MEDIQUE DIOTAME- bismuth subsalicylate tablet, chewable Unifirst First Aid Corporation

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.

Medique Diotame

Drug Facts

Active ingredient (in each tablet)

Bismuth Subsalicylate 262 mg

(each tablet contains 102 mg salicylate)

Purpose

antidiarrheal/antacid

Uses

relieves

- traveler's diarrhea
- diarrhea
- upset stomach reliever due to overindulgence in food and drink, including:
 heartburn
 indigestion
 nausea
 gas
 belching
 - fullness

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 stool
- an ulcer
- a bleeding problem

Ask a doctor before use if you have

- fever
- mucus in the stool

Ask a doctor or pharmacist if you are taking any drug for

- anticoagulation (thinning of the blood)
- diabetes
- gout

arthritis

When using this product a temporary and harmless darkening of the tongue and/or stool may occur.

Stop use and ask a doctor if

- symptoms get worse or lasts more than 2 days
- 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 accidental overdose, contact a physician or poison control center immediately (1-800-222-1222).

Directions

- chew or dissolve in mouth
- do not swallow tablets whole
- drink plenty of clear fluids to help prevent dehydration, which may accompany diarrhea

Adults and children: (12 years and over)

- chew 2 tablets every 1/2 to 1 hour as needed
- do not exceed 16 tablets in 24 hours
- use until diarrhea stops but not more than 2 days

Children under 12 years:

ask a doctor

Other information

- phenylketonurics: contains phenylalanine 1.1mg per tablet
- calcium content per tablet: 73 mg
- store at room temperature 59°-86°F (15°-30°C)
- tamper-evident sealed packets
- do not use any opened or torn packets

Inactive ingredients

acacia gum, aspartame, calcium carbonate, D&C red #27 aluminum lake, dextrates, flavoring, magnesium stearate, maltodextrin, microcrystalline cellulose, peppermint flavor, silicon dioxide

Questions or comments? 1-800-634-7680

Medique Diotame Label

Medique®

Diotame

Bismuth Subsalicylate

Chewable Tablets

Upset Stomach/Diarrhea • Bismuth Subsalicylate 262 mg

Tamper Evident Unit Dose Packets



MEDIQUE DIOTAME

bismuth subsalicylate tablet, chewable

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:47682-210
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
	BISMUTH SUBSALICYLATE	262 mg	

Inactive Ingredients		
Ingredient Name	Strength	
ASPARTAME (UNII: Z0H242BBR1)		
CALCIUM CARBONATE (UNII: H0G9379FGK)		
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)		
D&C RED NO. 27 (UNII: 2LRS185U6K)		
DEXTRATES (UNII: G263MI44RU)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)		
MALTODEXTRIN (UNII: 7CVR7L4A2D)		

ACACIA (UNII: 5C5403N260)

Product Characteristics			
Color	pink	Score	no score
Shape	ROUND	Size	16mm
Flavor	PEPPERMINT	Imprint Code	RH;046
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:47682-210- 83	15 in 1 BOX	04/01/2014	
1	NDC:47682-210- 99	2 in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:47682-210- 33	50 in 1 BOX	04/01/2014	
2		2 in 1 PACKET; Type 0: Not a Combination Product		
3	NDC:47682-210- 13	250 in 1 BOX	04/01/2014	
3		2 in 1 PACKET; Type 0: Not a Combination Product		
4	NDC:47682-210- 64	12 in 1 BOX	04/01/2014	
4		2 in 1 PACKET; Type 0: Not a Combination Product		
5	NDC:47682-210- 99	2 in 1 PACKET; Type 0: Not a Combination Product	04/01/2014	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part335	04/01/2014	

Labeler - Unifirst First Aid Corporation (832947092)

Revised: 5/2022 Unifirst First Aid Corporation