNII: ZK64F7XSTX)	
D&C RED NO.30 (UNII: 2S42T2808B)	
CALCIUM CARBONATE (UNII: H0 G9 379 FGK)	
MANNITOL (UNII: 30WL53L36A)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STARCH, CORN (UNII: O8232NY3SJ)	

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:49035-346- 10	1 in 1 CARTON	07/30/2019			
1	40 in 1 BOTTLE, PLASTIC; Type 0: Not a Combinatio Product	n			
Marketing Information					
Marketing Cate	gory Application Number or Monograph Cita	tion Marketing Start Date	Marketing End Date		

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part335	07/30/2019	

Labeler - Wal-Mart Stores Inc (051957769)

Establishment					
Name	Address	ID/FEI	Business Operations		
LNK International, Inc.		038154464	PACK(49035-346)		
Establishment					
Name	Address	ID/FEI	Business Operations		

LNK International, Inc.	832867894	MANUFACTURE(49035-346)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	PACK(49035-346)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	PACK(49035-346)

Revised: 5/2020

Wal-Mart Stores Inc