



G-ænial™ Universal Injectable

UNIVERSAL LIGHT-CURED RADIOPAQUE INJECTABLE COMPOSITE

For use only by a dental professional in the indications for use.

INDICATIONS FOR USE

- Direct Restorative for Class I, II, III, IV and V cavities
- Fissure sealant
- Sealing of restorative areas
- Repair of (n)direct aesthetic restorations, temporary crown & bridge defect margins and margins area in enamel
- Blocking out undercuts
- Liner or base
- Restoration of crowns & bridges, inlays and veneers using the indirect technique in combination with GRADIA or GRADIA PLUS components (please refer to its dedicated IFU).
- Splitting of teeth in combination with fibres such as GC EverStick fibres. Follow manufacturer's instructions.

CONTRAINDICATIONS

- Direct pulp capping
- Avoid use of this product in patients with known allergies to methacrylate monomer or methacrylate polymer.

COMPOSITION

Barium sulphate, dimethacrylate, initiator, pigment, silicon dioxide, stabiliser

PRODUCT DESCRIPTION

G-ænial Universal Injectable is a light-cure, radio-opaque restorative material to be used for direct restorations as a Type 1 and Class 2 (Group 1) per ISO standard 4049. This material has a radiopacity equivalent to 2.5 - 3.0 mm of aluminium (density is approximately 2.5 - 3.0 mm). The particle size of inorganic fillers range is 0.01 - 0.5 µm. The total amount of inorganic filler is approximately 46-49%.

DIRECTIONS FOR USE

Select shade from 16 shades of XBW, BW, A1, A2, A3, A3.5, A4, B1, B2, CV, CVD, AO1, AO2, AO3, AE, AE. A, B, C, D, shades are based on Vita® Shade.

Prepare cavity using standard techniques. Dry by gently blowing with oil free, Rubber dam is recommended to isolate the preparation from contamination with saliva, blood or sulcus fluid.

For pulp capping, use calcium hydroxide.

Finishing and polishing using standard techniques.

1) Dispensing from the syringe

Hold the syringe upright and remove plunger by turning counterclockwise.

2) Promptly and securely attach the dispensing tip to the syringe by turning clockwise.

3) Place the light protective cap until use.

4) Remove cap from the dispensing tip.

Note: Take care not to attach the dispensing tip too tightly. This may damage the cavity preparation.

5) Place the dispensing tip directly on the prepared cavity, make sure that the threads are free of coronal material.

Prior to injection, make sure into the cavity, make sure to check the following:

- Dispensing tip is securely attached to the syringe.
- Any possible air from the dispensing tip is removed by gently pushing forward the syringe plunger with the tip pointing upwards until material reaches the opening of the tip (Fig. 2).

6) Place the dispensing tip close as possible to the prepared cavity, slowly push the plunger to extrude material. Alternatively, dispense material onto a mixing pad and transfer to the cavity using a suitable instrument.

Note: If plugged, remove the dispensing tip and extrude a small amount of material directly into the cavity.

7) Minimize exposure to ambient light. Ambient light can shorten the manipulation time.

8) After use, immediately remove all excess of the dispensing tip and dry the syringe with the wing cap.

9) Inserting from a G-ænial Universal Injectable Unit into the Unittip APPLICATOR (I) equivalent. Remove the cap and extrude material directly into the prepared cavity. Use steady pressure (Fig. 3). Maintain pressure on the applicator while removing the Unittip APPLICATOR (I) and bring loose from the applicator.

a. The material may be difficult to extrude immediately after removing from cold storage. Prior to use, leave to stand for a few minutes at room temperature.

b. For first use, apply pressure slowly and gradually to control extrusion of material.

Clinical Hints

In order to inject effectively, use the surface tension of the material to ensure uniformity across the entire surface of the restoration during and after cure. Once the required amount has been injected, release the pressure on the plunger and withdraw the syringe in a direction perpendicular to the surface. This will allow the material to flow into the cavity and the dispensing tip and provides a smooth surface over the restoration.

Light-curing
Use G-ænial Universal Injectable using a light curing unit. Keep light guide as close as possible to the surface. Refer to the following chart for Irradiation Time and Effective Depth of Cure.

Irradiation Time and Effective Depth of Cure (ISO 4049)

10 sec. (high power LED) (>1200 mW/cm²)

20 sec. (Halogen LED) (>700 mW/cm²)

1.0 mm (XBW, BW, A3.5, A4, AO1, AO2, AO3, AE)

2.0 mm (the effective wavelength range of each dental curing unit must cover 450 - 480 nm)

Note: a. The material should be placed and light-cured in layers. b. For maximum layer thickness, please consult our table.

c. Lower light intensity may cause insufficient curing and may result in shrinkage.

d. For the indirect technique, light-cure each layer for 30 seconds with LABOLIGHT LV-III. Final cure for 3 minutes using LABOLIGHT LV-III.

6) Finishing and Polishing
Finish and polish using standard techniques.

SHADES

XBW, BW, A1, A2, A3, A3.5, A4, B1, B2, CV, CVD, AO1, AO2, AO3, AE, AE.

STORAGE

Recommended for optimal performance, store in a cool and dark place (4-25°C/39-77.0°F) away from high temperatures or direct sunlight.

PACKAGES

1) Syringe 1.7 g (0.10 mL) x 1, Dispensing Tip Long Needle x 10, Light-protective cap x 1

2) Syringe 1.7 g (0.10 mL) x 1, Dispensing Tip Needle x 5, Dispensing Tip Long Needle x 5, Light-protective cap x 1

3) Syringe 1.7 g (0.10 mL) x 1, Dispensing Tip Needle x 10, Dispensing Tip Long Needle x 10, Light-protective cap x 2

4) Dispensing Tip Refill

5) Dispensing Tip Refill

6) Dispensing Tip Long Needle x 30, Light-protective cap x 2

7) Dispensing Tip Long Needle x 30, Light-protective cap x 2

8) Unittip

1) Unittip 0.27 g (0.16 mL) x 15

Note: All packaging types may not be available in all countries.

CAUTION

1. In case of contact with oral tissue or skin, remove immediately with water and alcohol.

2. Flush with water. To avoid contact, a rubber dam and COCCA BUTTER can be used to isolate the operation field from the skin or oral tissue.

3. In case of contact with eyes, flush immediately with water and seek medical attention.

4. Take care to avoid ingestion of the material.

5. Avoid putting the product away from the patient to ensure the safety of the patient and prevent the patient from extruding paste to flowing properly.

6. Do not mix with other similar products.

7. Dispensing tips are for single use only. To prevent cross contamination between patients, do not reuse the dispensing tip.

8. Wear plastic or rubber gloves during operation to avoid direct contact with an irritant resin layers in order to prevent possible sensitivity.

9. Wear protective eye glasses during light curing.

10. When polishing the finished material, use a dust collector and wear a dust mask to avoid inhalation of cutting dust.

11. Avoid getting material on clothing.

12. In case of contact with unintended prosthetic appliances, remove with instrument, sponge or cotton pellet before light-curing.

13. Do not use G-ænial Universal Injectable in combination with eugenol containing materials as eugenol may hinder G-ænial Universal Injectable from setting.

14. Do not view the dispensing tip with excess alcohol as this may cause contamination of the paste.

15. Dispense 10 ml water into a clean glass container.

16. In rare cases the product may cause sensitivity in some people. If any such reactions are experienced, discontinue use of the product and seek medical attention.

17. Personal protective equipment (PPE) such as gloves, face masks and safety eyewear should always be worn.

Some products referred in the present IFU may be classified differently according to GHS. Always familiarise yourself!



