MIPASTE PLUS MELON- mipaste plus melon paste, dentifrice GC America Inc.

Active Ingredient Sodium fluoride 0.20% (w/w)

Purpose Anticavity

Use

• aids in the prevention of dental cavities

Warnings

Keep out of reach of children under 6 years of age.

Do not use on patients with a milk protein or hydroxybenzoates allergy. In case of allergic reaction; stop use, rinse mouth with water and seek medical advice. If you accidentally swallow more than used for brushing, get medical help or contact a Poison Control Center right away.

Warnings

Keep out of reach of children under 6 years of age.

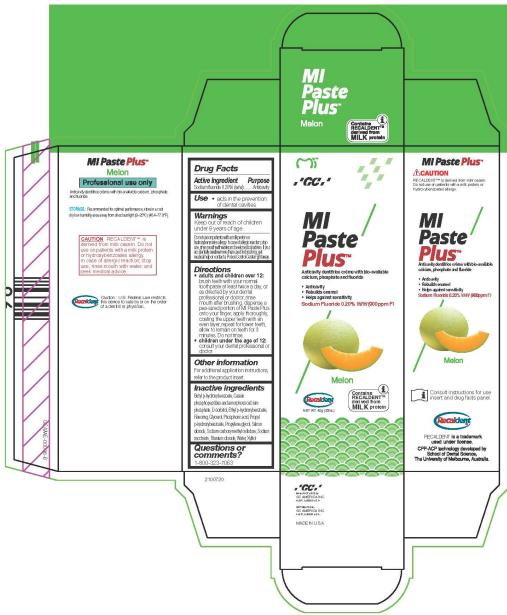
Directions

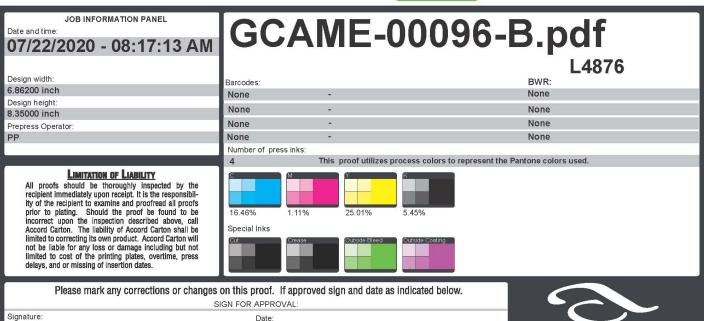
adults and children over 12: brush teeth with your normal toothpaste at least twice a day, or as directed by your dental professional or doctor, rinse mouth after brushing, dispense a pea-sized portion of MI Paste Plus onto your finger, apply thoroughly, coating the upper teeth with an even layer, repeat for lower teeth, allow to remain on teeth for 3 minutes. Do not rinse.
children under the age of 12: consult your dental professional or

Inactive ingredients

doctor

Butyl p-hydroxybenzoate, Casein phosphopeptides and amorphous calcium phosphate, D-sorbitol, Ethyl p-hydroxybenzoate, Flavoring, Glycerol, Phosphoric acid, Propyl p-hydroxybenzoate, Propylene glycol, Silicon dioxide, Sodium carboxymethyl cellulose, Sodium saccharin, Titanium dioxide, Water, Xylitol





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MIPASTE PLUS MELON

mipaste plus melon paste, dentifrice

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61596-804
Route of Administration	DENTAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)	FLUORIDE ION	0.2 g in 100 g	

Inactive Ingredients				
Ingredient Name	Strength			
BUTYLPARABEN (UNII: 3QPI1U3FV8)				
CALCIUM PHOSPHATE, UNSPECIFIED FORM (UNII: 97Z1W3NDX)				
GLYCERIN (UNII: PDC6A3C0OX)				
PHOSPHORIC ACID (UNII: E4GA8884NN)				
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K6790BS311)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
WATER (UNII: 059QF0KO0R)				
XYLITOL (UNII: VCQ006KQ1E)				
SACCHARIN SODIUM (UNII: SB8ZUX40TY)				
SORBITOL (UNII: 506T60A25R)				
ETHYLPARABEN (UNII: 14255EXE39)				
PROPYLPARABEN (UNII: Z8IX2SC1OH)				
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61596- 804-10	10 in 1 BOX	02/03/2022	
1	NDC:61596- 804-41	1 in 1 BOX, UNIT-DOSE		
1	NDC:61596- 804-40	40 g in 1 TUBE; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M021	02/03/2022		

Labeler - GC America Inc. (005473608)

Registrant - GC America Inc. (005473608)

Establishment				
Name	Address	ID/FEI	Business Operations	
GC America Inc.		005473608	manufacture(61596-804)	

Revised: 1/2024 GC America Inc.