

DuraShield[®]

5% SODIUM FLUORIDE CLEAR VARNISH *CV*

DIRECTIONS FOR USE

Manufactured for:



Sultan Healthcare
1301 Smile Way • York, PA 17404-0807 • USA
Toll Free: 800-637-8582 • Phone: 201-871-1232
Fax: 201-871-0321 • www.sultanhealthcare.com

MADE IN U.S.A.



0031103DF, R5-073114

Description

DuraShield[®] CV Fluoride Varnish is a topical dental desensitizing varnish containing 5% (w/w) sodium fluoride. It may be applied to exposed enamel, dentin and cementum to help relieve the symptoms associated with dental sensitivity.

Composition

DuraShield[®] CV contains 5% (w/w) sodium fluoride in an alcohol solution of synthetic resin and rosin. Each unit-dose package contains an average of 20 mg of sodium fluoride (NaF), equivalent to 9 mg fluoride ion.

Indications for Use

DuraShield[®] CV 5% Sodium Fluoride Varnish is indicated for sealing of dentinal tubules for the treatment of hypersensitive teeth and for sensitive root surfaces.

Contraindications

This product should not be used in individuals with known sensitivities to the components of this product. This product should not be used as a cavity liner, base or as a varnish under any permanent restoration. • Contraindicated for use on patients with:

- Ulcerative gingivitis or stomatitis
- Known sensitivity to colophony resin (or similar materials)

 • Not to be used as a systemic treatment

Warnings

- Do not intentionally misuse by swallowing the uncured material. Keep out of reach of children. For professional dental use only.
- Contains ingredients that may be irritating to the skin and eyes. Avoid contact with soft oral tissues, eyes, and skin.

Precautions

Use only as directed. Not for unsupervised home use. Avoid using more than one (1) unit dose package per patient per treatment. Discontinue use of other prescription fluorides (gels, foams, etc.) and fluoride supplements for 48 hours after treatment with *DuraShield[®] CV*. Safety and effectiveness below age 3 not established. No long term animal studies have been conducted for this product to evaluate carcinogenic, mutagenic, or impairment of fertility. Keep out of direct sunlight, store at room temperature 20°-25°C (68°-77°F).

Adverse Reactions

Reactions such as edematous swellings, dyspnea, eczema, atopic dermatitis, urticaria, gastric distress, headache, and weakness have occurred. Patients who have sensitive digestive systems may experience nausea. Developing teeth in children under 6 may permanently discolor if excessive amounts of this product are swallowed.

Step by Step Instructions

- 1) Tooth surfaces should be clean and free from obvious plaque and calculus.
- 2) Open the unit-dose package by peeling the foil away from the rigid container. The unit dose packaging can be held in a variety of ways. The tab attached to the well may be bent so that the package may be held between the fingers of the non-operating hand (Figure 1). It can also be held between the pointer finger and thumb (Figure 2) or be placed flat on a surface (Figure 3).

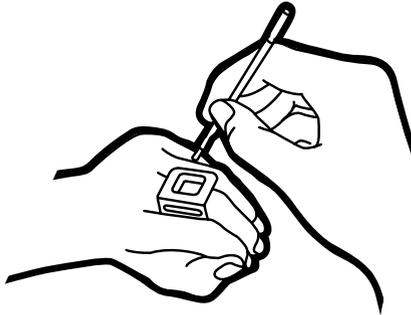


Figure 1

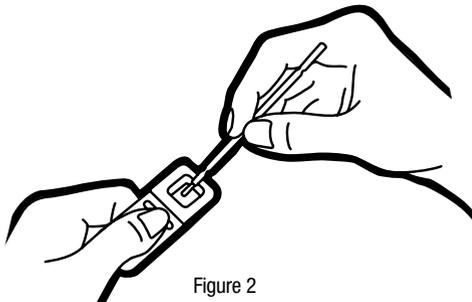


Figure 2

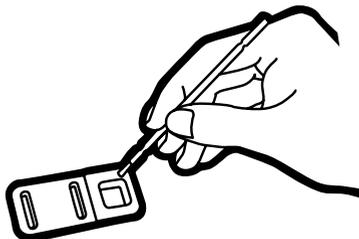


Figure 3

- 3) Using the supplied applicator brush, thoroughly mix the *DuraShield*[®] CV varnish until the appearance is even and streak-free. This step is important since the components of the product can separate during transportation and storage.
- 4) Pick up the varnish using the applicator brush and very quickly apply to the teeth using broad, even strokes. It is not necessary to attempt to smooth the varnish. Best results are obtained by using quick, broad and even brush strokes and not disturbing the varnish with the brush once it is applied to the tooth surface. Avoid contaminating the brush with moisture or saliva. *DuraShield*[®] CV is designed to set in a wet environment with the presence of normal amounts of saliva. In a case of excess saliva, blot it away with gauze.
- 5) Allow the patient to close. This will “set” the varnish. Best results are obtained if the varnish is allowed to sit undisturbed for 5-10 seconds before the patient closes.
- 6) *DuraShield*[®] CV should remain on the teeth for a minimum of two (2) hours and up to twelve (12) hours. The patient should avoid consuming hot liquids, alcohol or sticky foods during the initial 2 hour period. The patient will be able to feel the varnish on their teeth and it may be visible to the dental professional. The varnish coating should not be visible to others at a normal social distance.
- 7) *DuraShield*[®] CV can be removed after the treatment period by normal tooth brushing and flossing.
- 8) Distribute post-application instruction sheet to your patient to explain the details described in steps 6 and 7.

Storage

Store at normal room temperature 20°-25°C (68°-77°F).

NOTE: Due to the nature of the ingredients in this product, a color shift may occur over time in an unopened package. As long as the product is within stated expiration date, the product performance should not be effected.

DuraShield[®]
5% SODIUM FLUORIDE CLEAR VARNISH CV

Sultan
SultanHealthcare