

APACAL ART

PHOTO CURE PULP PROTECTANT / LINER

PREVESTDenPro®
THE FUTURE OF DENTISTRY

Product Description :

ApaCal ART is a Photo Cure resin modified Calcium Hydroxide/ Tri-calcium Phosphate pulp protectant/liner fortified with Hydroxyapatite. It is designed to perform as a barrier and to protect dental pulpal complex. Its unique Active Release Technology is useful in pulp capping and as protective base/liner under dental filling materials, cements and other restorative materials. It is supplied in paste form which can be syringed using delivery tips.

Composition : Urethane Dimethacrylate, Triethylene Glycol Dimethacrylate, Calcium Hydroxide, Tricalcium Phosphate, Hydroxyapatite, Photoinitiators, Stabilizers and Radiopacifiers.

Benefits :

1. Accelerated release of calcium ions
2. Accelerated formation of dentine bridge
3. Better radiopacity.

Intended Purpose / Intended use: It is intended to be used as a liner for pulp protection in direct and indirect pulp capping.

Indications for use:

1. **Direct Pulp Capping :** ApaCal ART can be placed directly on dental pulp after achieving complete haemostasis.
2. **Indirect pulp capping :** ApaCal ART can be used as a pulp protective agent in deep cavities.
3. **Liner :** ApaCal ART can be used as an effective cavity liner under various restorations. ApaCal ART can protect the pulp from physical, chemical and thermal insults.

Instructions for use :

Direct Pulp Capping :

1. Ensure proper isolation under rubber dam.
2. Carious excavation must be thoroughly completed.
3. Complete haemostasis must be ensured using saline dampened cotton pellet.
4. Remove excess moisture using a dry cotton pellet.
5. Apply ApaCal ART without any void incorporation.
6. Avoid increments over 1mm.
7. Cure for 40 sec minimum using a visible light curing device.
8. Restore using an appropriate restorative material.

Indirect Pulp Capping, Liner :

1. Isolate the tooth using a rubber dam.
2. Ensure complete caries excavation.
3. Apply ApaCal ART uniformly over the base of the cavity.
4. Do not place ApaCal ART in increments exceeding 1 mm.
5. Cure using a visible light curing device.
6. Restore using an appropriate restorative material.

Warnings : ApaCal ART contains polymerizable methacrylate monomers. Avoid prolonged contact with skin and oral mucosa. Allergic reactions, skin rash and mucosal irritation may result in susceptible individuals. Avoid usage on adults with known methacrylate allergies.

Precautions:

1. Avoid placing ApaCal ART in wet environment. In case of pulp exposure, ensure hemostasis before placement.
2. Use of rubber dam is necessary for reliable results.
3. Avoid exposure to oral environment.
4. Avoid increments in excess of 1 mm.
5. Check expiry date before clinical use.
6. The dispensed material shall not be placed back in container and the dose once applied and used shall not be reused.

Contraindications: Do not use in patients if allergic to any of its components.

Storage Conditions : Store at temperature between 10°C(50°F) to 24°C(75°F). Close the cap carefully after use. Keep away from moisture. Shelf life not affected after opening if stored in a cool dry place.

Shelf Life : 3 years from the date of manufacturing.

Presentation :

Ref. 30001-1

Trial Pack : 1 x Syringe 2g, 5 x Applicator Tips.

Ref. 30001

Intro Pack : 2 x Syringe 2g, 10 x Applicator Tips.

Disposal conditions :

To be disposed off based on the prevailing rules of the country in which it is used.

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| Revision : | 09 |
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UDI Symbol for "UNIQUE DEVICE IDENTIFIER"

LOT Symbol for "BATCH CODE" Symbol for "USE-BY DATE" Symbol for "NON STERILE" Symbol for "KEEP DRY"

Symbol for "CAUTION" Symbol for "CONSULT INSTRUCTION FOR USE" REF Symbol for "CATALOGUE NUMBER"

EC REP Symbol for "AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY/EUROPEAN UNION"

Symbol for "KEEP OUT OF THE REACH OF CHILDREN" Symbol for "MANUFACTURER" Symbol for "DO NOT USE IF PACKAGE IS DAMAGE"

Symbol for "TEMPERATURE LIMIT" Symbol for "KEEP AWAY FROM SUNLIGHT" MD Symbol for "MEDICAL DEVICE"

The material has been developed solely for professional dental use. Application should be carried out strictly according to the instruction for use. Liability cannot be accepted for damages resulting from failure to observe the instructions of the stipulated area of applications. The user is responsible for testing the material for its suitability and use for any purpose not explicitly stated in this instruction sheet. Description and data constitute no warranty of attributes and are not binding. For feedback, complaints and reporting of unexpected events contact customer care.