

IFU Size : 161 H x 104 W

BIOENAMEL

RE-MINERALIZING & DESENSITIZING GEL



Product Description : BioEnamel is a re-mineralizing gel which reduces post whitening sensitivity and effectively enhances the re-mineralization of the enamel.

Composition :

Remineralizing agent, Glycerine, Thickening agent and Flavouring agent.

Intended Purpose/Intended Use : It is intended to be used for remineralizing and de-sensitizing agent.

Indications for Use :

- ◆ Remineralization of de-mineralized tooth structure.
- ◆ Post whitening sensitivity.
- ◆ Sensitivity caused due to non-carious lesions and sensitivity after oral prophylaxis.

Instructions for Use :

1. Bio Enamel is presented in a convenient dispenser pen with paint on brush for easy application. The gel will be dispensed on the brush tip by gently rotating bottom of the pen clockwise. First time use requires additional rotations for the gel to appear on the brush tip.
2. Brush your teeth each time before applying BioEnamel. BioEnamel is more effective on clean teeth.
3. Apply a small amount of BioEnamel in a thin layer and cover the entire area under treatment.
4. Avoid lips from contacting teeth for 30 - 60 sec.
5. Leave the BioEnamel on the tooth surface and avoid rinsing, brushing your teeth for 4 to 6 hours.
6. Apply BioEnamel as often as needed.

The dispensed material shall not be placed back in container and the dose once applied and used shall not be reused.

Warnings : Avoid prolonged or repeated contact with skin (allergic contact dermatitis), and eyes. 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 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 :

Always close the pen with lid after use to avoid drying of the gel on the brush bristles.

Contraindications :

This product is contraindicated for use in or by individuals who have known hypersensitivity to any of the constituents of the products.

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.

Ref. 90012

Presentation :

1 x 2ml Dispensing Pen.

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

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UDI Symbol for "UNIQUE DEVICE IDENTIFIER"

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

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

EC REP Symbol for "AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY/EUROPEAN UNION" SINGLE PATIENT MULTIPLE USE Symbol for "SINGLE PATIENT MULTIPLE USE"

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

TEMPERATURE LIMIT Symbol for "TEMPERATURE LIMIT" KEEP AWAY FROM SUNLIGHT 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.