

**BISMATROL- bismuth subsalicylate liquid**  
**Aidarex Pharmaceuticals LLC**

*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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**Bismatrol**

**Active ingredient (in each 15 mL tbs p)**

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°F or 40°C)
- **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.

Repackaged By :

Aidarex Pharmaceuticals LLC,  
Corona, CA 92880

## Principal Display Panel

Bismatrol

soothing, coating action provides

fast relief for heartburn, indigestion, nausea, upset stomach and diarrhea

compare to the active ingredient in pepto-bismol<sup>®</sup>

8 FL OZ (236 mL)

CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION. SEE PACKAGE INSERT. KEEP OUT OF REACH OF CHILDREN. STORE AT CONTROLLED ROOM TEMP. 15-30C (59-86F)

Packaged and Distributed by: **AIDAREX PHARMACEUTICALS LLC.**

**BISMATROL**

**262mg/15ml**

**8 OZ**

EACH 15 ML CONTAINS THE FOLLOWING ACTIVE INGREDIENTS:  
 BISMUTH  
 SUBSALICYLATE.....262mg

**SUSPENSION**

GENERIC FOR : PEPTO-BISMOL  
 NDC: 53217-0060-01

TAKE \_\_\_ Tbsp \_\_\_ TIMES DAILY  
 TO ME \_\_\_ Tbsp \_\_\_ VEGES AL DIA

MFG: FOR: MAJOR PHARMACEUTICALS LIVONIA, MI 48150

BISMATROL 262mg/15ml  
 NDC: 53217-0060-01  
 RX QLS0000 8 OZ

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 RX QLS0000 8 OZ

BISMATROL 262mg/15ml  
 NDC: 53217-0060-01  
 RX QLS0000 8 OZ

PATIENT  
 LOG  
 CIPART  
 PREP. THERP.  
 PREP. THERP.

**KEEP OUT OF REACH OF CHILDREN SECTION**  
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## BISMATROL

bismuth subsalicylate liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:53217-060(NDC:0904-1313)
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>BISMUTH SUBSALICYLATE</b> (UNII: 62TEY51RR1) (BISMUTH CATION - UNII:ZS9CD118YE)	BISMUTH SUBSALICYLATE	262 mg in 15 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>BENZOIC ACID</b> (UNII: 8SKN0B0MIM)	
<b>D&amp;C RED NO. 22</b> (UNII: 1678RKX8RT)	
<b>D&amp;C RED NO. 28</b> (UNII: 767IP0Y5NH)	
<b>HYDROXYETHYL CELLULOSE (2000 MPAS AT 1%)</b> (UNII: S38J6RZN16)	
<b>POTASSIUM HYDROXIDE</b> (UNII: WZH3C48M4T)	
<b>WATER</b> (UNII: 059QF0K00R)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>SALICYLIC ACID</b> (UNII: O414PZ4LPZ)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	

## Product Characteristics

<b>Color</b>	PINK	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	WINTERGREEN	<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53217-060-01	236 mL in 1 BOTTLE, PLASTIC		

## Marketing Information

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

**Labeler** - Aidarex Pharmaceuticals LLC (801503249)

Revised: 12/2013

Aidarex Pharmaceuticals LLC