SOOTHE- bismuth subsalicylate tablet, chewable
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 44-319-Delisted

Active ingredient (in each tablet)

Bismuth subsalicylate 262 mg

Purpose

Upset 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
- ringing in the ears or loss of hearing occurs
- symptoms get worse or last more than 2 days
- 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
- chew or dissolve in mouth
- drink plenty of clear fluids to help prevent dehydration caused by diarrhea
- adults and children 12 years and over: 2 tablets every 1/2 to 1 hour as needed. Do not exceed 8 doses (16 tablets) in 24 hours.
- 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 25ºC (77ºF); 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

Walgreens

Compare to Pepto-Bismol®
active ingredient††

NDC 0363-0319-01

Soothe®
BISMUTH SUBSALICYLATE, 262 mg /
UPSET STOMACH RELIEVER / ANTI-DIARRHEAL

CHEWABLE

• Multi-symptom relief of nausea,
heartburn, indigestion,
upset stomach & diarrhea

NEW
LOOK
SAME GREAT
QUALITY

30
CHEWABLE
TABLETS

Actual Size

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

Walgreens Pharmacist Recommended
Walgreens Pharmacist Survey
††This product is not manufactured or distributed by
Procter & Gamble, owner of the registered trademark
Pepto-Bismol®.
50844 ORG021531901

DISTRIBUTED BY: WALGREEN CO.
200 WILMOT RD., DEERFIELD, IL 60015
walgreens
100% SATISFACTION
GUARANTEED

Walgreens 44-319

SOOTHE

bismuth subsalicylate tablet, chewable

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0363-0319
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 ALUMINUM LAKE (UNII: ZK64F7XSTX)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 3OWL53L36A)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	

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:0363-0319-01	5 in 1 CARTON	07/16/1998	05/15/2023
1		6 in 1 BLISTER PACK; 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	05/15/2023

Labeler - Walgreen Company (008965063)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	MANUFACTURE(0363-0319)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(0363-0319)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	PACK(0363-0319)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	PACK(0363-0319)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	PACK(0363-0319)

Revised: 5/2020

Walgreen Company