

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

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**Major Bismuth Subsalicylate**

**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.**

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## 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

**Relabeled By: Preferred Pharmaceuticals Inc.**

30 Chewable Tablets

<p><b>Bismuth Subsalicylate Tablets 262mg</b></p> <p>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><b>PREFERRED</b> Pharmaceuticals, Inc.     Anaheim, CA 92807</p> <p><b>Directions English</b> Take ___ tablet(s) every ___ hours.</p>	<p>CAUTION: Federal law PROHIBITS transfer of this drug to any person other than the patient for whom it was prescribed</p> <p><b>Instrucciones Espanol:</b> Toma ___ tableta(s) cada ___ horas.</p>	<p>Bismuth Subsalicylate Tablets 262 mg Qty: Ins: Lot#: Bat#:</p> <p>Prod# (NDC):</p> <p>Bismuth Subsalicylate Tablets 262 mg Qty: Ins: Lot#: Bat#: Prod# (NDC):</p> <p>Bismuth Subsalicylate Tablets 262 mg Qty: Ins: Insurance NDC: Lot#: Bat#:</p> <p>Bismuth Subsalicylate Tablets 262 mg Qty: Ins: Lot#: Bat#: Prod# (NDC):</p>	<p>Log</p> <p>Chart</p> <p>Billing</p> <p>Patient</p>
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## MAJOR BISMUTH SUBSALICYLATE

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

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>BISMUTH SUBSALICYLATE</b> (UNII: 62TEY51RR1) (SALICYLIC ACID - UNII:O414PZ4LPZ)	BISMUTH SUBSALICYLATE	262 mg

## Inactive Ingredients

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

## Product Characteristics

<b>Color</b>	PINK	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	16mm
<b>Flavor</b>		<b>Imprint Code</b>	G122
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68788-8239-3	5 in 1 BOX	04/06/2023	
1		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC Monograph Drug	335	04/06/2023	

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

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

## Establishment

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

Revised: 3/2024

Preferred Pharmaceuticals Inc.