

**BISMATROL- bismuth subsalicylate tablet, chewable**  
**Preferred Pharmaceuticals Inc.**

*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.

**Keep Out of Reach of Children**

**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 caused by diarrhea.

**Other information:**

**each tablet contains:**

- sodium less than 1 mg
- salicylate 102 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&C red 27 aluminum lake, flavor, magnesium stearate, mannitol, pregelatinized starch, saccharin sodium.

## Principal Display Panel

MAJOR

NDC 68788-7140-3

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®

**Relabeled By: Preferred Pharmaceuticals Inc.**

30 chewable tablets


**Bismatrol  
Chewable Tablets**

Generic for: Pepto-Bismol


Active ingredient (in each tablet): Bismuth subsalicylate 262mg (each tablet contains 102 mg salicylate)

**Pkg Size:** Exp Date:  
Lot#: Ins:  
Batch#: Ins:  
Mfg: Major Pharm., Livonia, MI  
Prod#: Warning

Soothing, coating action provides fast relief for heartburn, indigestion, nausea, upset stomach and diarrhea, 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. Allergy alert: Contains salicylate. Do not take if you are allergic to salicylates (including aspirin) or taking other salicylate products. Do not use if you have bloody or black stools, an ulcer, a bleeding problem. Ask a doctor or pharmacist before use if you are taking any drug for anticoagulation (thinning of the blood), diabetes, gout, arthritis or if you have a fever, muscle in the stool. When using this product, a temporary, but harmless, darkening of the stool and/or tongue may occur.



Asheville, CA 92007



Bismatrol Chewable Tablets  
Qty: Ins:  
Lot#: Bat#:  
Prod# (NDC):

Bismatrol Chewable Tablets  
Qty: Ins:  
Lot#: Bat#:  
Prod# (NDC):

Bismatrol Chewable Tablets  
Qty: Ins:  
Insurance NDC:  
Lot#: Bat#:

Bismatrol Chewable Tablets  
Qty: Ins:  
Lot#: Bat#:  
Prod# (NDC):

**Directions English**

Take \_\_\_ tablet(s)  
every \_\_\_ hours.

**Instrucciones Espanol:**

Toma \_\_\_ tableta(s)  
cada \_\_\_ horas.

Log

Chart

Billing

Patient

## BISMATROL

bismuth subsalicylate tablet, chewable

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68788-7140(NDC:0904-1315)
<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:ZS9CD1I8YE)	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

Color	pink	Score	no score
Shape	ROUND	Size	17mm
Flavor		Imprint Code	GDC122
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68788-7140-3	5 in 1 CARTON	04/19/2018	
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	04/19/2018	

**Labeler** - Preferred Pharmaceuticals Inc. (791119022)

**Registrant** - Preferred Pharmaceuticals Inc. (791119022)

## Establishment

Name	Address	ID/FEI	Business Operations
Preferred Pharmaceuticals Inc.		791119022	RELABEL(68788-7140)

Revised: 4/2023

Preferred Pharmaceuticals Inc.