

## **STOMACH RELIEF- bismuth subsalicylate tablet**

### **HEB**

*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.*

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### **HEB 44-346**

#### ***Active ingredient (in each caplet)***

Bismuth subsalicylate 262 mg

#### ***Purpose***

Upset stomach reliever/antidiarrheal

#### ***Uses***

relieves:

- traveler's 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)
- 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 or last more than 2 days
- 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***

**Compare to *Pepto-Bismol*<sup>®</sup> active ingredient\***

NDC 37808-346-08

**H-E-B<sup>®</sup>**

## **STOMACH RELIEF**

Bismuth subsalicylate 262 mg

Upset Stomach Reliever/Antidiarrheal

### **Relief of:**

- **Heartburn**
- **Upset Stomach**
- **Indigestion**
- **Nausea**
- **Diarrhea**

### **Multi-Symptom Relief**

**24 CAPLETS**

actual size

**MADE WITH PRIDE AND CARE FOR  
H-E-B<sup>®</sup>, SAN ANTONIO, TX 78204**

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

\*This product is not manufactured or distributed by Procter & Gamble, owner of the registered trademark Pepto-Bismol<sup>®</sup>.

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44-346

## STOMACH RELIEF

bismuth subsalicylate tablet

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37808-346
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
D&C RED NO. 27 (UNII: 2LRS185U6K)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
CALCIUM CARBONATE (UNII: H0G9379FGK)	
MANNITOL (UNII: 3OWL53L36A)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POVIDONE (UNII: FZ989GH94E)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

**Product Characteristics**

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

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37808-346-08	1 in 1 CARTON	05/06/2011	
1		24 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** - HEB (007924756)**Establishment**

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(37808-346)

<b>Establishment</b>			
<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
LNK International, Inc.		832867894	MANUFACTURE(37808-346)

<b>Establishment</b>			
<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
LNK International, Inc.		967626305	PACK(37808-346)

<b>Establishment</b>			
<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
LNK International, Inc.		868734088	PACK(37808-346)

Revised: 7/2019

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