

**BISMATROL- bismuth subsalicylate tablet, chewable**  
**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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**Major Bismatrol Chewable Tablets**

**Active ingredient (in each tablet)**

Bismuth subsalicylate 262 mg  
(total salicylate 102 mg per tablet)

**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 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**

- bloody or black stools
- 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**

- chew or dissolve in mouth
- adults and children 12 years and over: 2 tablets every 1/2 to 1 hour as needed
- do not take more than 8 doses (16 tablets) in 24 hours
- children under 12 years: ask a doctor
- drink plenty of fluids to help prevent dehydration which may accompany diarrhea.

### **Other information: each tablet contains:**

- sodium less than 1 mg
- salicylate 102 mg
- calcium 140 mg
- very low sodium
- avoid excessive heat (over 104°F or 40°C)
- **TAMPER EVIDENT: Do not use if individual compartments are torn or missing.**

### **Inactive ingredients**

calcium carbonate, D and C red 27 aluminum lake, flavor, magnesium stearate, mannitol, pregelatinized starch, saccharin sodium.

### **Principal Display Panel**

Bismatrol Chewable Tablets

soothing, coating action provides fast relief for heartburn, indigestion, nausea, upset stomach and diarrhea

compare to the active ingredient in Pepto-Bismol®

30 chewable tablets

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

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

**BISMATROL CHEW.**

**262mg**

**30 / BOX**

GENERIC FOR : PEPTO-BISMOL

NDC: 53217-0058-01

MFG: FOR: MAJOR PHARMACEUTICALS LIVONIA, MI 48150

EACH TABLET CONTAINS THE FOLLOWING ACTIVE INGREDIENTS:  
 BISMUTH  
 SUBSALICYLATE.....262mg  
 (SALICYLATE 102MG)  
 CHEWABLE

TABLET

TAKE \_\_\_\_\_ EVERY \_\_\_\_\_ HOURS \_\_\_\_\_ TIMES A DAY  
 TOMÉ \_\_\_\_\_ CADA \_\_\_\_\_ HORAS \_\_\_\_\_ VECES AL DÍA

BISMATROL CHEW. 262mg  
 NDC: 53217-0058-01  
 RX QLS0000 30 / BOX

BISMATROL CHEW. 262mg  
 NDC: 53217-0058-01  
 RXQLS0000 30 / BOX

BISMATROL CHEW. 262mg  
 NDC: 53217-0058-01  
 RXQLS0000 30 / BOX

RX QLS0000

PEEL HERE  
 PATIENT LOG  
 CHART  
 PEEL HERE

Repackaged By :  
 Aidarex Pharmaceuticals LLC,  
 Corona, CA 92880

## BISMATROL

bismuth subsalicylate tablet, chewable

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:53217-058(NDC:0904-1315)
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BISMUTH SUBSALICYLATE (UNII: 62TEY51RR1) (BISMUTH CATION - UNII:ZS9CD118YE)	BISMUTH SUBSALICYLATE	262 mg

### Inactive Ingredients

Ingredient Name	Strength
CALCIUM CARBONATE (UNII: H0G9379FGK)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 3OWL53L36A)	
STARCH, CORN (UNII: O8232NY3SJ)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	

### Product Characteristics

<b>Color</b>	PINK	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	17mm
<b>Flavor</b>		<b>Imprint Code</b>	GDC122

**Contains****Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53217-058-01	30 in 1 BLISTER PACK		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part335	01/03/2003	

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

Revised: 12/2013

Aidarex Pharmaceuticals LLC