BISMUTH SUBSALICYLATE- bismuth subsalicylate liquid
Lohxa

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.

Bismuth Subsalicylate

Active ingredient (in each 15 mL tbsp)

Bismuth subsalicylate 262 mg

Purpose

Upset stomach reliever and anti-diarrheal

Uses

relieves:

- diarrhea
- heartburn
- indigestion
- nausea
- upset stomach associated with these symptoms

Warnings

Reye's syndrome: Children and teenagers who have or are recovering from children 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

- bloody or black stool
- an ulcer
- a bleeding problem

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 of 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 immediately.

Directions

- shake well before use
- for accurate dosing, use dose cup
- adults and children 12 years and over: 1 dose (2 tbsp or 30 mL) every 1/2 to 1 hour as needed
- do not exceed 8 doses (16 tbsp or 240 mL) in 24 hours
- use until diarrhea stops but not more than 2 days
- children under 12 years: ask a doctor
- drink plenty of clear fluids to help prevent dehydration caused by diarrhea

Other information

- each Tbsp contains: sodium 5 mg, salicylate 130 mg, potassium 15 mg
- protect from freezing
- avoid excessive heat (over 104 ^{o}F or 40 ^{o}C)
- **FOR INSTITUTIONAL USE ONLY**

Inactive ingredients

benzoic acid, D and C red 22, D and C red 28, flavor, hydroxy ethyl cellulose, potassium hydroxide, purified water, saccharin sodium, salicylic acid, simethicone, xanthan gum.

Principal Display Panel

NDC 70166-059-01

OTC

BISMUTH SUBSALICYLATE

ORAL SUSPENSION

FOR ORAL USE ONLY

262 mg/ 15 mL

SHAKE WELL BEFORE USE

50 UNITS x 15mL

BISMUTH SUBSALICYLATE

ORAL SUSPENSION

262mg/15mL

3 70166 05901 4

LOT:

EXP:

Each 15mL contains:
Bismuth Subsalicylate 262mg
Store at Controlled Room Temperature 20 to 25 °C (68 to 77°F) [See USP Controlled Room Temperature].
See insert for dosage and administration. For Institutional Use.

Repackaged by:
Lohxa
Worcester, MA 01608 U.S.A

Lohxa

BISMUTH SUBSALICYLATE

bismuth subsalicylate liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:70166-059(NDC:0904-1313)
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BISMUTH SUBSALICYLATE (UNII: 62TEY51RR1) (BISMUTH CATION - UNII:ZS9CD1I8YE)	BISMUTH SUBSALICYLATE	262 mg in 15 mL

Inactive Ingredients	
Ingredient Name	**Strength**
BENZOIC ACID (UNII: 8SKN0B0MIM)	
D&C RED NO. 22 (UNII: 1678RKX8RT)	
D&C RED NO. 28 (UNII: 767IP0Y5NH)	
HYDROXYETHYL CELLULOSE (2000 CPS AT 1%) (UNII: S38J6RZN16)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SALICYLIC ACID (UNII: O414PZ4LPZ)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics			
Color	pink	**Score**	
Shape		**Size**	
Flavor	WINTERGREEN	**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:70166-059-01	50 in 1 CARTON	12/03/2018	11/20/2020
1		15 mL in 1 CUP, UNIT-DOSE; 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	05/30/2008	

Labeler - Lohxa (079872715)

Revised: 2/2021 Lohxa