

BISCO

FluoroCal[™]

5% Sodium Fluoride Varnish with Tri-Calcium Phosphate

Instructions for Use



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Caution: U.S. Federal law restricts this device to sale by or on the order of a licensed Dentist.

GENERAL INFORMATION

FluoroCal is a fluoride & calcium releasing varnish with Tri-Calcium Phosphates (TCP) for application to enamel and dentin for the treatment of hypersensitive teeth. **FluoroCal** delivers targeted and sustained release of fluoride & calcium over 24 hours¹. This varnish penetrates and seals dentin tubules, providing immediate relief of sensitivity. Available in multiple flavors; sweetened with Xylitol.

Intended user: Licensed dentist.

Indications for Use:

1. Treats hypersensitive teeth
2. Treats exposed dentin and root sensitivity

Contraindications:

- Do not use on patients with ulcerative gingivitis and stomatitis.
- Do not use on patients with colophony allergy/sensitivity.

Cautions:

- **FluoroCal** is flammable. Do not use near open flame. Keep away from sources of ignition. Do not store large quantities in one area.
- Keep away from direct sunlight.
- If **FluoroCal** comes into contact with the eyes, flush with copious amounts of water and seek medical attention.
- Cross-contamination: Product contains items that are designed for one time use. Do not clean, disinfect or reuse.
- In case of contact with skin, clothes, table or floor, rinse with soap and water.

Precautions:

- In rare cases, the product may cause sensitivity in some people. If any such reactions are experienced, discontinue the use of the product and refer to a physician.
- When **FluoroCal** is applied, patients should not use other prescriptive fluoride treatment such as fluoride gels during the same day. The routine use of fluoride tablets by patients should be interrupted for several days after treatment.
- Protective eyewear should be worn by the patient and dental staff.
- See individual component labels for specific expiration dates.
- Safety data sheet available on request.
- Safety data sheet available at www.bisco.com.
- Instructions for Use available upon request.
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Adverse Reactions:

- Edematous swelling has been reported only in rare instances in some fluoride varnish products, especially after application to extensive surfaces. Although extremely rare, dyspnea has occurred in asthmatic children. Nausea has been reported when extensive applications have been made to patients with sensitive digestive systems. If required, **FluoroCal** can be removed by thoroughly brushing once set. Seek medical attention.

INSTRUCTIONS FOR USE

1. Clean the tooth surfaces (prophylaxis is not required). Open **FluoroCal** unit-dose package. To open, bend corner backwards on the end that is closest to the brush. Foil will separate from unit. Peel back foil and remove brush. Applicator brush is contained within.
2. Thoroughly mix **FluoroCal** with the applicator brush for at least 5 seconds.
3. Apply **FluoroCal** evenly in a thin layer over treatment area.
4. Dry the treated surfaces with air for 10 seconds. Patient should refrain from eating or drinking for at least 1 hour.

DISPOSAL: Dispose of used or contaminated units. Refer to community provisions relating to waste. In their absence, refer to national or regional provisions relating to waste.

STORAGE: Store at room temperature (20°C/68°F - 25°C/77°F). Store away from direct sunlight.

WARRANTY: BISCO, Inc. recognizes its responsibility to replace products if proven to be defective. BISCO, Inc. does not accept liability for any damages or loss, either direct or consequential, stemming from the use of or inability to use the products as described. Before using, it is the responsibility of the user to determine the suitability of the product for its intended use. The user assumes all risk and liability in connection therewith.

* FluoroCal is a trademark of BISCO, Inc.

¹As tested in deionized water.