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

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.

Preferred Pharmaceuticals Inc.

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

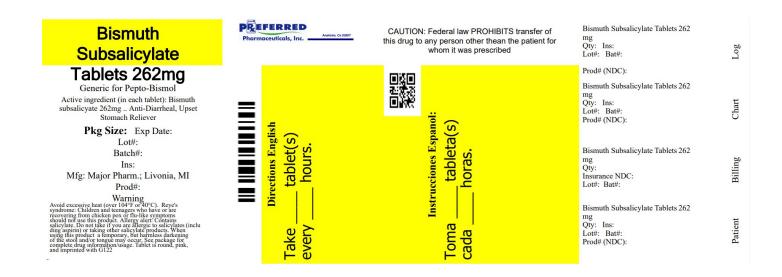
heartburn, indigestion

nausea, upset stomach

and diarrhea

Relabeled By: Preferred Pharmaceuticals Inc.

30 Chewable Tablets



MAJOR BISMUTH SUBSALICYLATE

bismuth subsalicylate tablet, chewable

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68788-8239(NDC:0904-7205)	
Route of Administration	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				

P	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				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
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.