STOMACH RELIEF- bismuth subsalicylate tablet CHAIN DRUG MARKETING ASSOCIATION INC

Quality Choice 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

- diabetes
- arthritis
- anticoagulation (thinning the blood)
- gout

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 right away.

Directions

- do not take more than directed
- 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.
- do not use for more than 2 days unless directed by a doctor
- 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

QC® QUALITY CHOICE

NDC 63868-691-40

*Compare to the Active Ingredient in Pepto-Bismol®

Stomach Relief Bismuth Subsalicylate 262 mg Upset Stomach Reliever/Antidiarrheal

Relieves Nausea, Heartburn, Indigestion, Upset Stomach, Diarrhea

actual size

40 Caplets

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

*This product is not manufactured or distributed by The Procter & Gamble Company, owner of the registered trademark Pepto-Bismol®. 50844 REV0521A34610

SATISFACTION GUARANTEED 100% **QC**

Distributed by C.D.M.A., Inc.© 43157 W 9 Mile Rd Novi, MI 48375 www.qualitychoice.com Questions: 800-935-2362



Quality Choice 44-346

STOMACH RELIEF bismuth subsalicylate tablet **Product Information HUMAN OTC DRUG Product Type** Item Code (Source) NDC:63868-691 **ORAL Route of Administration** Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BISMUTH SUBSALICYLATE (UNII: 62TEY51RR1) (SALICYLIC ACID - UNII:O414PZ4LPZ, BISMUTH CATION - UNII:ZS9CD1I8YE)	BISMUTH SUBSALICYLATE	262 mg

Inactive Ingredients	
Ingredient Name	Strength
CALCIUM CARBONATE (UNII: H0G9379FGK)	
STARCH, CORN (UNII: O8232NY3SJ)	
D&C RED NO. 27 ALUMINUM LAKE (UNII: ZK64F7XSTX)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 30WL53L36A)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

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

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:63868- 691-40	1 in 1 CARTON	03/31/2021			
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 Drug	M008	03/31/2021			

Labeler - CHAIN DRUG MARKETING ASSOCIATION INC (011920774)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	pack(63868-691)
LINK IIIterriational, IIIC.		030134404	pack(03000-091)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(63868-691)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		117025878	manufacture(63868-691)

Revised: 9/2023 CHAIN DRUG MARKETING ASSOCIATION INC