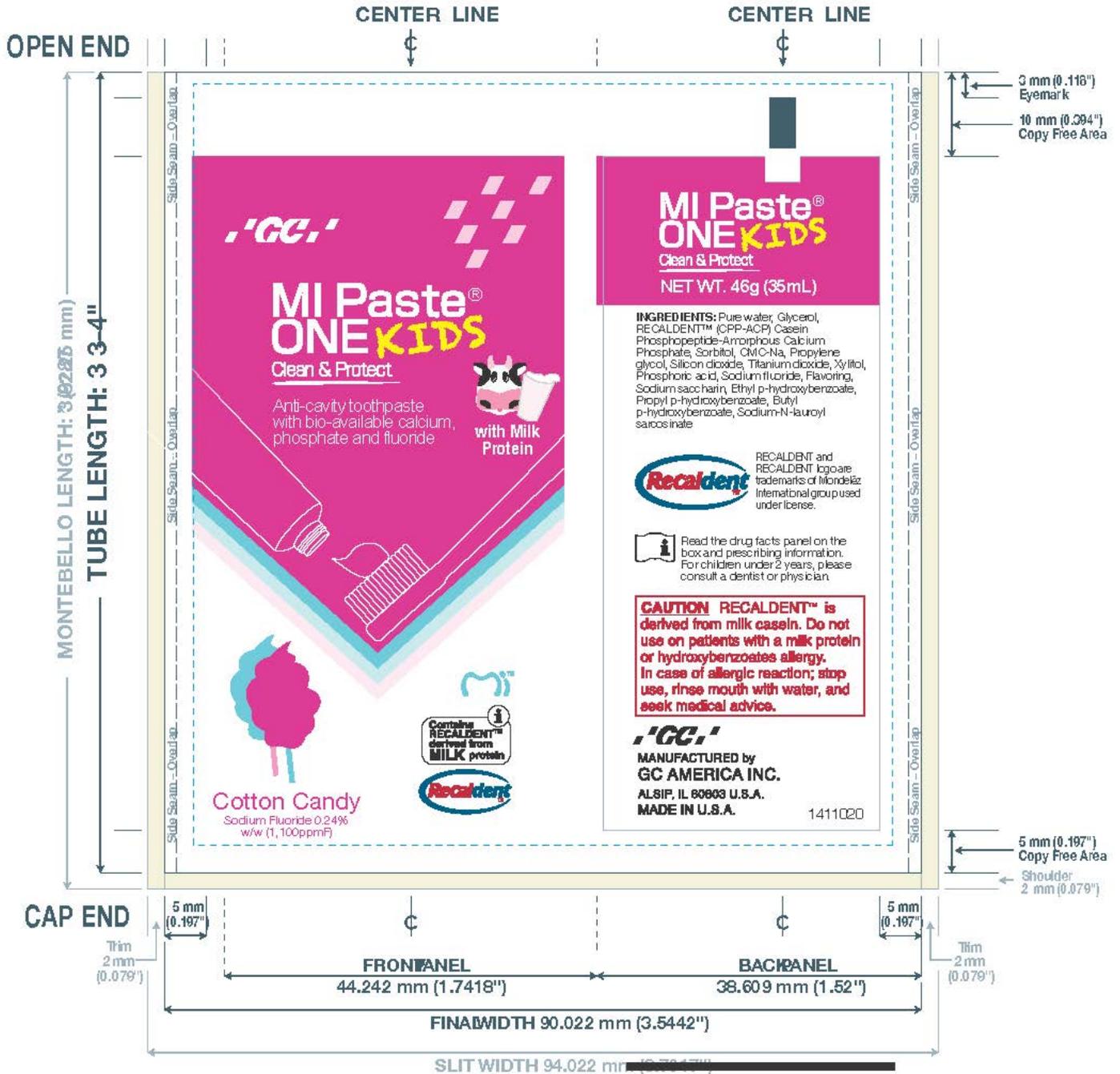


**MIPASTE ONE KIDS COTTON CANDY- mipaste one kids cotton candy paste, dentifrice**  
**GC America Inc.**

**MIPaste One Kids Cotton Candy**



Directions For adults and children 2 years of age or older, apply a small, pea-size amount of MI Paste ONE Kids to your toothbrush. For best results, brush for 2 minutes,

expectorate and avoid eating or drinking for 30 minutes after brushing. Use twice daily. Replace cap after use. For children under 2 years of age, consult a dentist or physician.

Warning Keep out of reach of children under 6 years of age. If more than the recommended amount of paste used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away. 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.

Inactive ingredients Pure water, Glycerol, RECALDENT CPP-ACP Casein Phosphopeptide-Amorphous Calcium Phosphate, Sorbitol, CMC-Na, Propylene glycol, Silicon dioxide, Titanium dioxide, Xylitol, Phosphoric acid, Flavoring, Sodium saccharin, Ethyl p-hydroxybenzoate, Propyl p-hydroxybenzoate, Butyl p-hydroxybenzoate, Sodium-N-lauroyl sarcosinate.

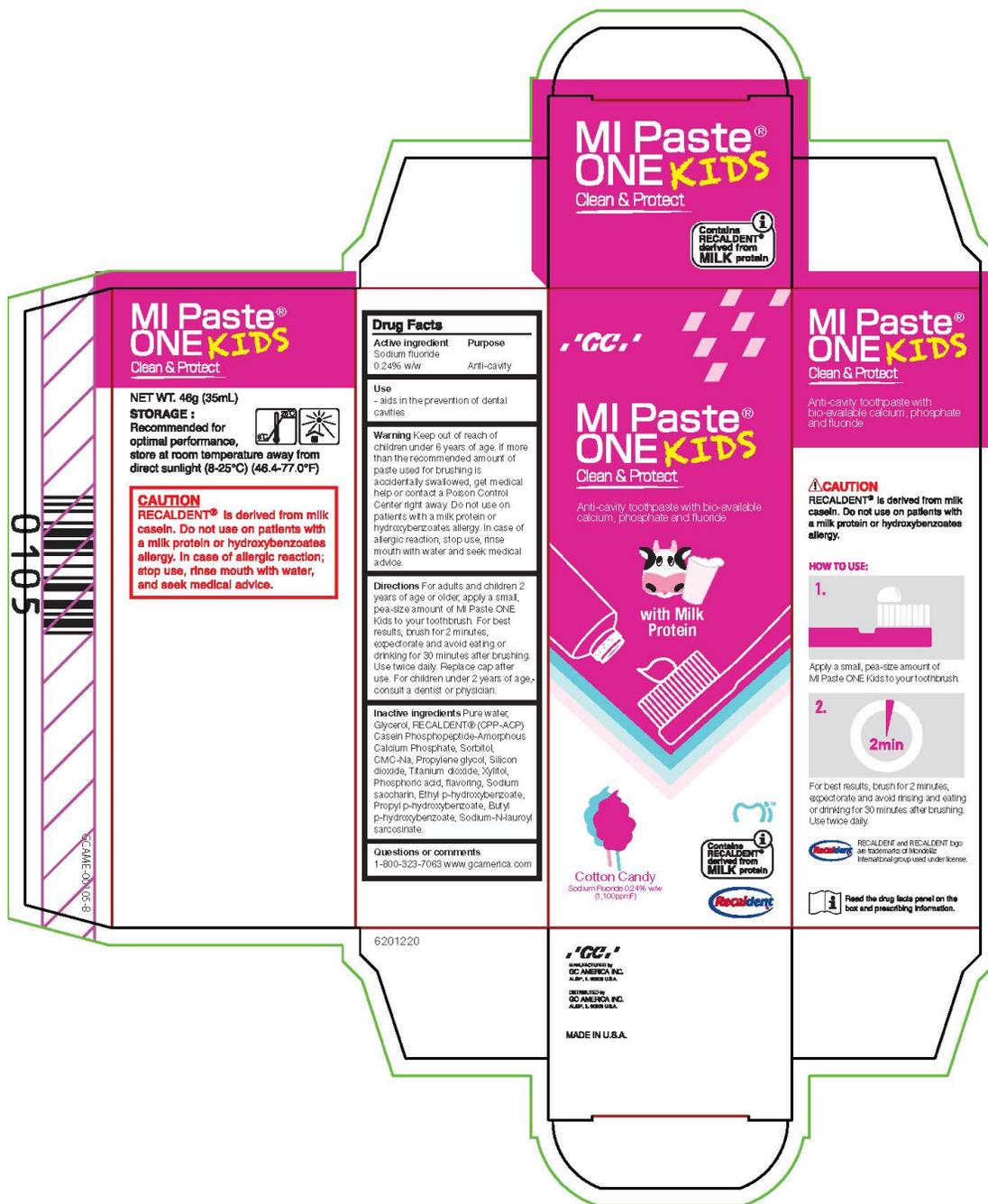
Use

- aids in the prevention of dental cavities

Warning Keep out of reach of children under 6 years of age. If more than the recommended amount of paste used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away. 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.

Purpose: Anticavity

Active ingredient  
Sodium Fluoride  
0.24% w/w



## MIPASTE ONE KIDS COTTON CANDY

mipaste one kids cotton candy paste, dentifrice

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:61596-102
<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:Q80VPU4080)	FLUORIDE ION	0.24 g in 100 g

## Inactive Ingredients

Ingredient Name	Strength
<b>BUTYLPARABEN</b> (UNII: 3QPI1U3FV8)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>XYLITOL</b> (UNII: VCQ006KQ1E)	
<b>SODIUM LAUROYL SARCOSINATE</b> (UNII: 632GS99618)	
<b>PHOSPHORIC ACID</b> (UNII: E4GA8884NN)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED</b> (UNII: K679OBS311)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>ETHYLPARABEN</b> (UNII: 14255EXE39)	
<b>CALCIUM PHOSPHATE, UNSPECIFIED FORM</b> (UNII: 97Z1W3NDX)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>SORBITOL</b> (UNII: 506T60A25R)	

## Product Characteristics

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

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61596-102-10	10 in 1 BOX	04/21/2021	
1	NDC:61596-102-02	1 in 1 BOX, UNIT-DOSE		
1	NDC:61596-102-01	0.46 g in 1 TUBE; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M021	04/21/2021	

**Labeler** - GC America Inc. (005473608)

## Establishment

Name	Address	ID/FEI	Business Operations
GC America Inc.		005473608	manufacture(61596-102)

