IFU Size : 161 H x 104 W

COPAL-F

CAVITY VARNISH WITH FLUORIDE



Product Description:

Copal-F is a Copal Gum based protective varnish for the insulation of the exposed dentine. reduces penetration of fluids into the tooth and subsequent placed restoration. Addition of Sodium Fluoride provides a thermal barrier for deep restoration. Alleviates thermal sensitivity.

Composition: Copal-Gum, Sodium Fluoride and Solvent.

Intended Purpose/Intended Use: It is intended to be used as a cavity liner and to seal exposed dentinal tubules.

Indications for Use:

Copal-F is used for lining of cavities. It is also used as a sealant to protect the exposed surfaces of dentin in teeth prepared for restorations. It is used as an immediate varnish prior to insertion of amalgam or cement.

Instructions for Use:

Prepare the cavity. Put small quantity of cavity varnish on a cotton pellet / microbrush and apply on the inner walls of cavity. Allow to dry for 40 seconds. Re-apply another layer if necessary. Use a new cotton pellet / microbrush for each application. It is recommended that two thin layers be applied instead of one thick layer. The dispensed material shall not be placed back in container and the dose once applied and used shall not be reused.

Avoid prolonged or repeated contact with skin (allergic contact dermatitis), and eves, Avoid prolonged inhalation. Do not take internally. Contact with the skin may cause irritation, burns of hypersensitivity. If contact with skin occurs immediately wipe off thoroughly with cotton and alcohol and then wash well with soap and water. If skin rash and sensitization or other allergic reaction occurs discontinue the use and seek medical attention.

If the product comes into contact with the eyes, rinse thoroughly with fresh water and consult a physician. It should not be used with patients who have a history of severe allergic reaction to any of the components.

Precautions: Avoid contact with skin and eves.

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: 40027

1 x 15ml Glass Bottle, 1 x Dispensing Dropper

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

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Revision: Date: 23-05-2023

Symbol for "HARMFUL IRRITANT" Symbol for "FLAMMABLE" UDI Symbol for "UNIQUE DEVICE IDENTIFIER" Symbol for "BATCH CODE" Symbol for "USE-BY DATE" Symbol for "NON STERILE" Symbol for "KEEP DRY"

Symbol for "CAUTION" [i] Symbol for "CONSULT INSTRUCTION FOR USE" | REF | Symbol for "CATALOGUE NUMBER" ECIREP Symbol for "AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY/EUROPEAN UNION

Symbol for "DO NOT USE IF PACKAGE IS DAMAGE" Y Symbol for "KEEP OUT OF THE REACH OF CHILDREN" M Symbol for "MANUFACTURER" "Symbol for "TEMPERATURE LIMIT" 🌋 Symbol for "KEEP AWAY FROM SUNLIGHT" 🔟 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.