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INSTRUCTION FOR USE

Preva GingivaGuard

(Light-Curing Gingival Resin Barrier)

Preva GingivaGuard is a light-curing, resin-based gingival barrier designed to protect gingival and adjacent soft tissues and to isolate the treatment area during dental procedures.

COMPOSITION

Urethane Dimethacrylate (UDMA), Triethylene Glycol Dimethacrylate (TEGDMA), Fumed Silica, Silanated Barium Glass Powder, Pigments, Photoinitiators, Stabilizers

INTENDED USE

Preva GingivaGuard is intended to be used as a temporary, light-cured protective barrier for the gingiva and adjacent soft tissues during dental procedures where isolation and protection of soft tissues are required.

INDICATIONS

- Protection of gingival tissues during in-office tooth-whitening procedures.
- Protection and isolation of gingival margins during dental procedures.
- Protection of soft tissues during acid-etching procedures.
- Protection of gingival tissues during air abrasion and other procedures where accidental contact with dental materials may cause irritation.
- Temporary sealing or isolation of gingival areas where additional soft-tissue protection is clinically required.

INSTRUCTIONS FOR USE

1. Preparation

- Ensure that the treatment area is clean and dry.
- Isolate the teeth and surrounding tissues using appropriate clinical techniques, such as cheek retractors, cotton rolls, suction, or other suitable isolation methods.
- Inspect the gingival tissues before application. Do not apply the material to open wounds, ulcerated areas, or visibly damaged soft tissue.
- Remove the syringe cap and securely attach a new disposable applicator tip.
- Verify that the material flows properly before intraoral application.

2. Application

- Apply a thin, continuous bead of Preva GingivaGuard directly along the gingival margins and onto adjacent soft tissues requiring protection.
- Ensure that the material completely covers the area requiring protection without gaps.
- Extend the barrier sufficiently to protect the gingival tissue from accidental contact with the material being used during the dental procedure.
- Build the barrier to approximately 1.5–2.0 mm thickness to provide adequate protection and facilitate removal after the procedure.

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- Carefully inspect the applied material before curing to ensure complete and continuous coverage.

3. Light Curing

- Use a suitable dental LED or halogen curing light.
- Position the curing light according to the curing-light manufacturer's instructions.
- Light-cure the applied Preva GingivaGuard for approximately 20–30 seconds, moving the light slowly across the entire surface to ensure uniform polymerization.
- For larger areas, cure the barrier in sections as necessary to ensure complete polymerization.
- After curing, carefully check the barrier for adequate hardness, retention, and complete coverage.
- If any uncured or inadequately protected areas are identified, apply additional material as necessary and light-cure again before proceeding with the dental procedure.

4. During the Procedure

- Confirm that the cured barrier remains securely in position before applying bleaching agents, etchants, or other dental materials.
- Avoid intentionally applying treatment materials directly onto the gingival barrier unless required by the specific clinical procedure.
- Periodically inspect the barrier during treatment, particularly during procedures involving potentially irritating materials.
- If the barrier becomes displaced, damaged, or detached, stop the procedure as appropriate and replace or repair the barrier before continuing.

5. Removal

- After completion of the dental procedure, thoroughly remove or rinse away the treatment material according to its manufacturer's instructions.
- Using a suitable blunt dental instrument, gently lift an edge of the cured Preva GingivaGuard.
- Carefully peel the barrier away from the gingival tissue.
- Avoid excessive force or trauma to the gingiva during removal.
- Inspect the oral cavity carefully and ensure that all remnants of the barrier have been removed.
- Rinse the treated area thoroughly with water as clinically appropriate.

WARNINGS

- For professional dental use only.
- The product should be used only by, or under the supervision of, a qualified dental professional.
- Do not swallow or take internally.
- Avoid contact of uncured material with skin, eyes, and unnecessary areas of oral soft tissue.
- Unpolymerized methacrylate-containing material may cause irritation or sensitization in susceptible individuals.

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- Do not use in patients with a known allergy or hypersensitivity to methacrylates or any other component of the product.
- Do not apply to open wounds, ulcerated tissues, or visibly damaged gingiva.
- Keep out of reach of children.

PRECAUTIONS

- Avoid direct contact with uncured material.
- Maintain adequate isolation of the treatment area.
- Ensure that the protective barrier completely covers the gingival tissue requiring protection before beginning the procedure.
- Check the integrity of the barrier throughout the dental procedure.
- Do not use excessive curing-light exposure beyond that required for adequate polymerization.
- Prevent contamination of the syringe and its contents.
- Disposable applicator tips must not be reused.

Eye Contact

- Uncured material may cause eye irritation. In case of accidental eye contact, immediately rinse thoroughly with plenty of clean water and seek medical attention if irritation persists or if clinically indicated.

Skin Contact

- Avoid contact of uncured material with skin. In case of accidental contact, immediately remove the material and wash the affected area thoroughly with soap and water.
- If irritation, rash, sensitization, or another allergic reaction develops, discontinue exposure and seek appropriate medical attention.

Accidental Ingestion

- If accidentally swallowed, rinse the mouth thoroughly with water. Seek medical advice if a significant quantity has been swallowed or if adverse symptoms occur.

CONTRAINDICATIONS

Preva GingivaGuard should not be used:

- In patients with a known allergy or hypersensitivity to methacrylates or any other component of the product.
- On open wounds, ulcerated areas, actively bleeding tissues, or visibly damaged gingiva.
- In clinical situations where adequate isolation, application, or complete light curing of the material cannot be achieved.

STORAGE

- Store in a cool, dry place.
- Protect from direct sunlight and other sources of intense light.
- Protect from excessive heat.
- Do not freeze.
- Keep the syringe tightly closed when not in use.
- Close the syringe cap securely immediately after dispensing.
- Do not use after the expiry date stated on the packaging.



SHELF LIFE

3 years from the date of manufacture, when stored under the recommended storage conditions.

PRESENTATION

Ref. No.: PL-0310– Preva GingivaGuard – 2 × 1.2 mL

Syringes

Ref. No.: PL-0310–1– Preva GingivaGuard – 4 × 1.2 mL

Syringes

DISPOSAL

Dispose of unused or expired material, used applicator tips, empty syringes, and packaging in accordance with applicable local regulations and the prevailing waste-disposal requirements of the country in which the product is used.

CONTACT

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Failure to comply with the specified storage conditions may alter the working characteristics of the material and reduce its shelf life.

The manufacturer is not responsible for any loss of quality resulting from non-compliance with the specified conditions for transportation, storage, and use of this product. The user assumes full responsibility for using the material for any purposes other than those specified by the manufacturer. This material is intended solely for professional dental use. Application must be carried out strictly according to the instructions for use. The manufacturer accepts no liability for damages resulting from failure to follow the provided instructions or for use beyond the stipulated applications. The user is responsible for assessing the material's suitability for any purpose not explicitly stated in this instruction sheet. The descriptions and data provided do not constitute a warranty of attributes and are not legally binding.

This product is specially formulated for use in dentistry and to be used by qualified dental personnel

 Symbol for "TEMPERATURE LIMITATION"

 Symbol for "KEEP OUT OF THE REACH OF CHILDREN"

 Symbol for "DO NOT USE IF PACKAGE IS DAMAGE"

 Symbol for "KEEP AWAY FROM SUNLIGHT"

 Symbol for "MANUFACTURER NAME & ADDRESS"

 Symbol for "CONSULT INSTRUCTION FOR USE"

 Symbol for "CATALOGUE NUMBER"

 Symbol for "MEDICAL DEVICE"

 Symbol for "NON STERILE"

 Symbol for "USE BY"

 Symbol for "BATCH CODE"

 Symbol for "CAUTION"

 Symbol for "KEEP DRY"

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