

**MIPASTE PLUS VANILLA- mipaste plus vanilla paste, dentifrice  
GC America Inc.**

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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

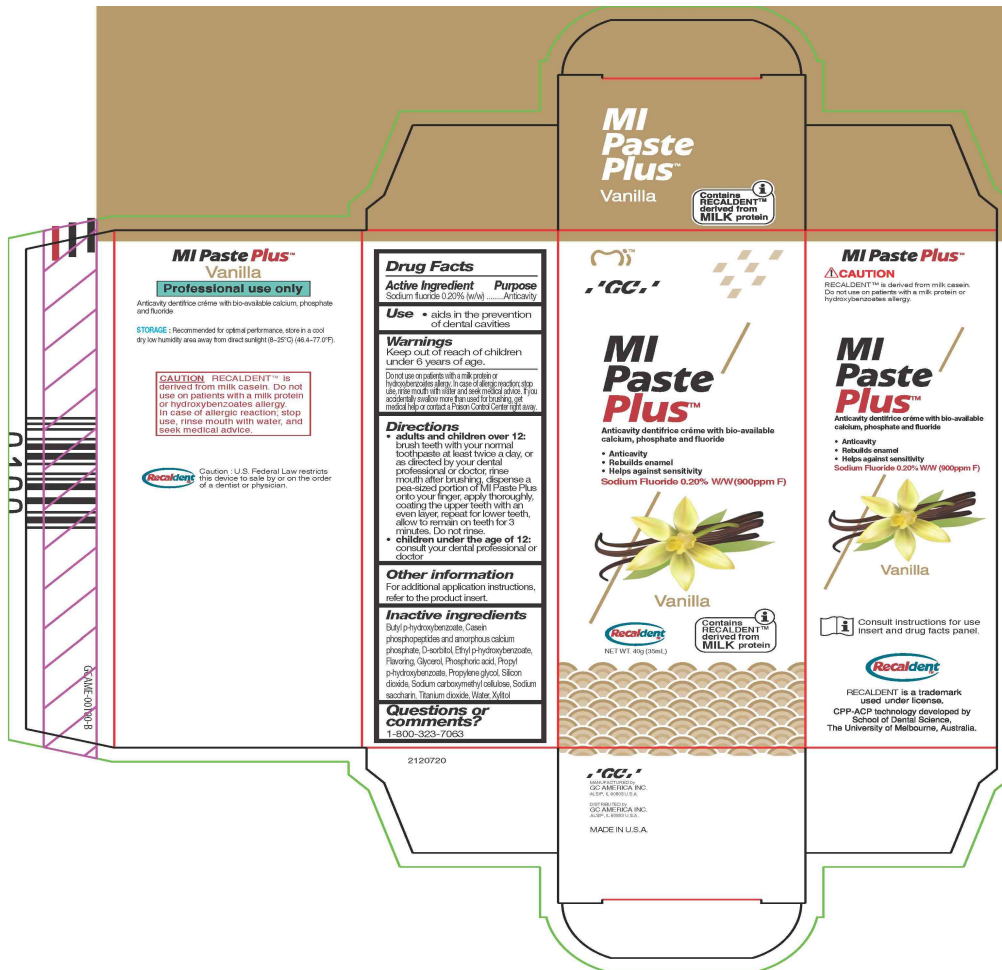
under 6 years of age.


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 doctor

Inactive ingredients

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 VANILLA

mipaste plus vanilla paste, dentifrice

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:61596-802
<b>Route of Administration</b>	DENTAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>SODIUM FLUORIDE</b> (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.2 g in 100 g

**Inactive Ingredients**

Ingredient Name	Strength
<b>BUTYLPARABEN</b> (UNII: 3QPI1U3FV8)	
<b>CALCIUM PHOSPHATE, UNSPECIFIED FORM</b> (UNII: 97Z1W3NDX)	
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
<b>CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED</b> (UNII: K679OBS311)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>XYLITOL</b> (UNII: VCQ006KQ1E)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>ETHYLPARABEN</b> (UNII: 14255EXE39)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>PHOSPHORIC ACID</b> (UNII: E4GA8884NN)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	

**Product Characteristics**

<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	VANILLA	<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61596-802-10	10 in 1 BOX	02/03/2022	
1	NDC:61596-802-41	1 in 1 BOX, UNIT-DOSE		
1	NDC:61596-802-40	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**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
GC America Inc.		005473608	manufacture(61596-802)

Revised: 1/2024

GC America Inc.