

VELLA™ 5% Sodium Fluoride Varnish (22600ppm Fluoride Ion)

Caution: U.S. Federal Law restricts this device to sale by or on the order of a medical or dental professional.

VELLA™ Varnish is a 5% sodium fluoride varnish for application to enamel or dentin for the treatment of dental hypersensitivity and for use as a cavity varnish. 1 mL of VELLA contains 50 mg of sodium fluoride (22.6 fluoride ion). VELLA is tolerant of moisture and saliva and will adhere to moist surfaces.

Indications for Use: Dentinal hypersensitivity and cavity varnish.

Contraindications: Ulcerative gingivitis, stomatitis.

Precautions: For 24 hours post treatment with VELLA, other fluorides such as gels, foams, and rinses should not be administered. The patient should discontinue use of fluoride tablets for 2-3 days following treatment.

Warnings: Edematous swelling has been reported only in rare instances, especially following application to extensive surfaces with fluoride varnish. Dyspnea, although extremely rare, has occurred in asthmatic people. Nausea can occur in patients with known sensitive digestive systems, especially following extensive applications.

Administration: For the treatment of dentin hypersensitivity, in most cases, two applications at several days interval are sufficient. The fluoride content of VELLA Varnish is such that neither acute nor chronic side effects are to be expected if applied according to instructions.

MSDS: To obtain MSDS visit, www.preventech.com or call Preventech at 1-800-474-8681.

VELLA™ Varnish Instructions for Use

- For optimum results, prior to applying VELLA lightly dry excessive saliva with air or by rubbing with a 2 x 2 gauze along the tooth surface. If biofilm or calculus is present, a prophylaxis can be conducted using nada™ Pumice Paste.
- 2. Gently peel open the foil sealing material starting from the unsealed tab on the left side. Lift straight up to avoid ripping.
- 3. Remove the applicator brush and use the bristle end to thoroughly mix VELLA until it reaches a uniform consistency.
- 4. Apply a thin coat of **VELLA** evenly to all of the desired tooth surfaces.
- 5. Let VELLA dry for approximately 20 seconds and then instruct the patient to close their mouth.
- 6. VELLA hardens on contact with saliva so the patient may leave immediately after the application.
- Instruct the patient to allow VELLA to remain in contact with the tooth surface for a minimum of four hours
 after treatment (treatment period is approximately 4-6 hours). For maximum fluoride uptake, VELLA can
 remain on the teeth overnight and brushed off the next morning.
- 8. It is recommended that the patient be instructed (see Patient Instructions) to only eat soft foods and drink cold liquids for two hours after VELLA treatment. Eating hard foods and brushing/flossing should be avoided during the treatment period.



Preventive Technologies, Inc.

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