premier.) Premier[®] Tastytooth[®] Varnish

5% Sodium Fluoride Varnish

Description:

Tastytooth® 5% Sodium Fluoride Varnish is a fluoride-containing preparation for the treatment of dentinal hypersensitivity, and for the reduction of post-operative sensitivity. ImL of varnish contains 50mg of sodium fluoride, equivalent to 22.6mg fluoride ion. Tastytooth Varnish is sweetened with sucralose and xylitol, and flavored. Varnish is packaged in a molded opaque acclar tray and sealed with a metalized foil. Applicator is bulk packed in a sealed plastic container.

Indications for use:

Tastytooth Varnish is a fluoride-containing preparation for the treatment of dentinal hypersensitivity and for the reduction of post-operative sensitivity.

Dosage:

For the treatment of dentin hypersensitivity, generally, two applications at several days' interval are sufficient for effective treatment. The fluoride content of Tastytooth Varnish is dosed in such a way that neither acute nor chronic side effects are to be expected if applied according to instructions.

Directions for separating single unit-dose from strip:

- 1. Hold strip in your hand and bend one unit completely in one direction.
- 2. Bend same unit completely in the opposite direction.
- 3. Bend the same unit completely in the opposite direction again until the unit breaks or snaps apart from the strip.

Directions for use:

- A "pre-treatment" prophylaxis cleaning and polishing are not necessary before varnish application; however, treated area should be free of excessive plaque build-up.
- Peel off the foil top of the unit-dose container to expose the varnish. Stir varnish with applicator brush. Mix thoroughly as some phase separation of varnish components may occur during storage.
- Apply a very thin coat of varnish evenly to the surface being treated. One or two brush loads of varnish may be satisfactory for an entire quadrant when used for routine application in recall visits.

To limit ingestion, determine the proper application amount for the patient.

Age appropriate application recommendations:

Patients with primary dentition or treatment requiring limited tooth surface coverage

· Restrict amount between 1 to 2 brush loads per quadrant for coverage

Patients with mixed dentition or extensive tooth surface coverage

- · More than a few brush loads per quadrant for treatment
- \cdot Do not use this amount for patients with primary dentition only

Patients with permanent dentition who require extensive tooth surface coverage

- \cdot More than a few brush loads per quadrant for treatment
- \cdot Do not use this amount for patients with primary dentition only
- 4. Tastytooth Varnish hardens on contact with saliva and/or water. The patient may leave immediately following application of the product. (Post-treatment patient care instructions are available for download at premierdentalco.com)
- 5. Instruct patient to avoid hard food and hot beverages for the next 2 hours and avoid brushing and flossing for 4 hours after application.

Note:

Tastytooth Varnish also covers moist teeth with a coating of protective film for several hours; however, it is best to avoid applying the varnish over excessive saliva. It is recommended that patient be instructed to eat only soft foods for two hours after treatment with varnish. Longer contact time provides greater

protection. Patient should avoid brushing the treated teeth for four hours after application. Alcoholic beverages, mouthwashes or rinses containing alcohol can accelerate the dissolution of the varnish and also should be avoided for at least four hours after application.

Contraindications:

Ulcerative gingivitis, stomatitis, known sensitivity to colophony (kolophonium), rosin or similar agents. Direct ingestion should be avoided. Not for systemic treatment.

Interactions:

When Tastytooth Varnish is applied, other fluoride preparations such as fluoride gels should not be administered during the same day. The routine use of fluoride tablets should be interrupted for 2-3 days after treatment.

Adverse reactions:

Edematous swelling has been reported only in rare instances in some fluoride varnish products, especially after application to extensive surfaces. Dyspnea, although extremely rare, has occurred in asthmatic people. Nausea has been reported when extensive applications have been made. If required, varnish film can be removed with a thorough brushing.

Supplied:

Single-dose packages of 5% NaF varnish in 0.5mL unit-dose containers in Caramel, Bubblegum and Melon flavor. Applicator brush packaged in bulk container of 100.

Caution:

Federal (U.S.A.) Law restricts the use of this device for sale by or on the order of a medical or dental professional. For use in the oral cavity.

Storage and disposal:

Keep out of direct sunlight, store at a controlled room temperature: 68°F -77 °F (20°C -25 °C). Do not use after expiration date. See the Safety Data Sheet (available at premierdentalco.com or through your local subsidiary).

Warranty and limitation of liability

Premier Dental Products Company ("Company") warrants that the Product will be free from defects in material and manufacture. Company makes no other warranties. In particular, and without limitation, Company makes no warranty, implied or otherwise, as to the Product's merchantability or fitness for any particular purpose.

For any patient on whom use of the Product is contemplated, User is solely responsible for determining whether the Product is suitable for such use according to the information set forth in the enclosed directions for use.

If the Product is defective within the warranty period, the sole remedy available to User, and the sole obligation of Company, shall be the Product's repair or replacement.

Unless otherwise required by law, Company will not be liable for any loss or damage arising from this Product or its use, whether such loss or damage is direct, indirect, special, incidental or consequential, and regardless of the theory of loss or damage asserted (which theories include, without limitation, warranty, contract, negligence and strict liability).

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To obtain an SDS, visit premierdentalco.com or call Premier customer service at 610-239-6000.



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