

V-*varnish*[™] Premium

Cavity Varnish



Instruction for Use

VERICOM CO., LTD.

Dental Materials

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Eng

Description

V-*varnish*[™] Premium is cavity varnish containing 5% sodium fluoride (F ion: 22,600ppm). It is applied to teeth for the purpose of dentinal hypersensitivity treatment. V-*varnish*[™] Premium consists of rosin which adheres to the surface of the teeth, seals exposed dentin tubules. V-*varnish*[™] Premium has four flavors such as bubblegum, strawberry, melon and mint and two colors (clear and white). It is packed in single dose package allows easy mixing and application.

Composition

- Rosin
- Sodium Fluoride
- Ethanol
- Xylitol
- TCP

Indications

For treatment of dentinal hypersensitivity secondary exposed dentin and root surface, through the precipitate formed by sodium fluoride and tricalcium phosphate deposit in dentin tubule and precede a physical barrier.

Contra-Indications

1. Do not use on patients with ulcerative gingivitis or stomatitis.
2. If patients are known to be allergic to ingredients including fluoride, rosin or similar materials, V-*varnish*[™] Premium should not be used.

Recommended Procedure

1. Thoroughly clean the teeth and remove excess moisture with cotton rolls and air.
2. Peel back the foil cover until the well containing V-*varnish*[™] Premium is exposed.
3. Mix V-*varnish*[™] Premium using a brush thoroughly.
4. Apply V-*varnish*[™] Premium thinly with a brush.
5. It is recommended to remain V-*varnish*[™] Premium on the teeth surface as long as possible at least 4hours.

Precautions

1. It should be used by a dentist and dental professional. Observe the procedure and the precautions.
2. Keep it away from a reach of non-dental users including children, old people and others.
3. Avoid contact with soft oral tissues, eyes and skin. If contact with soft oral tissue occurs, remove by gentle brushing. If contact with eyes or skin occurs, flush immediately with a large amount of water.
4. After the application of V-*varnish*[™] Premium, patients should avoid chewing hard food, drinking liquids containing alcohol and brushing for 4 to 6 hours.
5. To avoid ingestion, use only enough varnish to form a thin coating on the desired treatment area. If patient swallows the unintended

- fluoride varnish, it may occur the gastric irritation and should be consulted a doctor immediately.
6. Do not get other fluoride treatments on the same day. Also refrain from using fluoride supplements and rinses for several days after treatment.
7. Using protective gloves and protective eyeglass are recommended.
8. Do not use if the package is damaged.
9. Dispose the remained materials after using V-*varnish*[™] Premium because it is a single dose package.
10. Do not use after expiry date. (Shelf life: 2 years)

Dosage

Intended use population of V-*varnish*[™] Premium is both children (from ages 6 months to 16 years) and adults.

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. (When used once, maximum capacity is 0.4ml)

The application of V-*varnish*[™] Premium is usually repeated every 6 months. But, if more treatment is needed, it could be applications every 3 months. The patient should not brush the teeth or chew food for 4 hours after treatment.

Please consult your local authority's recommended for guidance on the amount of fluoride to be used for specific patients.

Warning

1. Edematous swelling or Nausea 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. If required, extensive applied varnish can be removed with a thorough brushing.
2. Recommended to avoid its use in pregnant women and during lactation.

Storage

1. Do not store at elevated temperature or intense light.
2. Keep out of direct sunlight, store at room temperature.

Disposal

Disposal of contents/container in accordance with applicable local/regional/national/international regulations.

Warranty

VERICOM CO., LTD. will replace product that is proven to be defective. VERICOM CO., LTD. does not accept liability for any damage or loss, direct or consequential, stemming from the use of or inability to use the product described. Before using, it is the responsibility of the user to determine the suitability of the product for its intended use. The user assumes all risk and liability in connection therewith.



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Package

One unit dose package contains 0,4ml

Model Name	Product code	Number of unit-dose	Color/Flavor
V-varnish™ Premium Clear Bubblegum	VP320-S00B	50 single-unit-dose application sticks(1 stick: 0,4ml varnish + 1ea brush)	Clear/Bubblegum
	VP380-S00B	200 single-unit-dose application sticks(1 stick: 0,4ml varnish + 1ea brush)	
	VP340-U00B	100 unit-dose(0,4ml varnish) + 100ea brushes	
V-varnish™ Premium Clear Strawberry	VP320-S00S	50 single-unit-dose application sticks(1 stick: 0,4ml varnish + 1ea brush)	Clear/Strawberry
	VP380-S00S	200 single-unit-dose application sticks(1 stick: 0,4ml varnish + 1ea brush)	
	VP340-U00S	100 unit-dose(0,4ml varnish) + 100ea brushes	
V-varnish™ Premium Clear Melon	VP320-S00M	50 single-unit-dose application sticks(1 stick: 0,4ml varnish + 1ea brush)	Clear/Melon
	VP380-S00M	200 single-unit-dose application sticks(1 stick: 0,4ml varnish + 1ea brush)	
	VP340-U0MN	100 unit-dose(0,4ml varnish) + 100ea brushes	
V-varnish™ Premium Clear Mint	VP320-S00T	50 single-unit-dose application sticks(1 stick: 0,4ml varnish + 1ea brush)	Clear/Mint
	VP380-S00T	200 single-unit-dose application sticks(1 stick: 0,4ml varnish + 1ea brush)	
	VP340-U0MT	100 unit-dose(0,4ml varnish) + 100ea brushes	
V-varnish™ Premium White Bubblegum	VP320-S0WB	50 single-unit-dose application sticks(1 stick: 0,4ml varnish + 1ea brush)	White/Bubblegum
	VP380-S0WB	200 single-unit-dose application sticks(1 stick: 0,4ml varnish + 1ea brush)	
	VP340-U0WB	100 unit-dose(0,4ml varnish) + 100ea brushes	
V-varnish™ Premium White Strawberry	VP320-S0WS	50 single-unit-dose application sticks(1 stick: 0,4ml varnish + 1ea brush)	White/Strawberry
	VP380-S0WS	200 single-unit-dose application sticks(1 stick: 0,4ml varnish + 1ea brush)	
	VP340-U0WS	100 unit-dose(0,4ml varnish) + 100ea brushes	
V-varnish™ Premium White Melon	VP320-S0WM	50 single-unit-dose application sticks(1 stick: 0,4ml varnish + 1ea brush)	White/Melon
	VP380-S0WM	200 single-unit-dose application sticks(1 stick: 0,4ml varnish + 1ea brush)	
	VP340-U0WN	100 unit-dose(0,4ml varnish) + 100ea brushes	
V-varnish™ Premium White Mint	VP320-S0WT	50 single-unit-dose application sticks(1 stick: 0,4ml varnish + 1ea brush)	White/Mint
	VP380-S0WT	200 single-unit-dose application sticks(1 stick: 0,4ml varnish + 1ea brush)	
	VP340-U0WT	100 unit-dose(0,4ml varnish) + 100ea brushes	

Symbols

Symbol Title	Symbol	Description of Symbol
Manufacturer		Indicates the medical device manufacturer, as defined in EU directives 90/385/EEC, 93/42/EEC and 98/79/EC
Use-by date		Indicates the data after which the medical device is not to be used.
Authorized representative in the European Community		Indicates the authorized representative in the European Community.
Batch code		Indicates the manufacturer's batch code so that the batch or lot can be identified.
Catalogue number		Indicates the manufacturer's catalogue number so that the medical device can be identified.
Temperature limit		Indicates the temperature limits to which the medical device can be safely exposed.
Do not re-use		Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
Caution		Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
Consult instructions for use		Indicates the need for the user to consult the instructions for use.
Date of manufacture		Indicates the date when the medical device was manufactured.