

**MAJOR BISMUTH SUBSALICYLATE- bismuth subsalicylate tablet, chewable**  
**Preferred Pharmaceuticals Inc.**

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**Major Bismuth Subsalsicylate**

**ACTIVE INGREDIENT(in each tablet)**

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

**PURPOSE**

Upset stomach reliever and anti-diarrheal

**USE(S)**

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 behaviour 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 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 (1-800-222-1222) 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 clear fluids to help prevent dehydration caused 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 on open.**

## INACTIVE INGREDIENTS

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

## PRINCIPAL DISPLAY PANEL

MAJOR

NDC 68788-8239-3

\*Compare to the active ingredient in Pepto-Bismol®

**Bismuth Subsalicylate 262 mg**

Upset Stomach Reliever / Anti-diarrheal

Soothing, coating action provides fast relief for

heartburn, indigestion

nausea, upset stomach

and diarrhea

30 Chewable Tablets

**Relabeled By: Preferred Pharmaceuticals Inc.**

<p align="center"><b>Bismuth Subsalicylate Tablets 262mg</b></p> <p align="center">Generic for Pepto-Bismol</p> <p>Active ingredient (in each tablet): Bismuth subsalicylate 262mg .. Anti-Diarrheal, Upset Stomach Reliever</p> <p><b>Pkg Size:</b> Exp Date: #####/####/#### Lot#: _____ Batch#: _____ Ins: _____ Mfg: Major Pharm.; Livonia, MI Prod#: _____</p> <p><b>Warning</b> Avoid excessive heat (over 104°F or 40°C). Reye's syndrome: Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. Allergy alert: Contains salicylate. Do not take if you are allergic to salicylates (including aspirin) or taking other salicylate products. When using this product a temporary, but harmless darkening of the stool and/or tongue may occur. See package for complete drug information usage. Tablet is round, pink, and imprinted with G122</p>	  <p>Directions English Take ___ tablet(s) every ___ hours.</p>	 <p>GTIN ##### SN ##### EXP #####</p>	<p>CAUTION: Federal law PROHIBITS transfer of this drug to any person other than the patient for whom it was prescribed.</p>	<p>Bismuth Subsalicylate Tablets 262 mg Qty: Ins: Lot: Bat: Prod# (NDC):</p>	Log
				<p>Bismuth Subsalicylate Tablets 262 mg Qty: Ins: Lot: Bat: Prod# (NDC):</p>	Chart
				<p>Bismuth Subsalicylate Tablets 262 mg Qty: Insurance NDC: Lot: Bat:</p>	Billing
				<p>Bismuth Subsalicylate Tablets 262 mg Qty: Ins: Lot: Bat: Prod# (NDC):</p>	Patient

<b>MAJOR BISMUTH SUBSALICYLATE</b> bismuth subsalicylate tablet, chewable			
Product Information			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68788-8239(NDC:0904-7205)
<b>Route of Administration</b>	ORAL		

Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
BISMUTH SUBSALICYLATE (UNII: 62TEY51RR1) (SALICYLIC ACID - UNII:O414PZ4LPZ)		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	16mm	
Flavor		Imprint Code	G122	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68788-8239-3	5 in 1 BOX	02/07/2025	
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 Drug	M008	10/11/2021		

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

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

### Establishment

Name	Address	ID/FEI	Business Operations
Preferred Pharmaceuticals Inc.		791119022	RELABEL(68788-8239)