

MIPASTE ONE- sodium fluoride, potassium nitrate paste, dentifrice
GC America Inc.

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.

Active Ingredient

Sodium fluoride

0.24% w/w Anti-cavity

Potassium nitrate

5% (w/w)* Anti-sensitivity

*Maximum FDA sensitivity active ingredient

Use

-aids in the prevention of dental cavities

-builds increasing protection against painful sensitivity of the teeth to cold, heat, acids, sweets or contact

Warning

Warning If the sensitivity persists after 4 weeks of use, consult a dentist or physician. Keep out of reach of children. 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 and/or hydroxybenzoates allergy. In case of allergic reaction, stop use, rinse mouth with water and seek medical advice.

Directions

For adults and children 12 years of age or older, apply a small, pea-sized amount of MI Paste One to your toothbrush. For best results, brush for 2 minutes, expectorate and do not rinse; use twice a day. Replace cap after use. For children under 12 years of age, consult a dentist or physician.

Inactive ingredient

Pure water, Glycerol, RECALDENT™ (CPP-ACP) Casein Phosphopeptide-Amorphous Calcium Phosphate, Sorbitol, CMC-Na, Propylene glycol, Silicon dioxide, Titanium dioxide, Xylitol, Phosphoric acid, flavoring, Methyl salicylate, Sodium saccharin, Ethyl p-hydroxybenzoate, Propyl p-hydroxybenzoate, Butyl p-hydroxybenzoate, Sodium-N-lauroyl sarcosinate

Question or comments

1-708-323-7063 www.gcamerica.com

Warning

Keep out of reach of children.

Anti-cavity toothpaste with bio-available calcium.

Anti-cavity

Rebuilds enamel

Helps against sensitivity

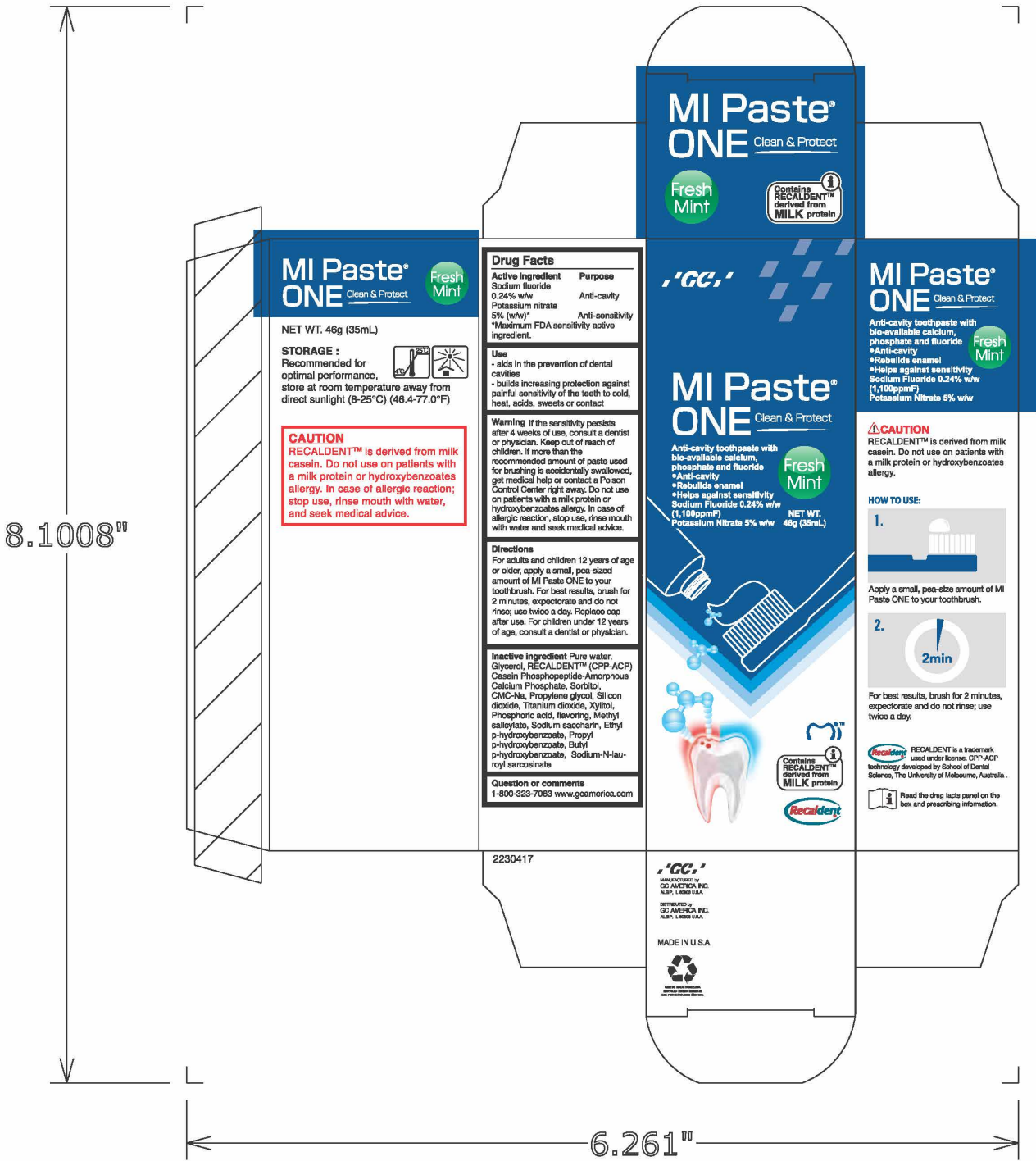
Sodium Fluoride 0.24% w/w (1,100ppmF)

Potassium Nitrate 5% w/w/

Tube box

P011518-0

GRAIN



PRINT SIDE

Tube

GC

MI Paste[®] ONE

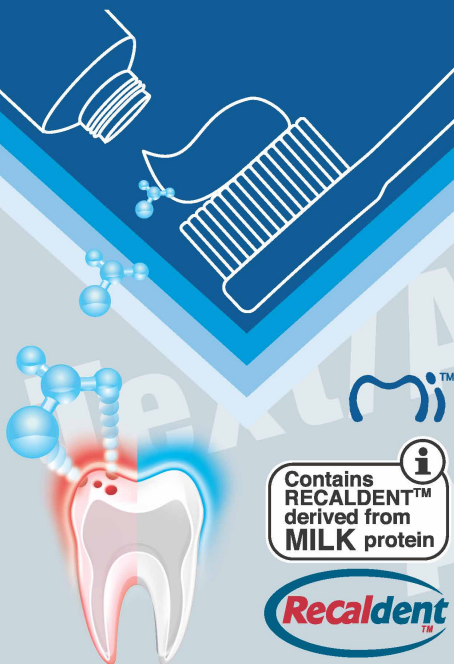
Clean & Protect

Anti-cavity toothpaste with
bio-available calcium,
phosphate and fluoride

- Anti-cavity
- Rebuilds enamel
- Helps against sensitivity

Sodium Fluoride
0.24% w/w (1,100ppmF)
Potassium Nitrate 5% w/w

Fresh
Mint



Contains
RECALDENT[™]
derived from
MILK protein



MI Paste[®] ONE

Clean & Protect

NET WT.
46g (35mL)

Fresh
Mint

INGREDIENTS : Pure water, Glycerol, RECALDENT[™] (CPP-ACP) Casein Phosphopeptide-Amorphous Calcium Phosphate, Sorbitol, CMC-Na, Propylene glycol, Silicon dioxide, Titanium dioxide, Xylitol, Phosphoric acid, Sodium fluoride, Potassium nitrate, Flavoring, Methyl salicylate, Sodium saccharin, Ethyl p-hydroxybenzoate, Propyl p-hydroxybenzoate, Butyl p-hydroxybenzoate, Sodium-N-lauroyl sarcosinate



RECALDENT is
a trademark used
under license.



Read the drug facts panel on the box and prescribing information.

CAUTION RECALDENT[™] is derived from milk casein. 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.

GC

MANUFACTURED by
GC AMERICA INC.

ALSIP, IL 60803 U.S.A.

MADE IN U.S.A.

2010317

MIPASTE ONE

sodium fluoride, potassium nitrate paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61596-437
Route of Administration	DENTAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.0024 g in 1 g
POTASSIUM NITRATE (UNII: RU45X2JN0Z) (NITRATE ION - UNII:T93E9Y2844)	POTASSIUM NITRATE	0.06 g in 1 g

Inactive Ingredients	
Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SORBITOL (UNII: 506T60A25R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
XYLITOL (UNII: VCQ006KQ1E)	
PHOSPHORIC ACID (UNII: E4GA8884NN)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
ETHYL PARABEN (UNII: 14255EXE39)	
BUTYL PARABEN (UNII: 3QPI1U3FV8)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM LAUROYL SARCOSINATE (UNII: 632GS99618)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	
CALCIUM PHOSPHATE (UNII: 97Z1WI3NDX)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61596-437-41	1 in 1 BOX	07/03/2017	
1	NDC:61596-437-40	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 not final	part356	07/03/2017	

Labeler - GC America Inc. (005473608)

Establishment

Name	Address	ID/FEI	Business Operations
GC America Inc.		005473608	manufacture(6 1596-437)

Revised: 1/2020

GC America Inc.