BISMATROL - bismuth subsalicylate liquid
ATLANTIC BIOLOGICALS CORP.

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.

Bismatrol

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

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. Reye's syndrome:

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 aretaking 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 F or 40 C) ^{oo}
- . **TAMPER EVIDENT:Do not use if imprinted shrinkband is missing or broken**

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.

BISMATROL (BISMUTH SUBSALICYLATE) LIQUID

17856-1313-03
BISMUTH SUBSALICYLATE (BISMATROL) ORAL SUSPENSION

UDOSE

See package insert for indications and dosage schedule

17856131303

Protect from freezing. Avoid excessive heat (over 104°F or 40°C).* SHAKE WELL BEFORE USE*
KEEP OUT OF THE REACH OF CHILDREN

17856-1313-03 **Dosage: 525 MG/30 ML**

BISMATROL **Qty: 50 Cups**

GTIN: 00117856131335
S/N: 00818600000001
Exp: 03/30/20
Lot: 008186

OTC

Packaged by: Unit Dose Solutions
Morrisville, NC 27560

Distributed by: AtlanticBiologicals Corp,
Miami Fl 33179

Rev.09/19

Call to Reorder: 800.509.7592

BISMATROL

bismuth subsalicylate liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:17856-1313(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:17856-1313-1	15 mL in 1 CUP; Type 0: Not a Combination Product	01/13/2021	
2	NDC:17856-1313-3	30 mL in 1 CUP; Type 0: Not a Combination Product	01/13/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part335	05/30/2008	

Labeler - ATLANTIC BIOLOGICALS CORP. (047437707)

Establishment

Name	Address	ID/FEI	Business Operations
ATLANTIC BIOLOGICALS CORP.		047437707	RELABEL(17856-1313) , REPACK(17856-1313)

Revised: 1/2021 ATLANTIC BIOLOGICALS CORP.