

INSTRUCTIONS FOR USE (IFU)

GC Tooth Mousse Plus®

TOPICAL CREME WITH CALCIUM, PHOSPHATE AND FLUORIDE

Prior to use, carefully read the instructions for use.

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DESCRIPTION

GC Tooth Mousse Plus® is a delicious tasting crème containing a milk-derived protein called RECALDENT™ with incorporated fluoride (CPP-ACPF: casein phosphopeptide-amorphous calcium phosphate fluoride). The level of fluoride is 0.2% w/w (900 ppm) which approximates that in adult strength toothpastes. Because calcium, phosphate and fluoride are carried in a special milk-derived protein called RECALDENT™ (CPP-ACP), they are available in a soluble form. This means GC Tooth Mousse Plus® can provide extra protection for teeth, buffer dental plaque acid from bacteria in the mouth and also protect teeth from acidic foods and drinks.

INDICATIONS

GC Tooth Mousse Plus® is a medical device designed for protecting teeth.

- Provides extra protection for teeth
- Buffers dental plaque acid from bacteria in the mouth
- Protects teeth from acidic foods and drinks

CONTRAINDICATIONS

GC Tooth Mousse Plus® contains CPP-ACP (RECALDENT™) which is derived from cow's milk. GC Tooth Mousse Plus® also contains hydroxybenzoates and soybean products. Do not use this product if you have a suspected or proven allergy to milk proteins, benzoate preservatives or soybean products. In case of an allergic reaction: stop use, rinse mouth with water and seek medical advice.

Do not use GC Tooth Mousse Plus® in children 6 years of age or less.

The overnight home application of GC Tooth Mousse Plus® is not recommended for children under the age of 12.

Do not swallow GC Tooth Mousse Plus®.

Do not use except on the advice of a dentist.

APPLICATION




You should discuss with your dentist how often and for how long you should apply GC Tooth Mousse Plus®. Application should occur after brushing teeth. In most situations, morning and night application is advised.

Do not use GC Tooth Mousse Plus® in children 6 years of age or less.

The overnight home application of GC Tooth Mousse Plus® is not recommended for children under the age of 12.

At home application:

Day and nighttime application after tooth brushing as recommended by a dental professional

	1. Squeeze a pea-size amount of GC Tooth Mousse Plus® onto a clean finger.
	2. Apply to all teeth with a clean finger and use your tongue to spread around evenly. For difficult areas (between the teeth) use an interproximal tooth cleaning brush or dental floss coated with GC Tooth Mousse Plus®.
 3 MINUTES	3. Leave GC Tooth Mousse Plus® on teeth for a minimum of 3 minutes avoiding spitting out and swallowing. Saliva will enhance the effectiveness of GC Tooth Mousse Plus® and the flavour will help stimulate saliva flow - the longer GC Tooth Mousse Plus® and saliva are maintained in the mouth (an additional 1 – 2 minutes), the more effective the result.
	4. Spit out excess. Any GC Tooth Mousse Plus® remaining on the surface can be left to gradually dissipate. Avoid rinsing, and do not eat or drink for 30 minutes following application.

At the dental practice:

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 (an additional 1 – 2 minutes) avoiding spitting out and avoiding swallowing. The longer GC Tooth Mousse Plus® and saliva are maintained in the mouth, the more effective the result.
6. Ask the patient to spit out 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 a sufficient amount of 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. 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 (an additional 1 – 2 minutes) avoiding spitting out and swallowing. The longer GC Tooth Mousse Plus® and saliva are maintained in the mouth, the more effective the result.
5. Ask the patient to spit out excess 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.

FLAVORS

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 40g (35mL)

1. Assorted Package
10 x 40g (4 Strawberry, 4 Mint, 2 Vanilla)
2. Single Flavor Package
10 x 40g in each flavor (10 Strawberry or 10 Vanilla or 10 Mint)
3. Refill Package
1 x 40g tube in each flavor

NOTE

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

CAUTION

1. Always replace cap after use and remove any residual paste or moisture around the tube neck or inside the cap.
2. In case of contact with eyes, flush immediately with water and seek medical attention.
3. In case of spillage on clothes, wash off with water.
4. If the product's odor, taste or appearance changes after opening, discontinue the use of the product and contact the distributor in your region, as listed below.
5. GC Tooth Mousse Plus® must always be used under adult supervision.
6. If any allergic symptoms are experienced, this may indicate sensitivity or allergy to the benzoate preservatives, soybean products or to some other component of the product such as a flavoring agent. In this event, discontinue the use of the product and refer to a physician.

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.gcaustralasia.com>

They can also be obtained from your supplier.

Undesired effects- Reporting:

If you become aware of any kind of undesired effect, reaction or similar events experienced by use of this product, including those not listed in this instruction for use, please report them directly through the relevant vigilance system, by selecting the proper authority of your country accessible through the following link:

https://ec.europa.eu/growth/sectors/medical-devices/contacts_en

as well as to our internal vigilance system:

vigilance@gc.dental

In this way you will contribute to improve the safety of this product.

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MANUFACTURED BY

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