

Caution: United States Federal law restricts this device for sale by, or on the order of, a licensed healthcare professional.

Description:

NUPRO® Sodium Fluoride White Varnish contains 5% sodium fluoride. The ideal application is for relief of dentinal hypersensitivity.

Composition:

1ml of fluoride varnish suspension contains 50 mg sodium fluoride, equivalent to 22.6 mg fluoride in a base of alcohol, rosin, and resin. Flavor added. Each 0.4 g patient dose cup contains 20 mg of sodium fluoride equivalent to 9 mg fluoride ion. Each 0.25 g patient dose cup contains 12.5 mg of sodium fluoride equivalent to 5.7 mg fluoride ion.

Medicinal Ingredients: 5% sodium fluoride (2.26% fluoride ion)

Non-Medicinal Ingredients: Urethane Dimethacrylate, Hydrogenated Rosin, Alcohol, natural and artificial flavors, Titanium Dioxide, Sucralose

Indications for Use:

NUPRO® 5% Sodium Fluoride White Varnish is indicated for sealing of dentinal tubules for the treatment of hypersensitive teeth, sensitive root surfaces and for cavity preparations.

Contraindications:

- Contraindicated for use with patients with:
 - Ulcerative gingivitis or stomatitis.
 - Known sensitivity to colophony (kolophonium, rosin, or resembling agents).
- Not to be used as a systemic treatment.

Warnings:

- Fluoride varnish contains ingredients that may be irritating to the skin and eyes. Avoid contact with soft oral tissues, eyes and skin. If contact with soft oral tissue occurs, remove by gentle brushing. If accidental contact with eyes occurs, flush affected area with generous amounts of water and seek medical attention. If accidental contact with skin occurs, wash immediately with soap and water.
- Caution: Flammable. See MSDS.
- Keep out of reach of children.

Precautions:

- For healthcare professional use only. Safety and effectiveness below age 3 have not been established. There have been no long-term animal studies with this product to evaluate carcinogenic, mutagenic, or impairment of fertility potential.
- For single use only. This risk of reuse of product for another patient could result in cross-contamination.
- Wear disposable gloves when handling product.



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Adverse Reactions:

- Edematous swellings have been reported in rare instances after application to extensive surfaces.
- Dyspnea (difficulty or labored breathing) associated with asthmatic children, has been reported in unique situations.
- Patients having sensitive digestive systems may experience nausea, usually after prolonged treatment. If needed, the varnish can easily be removed by toothbrushing and rinsing.
- Developing teeth of children under age 6 may become permanently discolored if excessive amounts are repeatedly swallowed.
- The following adverse reactions are possible in individuals hypersensitive to fluoride: eczema, atopic dermatitis, urticaria, gastric distress, headache, and weakness.

Recommended Application:

- Treatment of patients requiring limited coverage: Use approximately 0.25 g of NUPRO White Varnish.
- It is not necessary to use all the varnish provided. Use only enough varnish to form a thin film on the desired treatment area, taking into consideration the weight of the patient and the number of teeth being treated.
- Please consult your local authority's recommendation for guidance on the amount of fluoride to be used for specific patients.

Step-by-Step Instructions:

1. For best results, clean surfaces to be treated with NUPRO® Prophylaxis Paste. Rinse well with water.
2. Peel off foil lid. Choose a holding position that is most comfortable for you.
3. Mix thoroughly with applicator brush. Paint a thin layer of FLUORIDE VARNISH directly on to teeth using applicator brush provided.
4. Allow treated area to become wet either by gentle rinsing or natural salivary flow.
5. Dispose of the patient dose cup after treatment.
6. Instruct patient to remain on a soft-food diet, avoid mouth rinses containing fluoride or alcohol, avoid brushing or flossing treated area for at least **2 hours** after treatment. Inform your patient that the fluoride varnish may begin to gradually slough off the tooth surface after treatment. Varnish can also be removed after 2 hours by brushing and flossing.
7. Apply fluoride varnish to patients every 3-6 months as needed.

NUPRO® Prophy Grip Sterilization:

The NUPRO Prophy Grip Prophy Paste Holder can be sterilized utilizing the following procedure:

- Place the holder in a paper or paper/plastic steam sterilization pouch. Place the paper side up when using a paper/plastic pouch.
- Place the bagged holder into the steam autoclave. After warm-up is completed, operate at a sterilizing temperature and pressure of 273°F/31psi (134°C/216 kPa) for 12 minutes, followed by a 20-30 minute drying time. To maintain sterility, the holder should remain in the sealed pouch until ready for use.
- The holder can also be sterilized in an autoclave unbagged at the same temperature and pressure stated above for 3 minutes, followed by a 20-30 minute drying time. The holder should be used immediately.

Storage:

- Keep out of direct sunlight, store at room temperature: 5-25°C (41-77°F).
- Keep dry.

Expiration Date and Lot Number:

- The ReOrder Number, Lot Number and Expiration Date should be referenced in all correspondence requiring identification of the product.
- Do not use after expiration date.

For questions or comments about this or any DENTSPLY Professional product, call 1-800-989-8826 or visit our website at www.dentsply.com.



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