

STOMACH RELIEF- bismuth subsalicylate tablet, chewable
Harmon Store 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.

Core Values 44-319

Active ingredient (in each chewable tablet)

Bismuth subsalicylate 262 mg

Purpose

Upset stomach reliever/antidiarrheal

Uses

relieves:

- diarrhea
- traveler's diarrhea
- upset stomach due to overindulgence in food and drink, including:
 - indigestion
 - nausea
 - heartburn
 - belching
 - fullness
- gas

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 product

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

- diarrhea lasts more than 2 days
- ringing in the ears or loss of hearing occurs
- symptoms get worse

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

- chew or crush tablets completely before swallowing; do not swallow tablets whole
- drink plenty of clear fluids to help prevent dehydration caused by diarrhea
- adults and children 12 years and over: 2 chewable tablets every 1/2 to 1 hour as needed. Do not exceed 16 chewable tablets 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 tablet contains:** calcium 40 mg, salicylate 102 mg
- **TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF CELLOPHANE UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING**
- see end flap for expiration date and lot number
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- avoid excessive heat
- store in a dry place

Inactive ingredients

calcium carbonate, cherry flavor, D&C red #27 aluminum lake, D&C red #30 aluminum lake, FD&C red #40 aluminum lake, magnesium stearate, mannitol, povidone, saccharin sodium, stearic acid, talc

Questions or comments?

1-800-426-9391

Principal Display Panel

CORE VALUES™

Compare to active ingredient in Pepto-Bismol®†

Stomach Relief

Bismuth subsalicylate 262 mg

Chewable Tablets

Upset Stomach Reliever/

Antidiarrheal

Relieves:

- Nausea
- Heartburn
- Indigestion
- Upset Stomach
- Diarrhea

Actual Size

Chew or crush tablets completely before swallowing.

Do not swallow tablets whole.

30 chewable tablets cherry flavor

TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF CELLOPHANE UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING

Distributed by: Liberty Procurement, Inc.,

650 Liberty Ave., Union, NJ 07083 U.S.A

Satisfaction Guaranteed Or Your Money Back

Visit us at www.facevalues.com

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

50844 REV0119A31901

CORE VALUES™
Stomach Relief

Drug Facts KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

Active ingredient (in each chewable tablet) Purpose
Bismuth subsalicylate 262 mgUpset stomach reliever/antidiarrheal

Uses relieves ■ diarrhea ■ travelers' diarrhea
■ upset stomach due to overindulgence in food and drink, including:
■ indigestion ■ nausea ■ heartburn ■ belching ■ fullness ■ gas

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 ■ diarrhea lasts more than 2 days
■ ringing in the ears or loss of hearing occurs ■ symptoms get worse

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
■ chew or crush tablets completely before swallowing; do not swallow tablets whole
■ drink plenty of clear fluids to help prevent dehydration caused by diarrhea
■ adults and children 12 years and over: 2 chewable tablets every 1/2 to 1 hour as needed. Do not exceed 16 chewable tablets 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 tablet contains: calcium 40 mg, salicylate 102 mg
■ TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF CELLOPHANE UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING

Drug Facts (continued)
red #27 aluminum lake, D&C red #30 aluminum lake, FD&C red #40 aluminum lake, magnesium stearate, mannitol, povidone, saccharin sodium, stearic acid, talc

Questions or comments? 1-800-426-9391

Drug Facts (continued)
■ store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F) ■ see end flap for expiration date and lot number
■ avoid excessive heat ■ store in a dry place

Inactive ingredients calcium carbonate, cherry flavor, D&C

CORE VALUES™ Compare to active ingredient in Pepto-Bismol®†

Stomach Relief

Bismuth subsalicylate 262 mg
Chewable Tablets
Upset Stomach Reliever/
Antidiarrheal

- Relieves:
- Nausea
 - Heartburn
 - Indigestion
 - Upset Stomach
 - Diarrhea



Actual Size

Chew or crush tablets completely before swallowing. Do not swallow tablets whole.

30 chewable tablets cherry flavor

†This product is not manufactured or distributed by Procter & Gamble, owner of the registered trademark Pepto-Bismol®. 50844 REV0119A31901

TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF CELLOPHANE UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING

Distributed by: Liberty Procurement, Inc.,
650 Liberty Ave., Union, NJ 07083 U.S.A.
Satisfaction Guaranteed Or Your Money Back
Visit us at www.facevalues.com

B-0112-319-01
REV0119A31901

No Print/No Varnish Area
Lot no. & Exp. date



Core Values 44-319

STOMACH RELIEF

bismuth subsalicylate tablet, chewable

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63940-319
Route of Administration	ORAL		

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)	

D&C RED NO. 27 (UNII: 2LRS185U6K)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 3OWL53L36A)	
POVIDONE (UNII: FZ989GH94E)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics

Color	PINK	Score	no score
Shape	ROUND	Size	16mm
Flavor	CHERRY	Imprint Code	44;319
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63940-319-01	5 in 1 CARTON	07/16/1998	
1		6 in 1 POUCH; 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	07/16/1998	

Labeler - Harmon Store Inc. (804085293)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(63940-319)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	MANUFACTURE(63940-319)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	PACK(63940-319)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	PACK(63940-319)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	PACK(63940-319)

Revised: 3/2020

Harmon Store Inc.