

Product Description

NovaBright™ 5% Sodium Fluoride Varnish is a topical treatment for application to enamel and dentine for the treatment of hypersensitive teeth. 1mL of NovaBright contains 50 mg of sodium fluoride, which is equivalent to 22.6 mg of fluorine in an alcohol-based suspension of resins. The product is sweetened with xylitol.

INDICATIONS FOR USE

NovaBright™ 5% Sodium Fluoride Varnish is a fluoride containing preparation for use as a cavity varnish and for the treatment of dentin hypersensitivity.

CONTRADICTIONS

1. Known allergic reactions to fluoride.
2. Ulcerative gingivitis and stomatitis.
3. Avoid ingestion during application.
4. Known allergies to colophony or similar rosin materials.

PRECAUTIONARY INFORMATION FOR DENTAL PERSONNEL

Use only as directed. To limit ingestion, determine the proper dosage amount for the patient. Discontinue patient's use of other prescriptive fluoride preparations (i.e. gels, rinses) for 24 hours. Patients taking fluoride supplements should discontinue use of supplements for 2-3 days following treatment. Store at a controlled room temperature. Keep away from open flame and direct sunlight.

WARNING

Contains ingredients that may be irritating to the skin and eyes. 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.

Customer Information - No person is authorized to provide any information which deviates from the information provided in this instruction sheet.

Please Note: Due to the nature of the ingredients inside this product, a color change and/or separation of materials may occur over time in an unopened **NovaBright™** 5% Sodium Fluoride Varnish unit-dose. The product performance should not be affected if used within the stated expiration date.

Directions for Use

1. Clean teeth and remove obvious plaque and calculus from area to be treated. For best results, remove any excess moisture from the tooth surface.
2. Open the unit-dose of **NovaBright™** 5% Sodium Fluoride Varnish by gripping the rigid tray and slowly peeling back the foil cover, exposing the brush applicator and varnish well.
3. Remove applicator brush and thoroughly stir the **NovaBright™** 5% Sodium Fluoride Varnish in the well until the varnish appears to be uniformly mixed.
4. Paint a thin layer of varnish onto treatment area using broad and even strokes.
5. Let the varnish dry for approximately 10 seconds and then instruct the patient to close their mouth.
6. When dry, any excess varnish may appear "spotty" and may slide off the tooth surface. This will not affect the efficacy of the product as there is still a full layer of varnish on the tooth.
7. Dispose package and applicator after use.
8. Patient may leave immediately after treatment. Patient should be advised to not brush teeth for a minimum of 2 to 4 hrs.

STORAGE

Store at a controlled room temperature. Keep away from open flame and direct sunlight.

WARRANTY

Nanova Biomaterials, Inc. warrants this product will be free from defects in material and manufacture. User is responsible for determining the suitability of the product for user's application. If this product is defective within the warranty period, your exclusive remedy and Nanova Biomaterials, Inc.'s

sole obligation shall be repair or replacement of the Nanova Biomaterials, Inc. product.

LIMITATION OF LIABILITY

Except where prohibited by law, Nanova Biomaterials, Inc. will not be liable for any loss or damage arising from this product, whether direct, indirect, special, incidental or consequential, regardless of the theory asserted, including warranty, contract, negligence or strict liability.

Caution: Federal US law restricts this device to sale by or on the order of a dental professional