



5% SODIUM FLUORIDE VARNISH

Instructions For Use: Zooby Varnish

1. Peel open the foil lidding material starting from the unsealed tab.
2. For best results, dry teeth prior to application.
3. Apply a very thin coat of varnish evenly to all desired tooth surfaces.
4. Let the varnish dry for approximately 10 seconds and then instruct the patient to close their mouth.
5. Varnish hardens on contact with saliva, so the patient may leave immediately after application.
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. It is recommended that the patient be instructed to only eat soft foods and drink cold liquids for two hours after treatment. After six hours, the patient may consume hot drinks or alcohol (mouth rinses) and may brush or floss.

INDICATIONS: Zooby 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 dentinal hypersensitivity, two applications at several days' interval are sufficient in most cases. The fluoride content of Zooby Varnish is dosed in such a way that neither acute nor chronic side effects are to be expected if applied according to instructions. 1mL of varnish contains 50 mg of sodium fluoride, equivalent to 22.6 mg fluoride ion. Varnish is sweetened with sucralose and xylitol.

CONTRAINDICATIONS: Ulcerative gingivitis and stomatitis.

INTERACTIONS: When Zooby 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 several days after treatment.

ADVERSE REACTIONS: Edematous swellings have 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 children. Nausea has been reported when extensive applications have been made. If required, varnish film can be removed with a thorough brushing.

Hypersensitivity or allergic reactions may occur. If signs of an allergic reaction develop, discontinue use and seek appropriate medical attention.

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

 **Warning:** Avoid contact with eyes and skin. If contact occurs, flush immediately with plenty of water and consult a physician.

REF 295712

REF 295713

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Keep out of reach of children and do not store together with food.

Store at room temperature.

Refer to the Safety Data Sheet, available at www.younginnovations.com/resources, for additional information. For emergencies, contact INFOTRAC at 1-800-535-5053.

Rx ONLY Caution: Federal Law restricts this device to sale by or on the order of a dental professional.

2 SINGLE USE ONLY **MD** MEDICAL DEVICE

YOUNG
INNOVATIONS

 Manufactured by:
Young Dental Manufacturing Co.
13705 Shoreline Court East
Earth City, MO 63045
(800) 325-1881 • www.younginnovations.com

 15°C 59°F 30°C 86°F
**STORE BETWEEN
59 AND 86°F
(15 AND 30°C)**

Symbol	Description	Symbol	Description
REF	Product reference number		Manufacturer
	Temperature Limitation		Single Use Only
	Country of Origin		Importer
	Use By Date	LOT	Batch or lot code
CE	CE Marking Conformity		Caution
EU REP	Authorized Representative in the European Community	CH REP	Swiss Authorized Representative
UDI	Unique Device Identifier		Consult instructions for use
Rx ONLY	Caution: Federal Law restricts this device to sale by or on the order of a dentist	MD	Medical Device

CE
0297

EU REP
MDSS GmbH
Schiffgraben 41
30175 Hannover
Germany



Young Microbrush Ireland Ltd.
Clogherane, Dungarvan
Co. Waterford
X35 VE02, Ireland

Made in the USA



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