

# INSTRUCTIONS FOR USE (IFU)

## GC Tooth Mousse Plus™



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Prior to use, carefully read the instructions for use.

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## GC Tooth Mousse Plus™

TOPICAL CREME WITH CALCIUM, PHOSPHATE AND FLUORIDE

For use by or under the supervision of a dental professional in the recommended indications.

### DESCRIPTION

GC Tooth Mousse Plus is a water based creme containing RECALDENT™\* (CPP-ACP: Casein Phosphopeptide-Amorphous Calcium Phosphate) with incorporated fluoride. The level of fluoride is 0.2% w/w, (900ppm), which approximates that in adult strength toothpastes. When CPP-ACP is applied in the oral environment, it will bind to biofilms, plaque, bacteria, hydroxyapatite and soft tissue localizing bio-available calcium, phosphate and fluoride.

### IMPORTANT

Saliva will enhance the effectiveness of CPP-ACP and the flavor will help stimulate saliva flow. The longer CPP-ACP and saliva are maintained in the mouth, the more effective the result.

A topical paste containing bio-available calcium, phosphate and fluoride:

1. Provides extra protection for teeth.
2. Helps neutralize acid challenges from acidogenic bacteria in plaque.
3. Helps neutralize acid challenges from other internal and external acid sources.

### DIRECTIONS FOR USE

#### INDICATIONS

- a. Following in-office bleaching procedures.
- b. After ultrasonic, hand scaling or root planing.
- c. Following professional tooth cleaning (P.T.C.).
- d. Hypersensitivity prevention and control.
- e. As an alternative means of applying fluoride topically in children aged 6 and above.
- f. During orthodontic treatment.
- g. For high risk caries patients.
- h. To provide a topical coating for patients suffering from erosion, xerostomia or Sjögrens syndrome.
- i. For special needs adult patients.

#### IN-OFFICE APPLICATION

##### I. Custom tray application:

1. Before use rinse the custom tray thoroughly under running water.
2. Extrude a generous layer of GC Tooth Mousse Plus into the tray and apply to the upper and / or lower teeth.
3. Leave the tray undisturbed in the mouth for a minimum of 3 minutes.
4. Remove the tray.
5. Instruct the patient to use the tongue to spread the remaining GC Tooth Mousse Plus throughout the mouth. Instruct the patient to retain for as long as possible (another 1-2 minutes) avoiding expectoration and delaying swallowing. The longer GC Tooth Mousse Plus and saliva are maintained in the mouth, the more effective the result.
6. Ask the patient to expectorate thoroughly and if possible avoid rinsing. Any GC Tooth Mousse Plus remaining on the surface can be left to gradually dissipate. Advise the patient not to eat or drink for 30 minutes following application.
7. Any residual GC Tooth Mousse Plus in the tray should be rinsed or brushed off under running water immediately after use.

##### II. Non tray application:

1. If necessary, remove any excess saliva on the tooth surface with a cotton roll or pellet. However, it is NOT necessary to dry the teeth with compressed air.
2. Apply GC Tooth Mousse Plus to the tooth surfaces using an application swab, gloved finger or in difficult interproximal areas using an Interproximal Tooth Cleaning Brush.
3. Leave GC Tooth Mousse Plus undisturbed for a minimum of 3 minutes.
4. Then instruct the patient to use the tongue to spread the remaining GC Tooth Mousse Plus throughout the mouth. Request the patient to hold in the mouth for as long as possible (an additional 1-2 minutes) avoiding expectoration and delaying swallowing. The longer GC Tooth Mousse Plus and saliva are maintained in the mouth, the more effective the result.
5. Ask the patient to expectorate thoroughly and if possible avoid rinsing. Any GC Tooth Mousse Plus remaining on the surface can be left to gradually dissipate. Advise the patient not to eat or drink for 30 minutes following application.

#### AT-HOME APPLICATION

##### III. Day time application after tooth brushing as recommended by a dental professional:

1. Apply a sufficient amount of GC Tooth Mousse Plus to upper and lower teeth. A pea size amount for each arch is the minimum required. The material should be applied to the tooth surfaces using a clean dry finger or cotton tip. For difficult areas (between the teeth) use an Interproximal Tooth Cleaning Brush or dental floss coated with GC Tooth Mousse Plus.
2. Leave GC Tooth Mousse Plus on the teeth undisturbed for a minimum of 3 minutes.
3. Then use your tongue to spread the remaining GC Tooth Mousse Plus throughout the mouth. Hold in the mouth for as long as possible (a further 1-2 minutes) avoiding expectoration (spitting out) and delaying swallowing. The longer GC Tooth Mousse Plus and saliva are maintained in the mouth, the more effective the result.
4. Expectorate thoroughly and if possible avoid rinsing. Any GC Tooth Mousse Plus remaining on the surface can be left to gradually dissipate. Do not swallow. Do not eat or drink for 30 minutes following application.

#### IV. Night time application after tooth brushing as recommended by a dental professional:

Note: The overnight use is especially recommended for high-risk adult patients, but not recommended for children under 12.

1. Apply a sufficient amount of GC Tooth Mousse Plus to the upper and lower teeth. A pea size amount for each arch is the minimum required. The material should be applied to the tooth surfaces using a clean dry finger or cotton tip. For difficult areas (between the teeth) use an Interproximal Tooth Cleaning Brush or dental floss coated with GC Tooth Mousse Plus.
2. Leave GC Tooth Mousse Plus on the teeth undisturbed for a minimum of 3 minutes.
3. Then use your tongue to spread the remaining GC Tooth Mousse Plus throughout the mouth. Hold in the mouth for as long as possible (a further 1-2 minutes) avoiding expectoration (spitting out) and delaying swallowing. The longer GC Tooth Mousse Plus and saliva are maintained in the mouth, the more effective the result.
4. Expectorate thoroughly and if possible avoid rinsing. Any GC Tooth Mousse Plus remaining on the surface can be left to gradually dissipate overnight. Do not eat or drink for 30 minutes following application.

#### FLAVOURS

Strawberry, Vanilla, Mint

#### STORAGE

Recommended for optimal performance, store in a cool dry, low humidity area away from direct sunlight (8-25°C)(46.4-77.0°F).

#### PACKAGES

Tube containing 40 g (35 mL)

1. 3-Flavour Package  
10 x 40g (4 Strawberry, 4 Mint, 2 Vanilla)
2. Refill Package  
1 x 40g tube in each flavor

#### NOTE

GC Tooth Mousse Plus with its unique CPP-ACP formulation was developed at The School of Dental Science, The University of Melbourne, Victoria, Australia.

\*RECALDENT is a trademark used under license. CPP-ACP Technology has related patents or patents pending in Australia, NZ, Europe, Canada and USA.

#### CAUTION

1. Always replace the cap after use and remove any residual paste or moisture around the tube neck or inside the cap.
2. It is not recommended to use GC Tooth Mousse Plus on patients under the age of 6.
3. The overnight at home application is not recommended for children under 12.
4. In case of contact with eyes, flush immediately with water and seek medical attention.
5. In case of spillage on clothes, wash off with water.
6. If any angioedema symptoms are experienced, this may indicate sensitivity or allergy to the benzoate preservatives, or to some other component of the product such as a flavouring agent. In this event, discontinue the use of the product and refer to a physician.

#### CONTRAINDICATIONS

Casein phosphopeptides are derived from milk casein.

Do not use this material on patients with a proven or suspected milk protein allergy and / or with a sensitivity or allergy to benzoate preservatives.

Some products referenced in the present IFU may be classified as hazardous according to GHS.

Always familiarize yourself with the Safety Data Sheets available at:

<http://www.gceurope.com/>

They can also be obtained from your supplier.

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MANUFACTURED BY  
GC AMERICA INC.

3737 West 127th Street, Alsip, IL 60803 U.S.A.

DISTRIBUTED BY

 EU: GC EUROPE N.V.

Researchpark Haasrode-Leuven 1240, Interleuvenlaan 33,  
B-3001 Leuven, Belgium TEL: +32 16 74 10 00

GC AMERICA INC.

3737 West 127th Street, Alsip, IL 60803 U.S.A.

TEL: +1-708-597-0900

GC ASIA DENTAL PTE. LTD.

11 Tampines Concourse, #03-05 Singapore 528729

TEL: +65 6546 7588

GC AUSTRALASIA DENTAL PTY. LTD.

1753 Botany Rd, Banksmeadow, NSW 2019, Australia

TEL: +61 2 9301 8200

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