

Clinpro™

5% Sodium Fluoride White Varnish
with Tri-Calcium Phosphate



Technical Product Profile



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Introduction

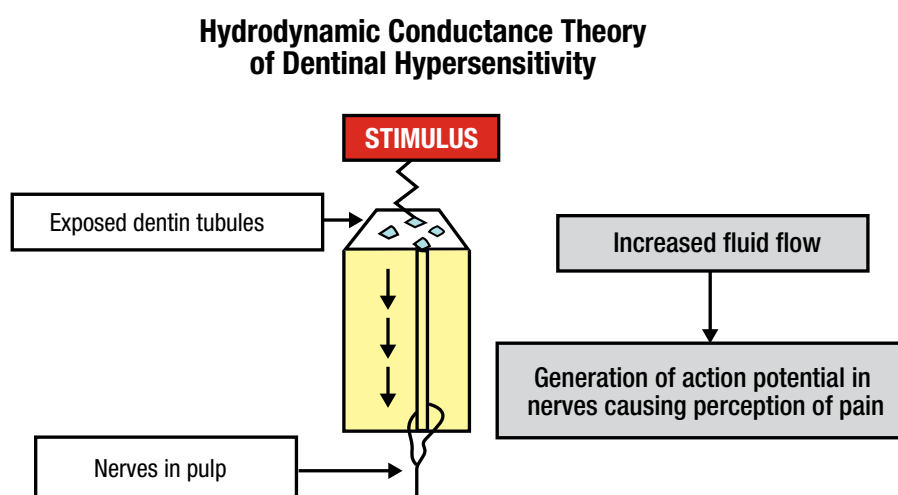
Dental varnish containing fluoride is recognized as an effective agent in the treatment of dentinal hypersensitivity.^{1,2,3} Varnish consists of rosin which adheres to the surface of the teeth, seals exposed dentin tubules, and slowly releases fluoride ions. Fluoride reacts with calcium to form insoluble globules of calcium fluoride. These globules deposit on tooth surfaces to provide additional blockage of exposed dentin tubules.

Ideally, patients have sufficient calcium in the saliva to react with fluoride; however, this may not be true in all patients. Factors affecting salivary components and flow include medications, age, gender, diet, health, genetics and salivary gland function.^{4,5,6,7} Decreased salivary calcium limits the formation of calcium fluoride. Dental products that provide both fluoride and calcium may help to increase formation of calcium fluoride on tooth surfaces including dentinal tubules.

Overview of dentinal hypersensitivity

Dentinal hypersensitivity is common but is under-reported to the dentist because the pain from sensitivity is often transient. Studies show that the prevalence of dentinal hypersensitivity may be as high as 57%.^{8,9,10}

Hypersensitivity often occurs when root dentin is exposed due to gingival recession. Dentin contains fluid-filled channels, or tubules. The fluid within the exposed tubules moves when stimulated by touch, temperature, chemicals, or osmotic changes. The movement of fluid and the transmission of ions creates pressure on the nerves in the pulp, resulting in the perception of pain. This is referred to as the hydrodynamic conductance theory. The theory was first reported by Gysi in 1900 and was studied and corroborated in the 1950s and 1960s.^{11,12,13} The hydrodynamic conductance theory remains the most widely accepted mechanism of dentinal hypersensitivity to date.



Treatment of dentinal hypersensitivity

There are two common methods to treat dentinal hypersensitivity:

1. Interfere with the signal transmission at the nerve endings
2. Reduce the movement of fluid within the tubules

Interfering with signals

Nerves transmit signals by exchanging potassium ions inside the nerve with sodium ions outside the nerve. By adding potassium outside the nerve, the nerve is unable to make the sodium/potassium exchange. Tooth sensitivity, and thus pain, can be reduced by blocking the nerve endings with potassium nitrate.¹⁴ While this approach may be effective, potassium nitrate toothpastes often require daily use to provide relief. In addition, the use of potassium nitrate to reduce sensitivity does not address the cause of the problem which is the change in pressure of fluid flow against the nerves.

Reducing fluid movement

The transmission of stimuli through the fluid in the dentin tubules can be reduced by occluding the tubules. This can be accomplished by applying either an immediate or a long-lasting barrier, or a combination of the two, over the dentin surface and within the tubules.

Immediate occlusion of tubules

A physical barrier applied to the surface of the tooth immediately blocks the opening of the dentin tubules. If the physical barrier is somewhat viscous, it will flow into the dentin tubules to further inhibit the movement of fluid against the nerve endings. A number of products including varnishes have been tested for their ability to form a barrier over and into dentin tubules to reduce sensitivity.¹⁵

Sustained occlusion of tubules

Another method to prevent fluid flow within dentinal tubules is to create an insoluble compound within the tubules. The agents used today in the treatment of hypersensitivity include fluoride and calcium phosphate.¹⁵ Fluoride is known to decrease the permeability of dentin by combining with calcium from the saliva or from dental products.² The combination of fluoride and calcium forms an insoluble precipitate that collects within the dentinal tubules. This blocks the transmission of ions in solution and decreases dentinal hypersensitivity.

Combined methods of tubule occlusion

A combination barrier provides both immediate and sustained occlusion of dentinal tubules. Dental varnish containing fluoride and calcium phosphate is an example of a combination barrier. The rosin in the varnish creates an immediate barrier, while the fluoride and calcium create a longer-lasting barrier.

The idea of using a natural rosin varnish to introduce sodium fluoride to teeth was first mentioned in 1964.¹⁶ Clinical trials showed that fluoride varnish decreased dentinal hypersensitivity.^{1,17} The mechanism by which varnishes decrease sensitivity is believed to be a combination of immediate (rosin) and sustained (insoluble calcium fluoride) barriers.

Various studies support the anti-hypersensitivity benefit of varnish.^{17,18,19,20,21} Ritter, et al., demonstrated that fluoride varnish was effective in reducing cervical dentin hypersensitivity at 2, 8 and 24 weeks after application. Hansen reported a cumulative success rate of 41% after 1 year.

Product Description

3M™ ESPE™ Clinpro™ 5% Sodium Fluoride White Varnish is a fluoride-containing varnish with a calcium phosphate ingredient for application to enamel and dentin. The product is saliva-activated; it will adhere to dry or moist teeth and will spread after application. Clinpro White Varnish is virtually invisible when applied to the teeth. The patented formula contains a modified rosin which migrates to tooth surfaces, including surfaces that may be difficult to reach.

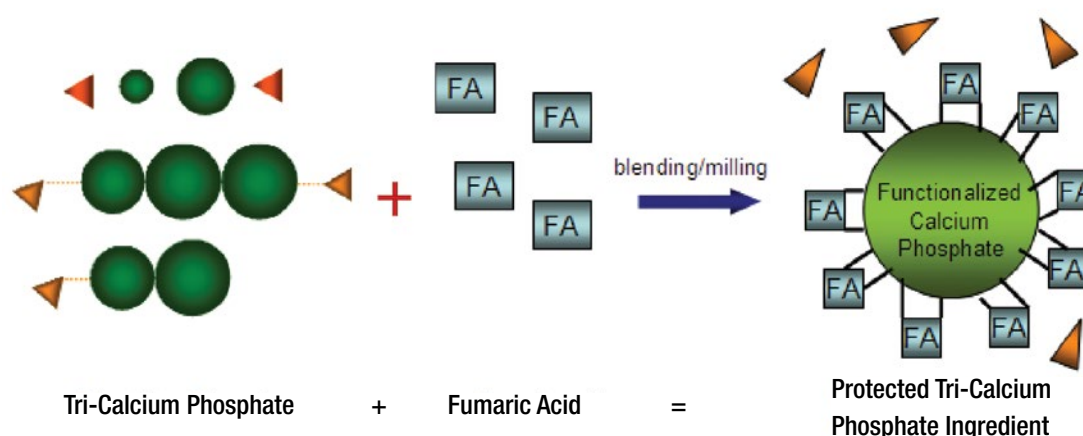
Indications

Clinpro White Varnish is a coating that contains fluoride, calcium and phosphate. It is indicated to treat hypersensitive teeth and exposed dentin and root surface sensitivity.

Composition

Clinpro White Varnish contains 5% sodium fluoride and an innovative tri-calcium phosphate ingredient which is sold exclusively through 3M ESPE. The varnish is an alcohol-based solution of modified rosin. Clinpro White Varnish is sweetened with xylitol and is available in mint flavor. Melon flavor is also available in the 500-pack. The product is supplied in unit-dose packages containing 0.5 ml of Clinpro White Varnish. Each 0.5 ml dose contains 25 mg sodium fluoride equivalent to 11.3 mg fluoride ion.

The tri-calcium phosphate in Clinpro White Varnish is unique. This innovative ingredient is prepared by combining tri-calcium phosphate with fumaric acid. The result is free phosphate and functionalized calcium oxide protected by fumaric acid.²² Similar tri-calcium-based materials and their successful incorporation into topically applied oral hygiene products have been described in detail by Karlinsey and Mackey.²³



The calcium, protected by fumaric acid, does not interact with the fluoride in Clinpro White Varnish until the product is applied to the teeth.

Unlike conventional varnishes, Clinpro™ 5% Sodium Fluoride White Varnish contains a modified rosin that is white or tooth colored. After Clinpro White Varnish is applied to the teeth, the product is virtually invisible. Patients find the appearance of Clinpro White Varnish to be highly acceptable. The natural tooth color of the product allows patients to return to their normal daily activities immediately after product application, without concerns about the appearance of varnish on their teeth.

Source:
3M ESPE internal data



Conventional rosin varnish on tooth



Clinpro™ White Varnish on tooth

Evaluations

Clinpro White Varnish creates a barrier that provides immediate and sustained occlusion of dentinal tubules.

Immediate occlusion

The modified rosin in Clinpro White Varnish covers, occludes and penetrates dentinal tubules to prevent the flow of fluid in the tubules. After application, the rosin quickly covers and flows into dentin tubules. The rosin slowly hardens to a lacquer-like state.

Scanning Electron Microscopy (SEM)

Methodology

Samples of bovine dentin were prepared for examination by SEM. The teeth were partially embedded in acrylic discs and ground flat until the dentin was exposed. The dentin surface was etched with 37% phosphoric acid to simulate open tubules that cause root sensitivity. Clinpro White Varnish was applied in a thin layer to the exposed moist dentin surface. Scanning electron micrographs were taken. The varnish layer was then carefully withdrawn to allow visualization of the treated dentin tubules. Additional scanning electron micrographs were taken.

Treated samples were also fractured to allow visualization of the varnish penetrating into the dentin tubules.

Results

Clinpro™ 5% Sodium Fluoride White Varnish covers and occludes open tubules (Figure 1). After the bulk of the varnish has been removed from the surface, Clinpro White Varnish can be seen at the tubule openings (Figure 2). A cross-sectional image shows that Clinpro White Varnish penetrates deep into the dentin tubules (Figure 3). This penetration prevents the flow of fluid and the transmission of ions in the tubules with a subsequent reduction in pain.

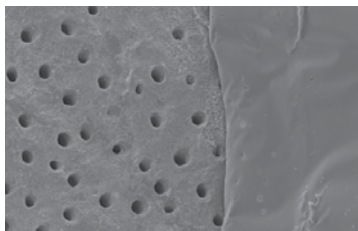


Figure 1: 1500x Magnification

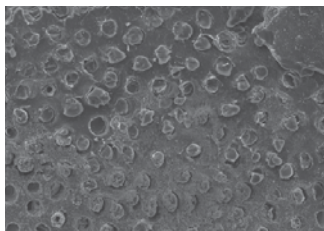


Figure 2: 1500x Magnification

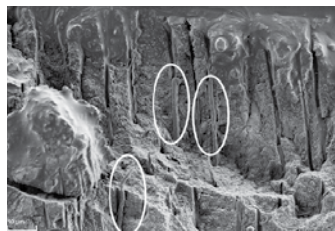


Figure 3: 2000x Magnification

Source:
3M ESPE internal data

Adhesion and migration

Patients may not know which tooth, or teeth, are causing hypersensitivity. Gillam et al., found that 48% of patients with dentinal hypersensitivity were able to locate an area of discomfort; however, only 22.7% were able to identify which tooth was the cause of their dental problem.²⁴ Thus, it would be beneficial for a sensitivity treatment to migrate to nearby tooth surfaces.

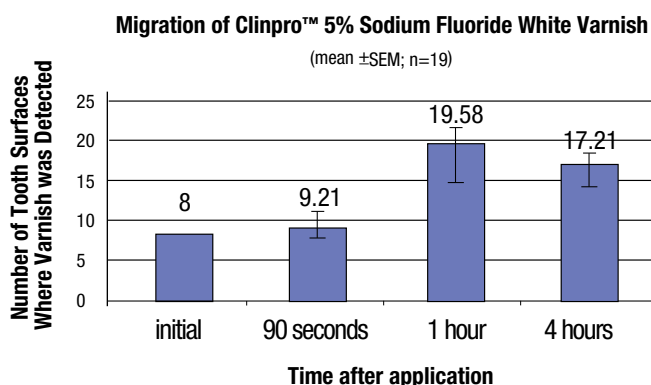
Clinpro White Varnish spreads to additional tooth surfaces after application. This is an advantage in the treatment of hypersensitive teeth, where the pain may be related to open tubules on several surfaces, including those in interproximal areas.

Methodology

The adhesion and migration of Clinpro White Varnish was assessed by 19 volunteer subjects. Clinpro White Varnish was initially applied to 8 anterior maxillary teeth. Subjects reported the location of the varnish immediately after application, 1 hour after application, and 4 hours after application.

Results

Migration of Clinpro White Varnish began almost immediately after application and continued for at least 4 hours, the duration of the study and the minimum amount of time that the product should remain on the teeth. Clinpro White Varnish spread to more than double the number of surfaces to which it was initially applied, proving the migration of the product.



Source:
3M ESPE internal data

Sustained occlusion

As the lacquer-like film of Clinpro™ 5% Sodium Fluoride White Varnish slowly wears away over time, the sodium fluoride and calcium phosphate in the coating dissolve and are released as ions. Fluoride ions react with free calcium originating either naturally in the mouth²⁵ or released from Clinpro White Varnish. The fluoride ions and the available calcium ions combine to form insoluble calcium fluoride. The insoluble globules of calcium fluoride provide occlusion of exposed dentin tubules for sustained relief of tooth hypersensitivity.² Thus, the ability of a varnish to occlude dentinal tubules is related to the amount of fluoride released from the varnish and the reaction with calcium in the mouth.

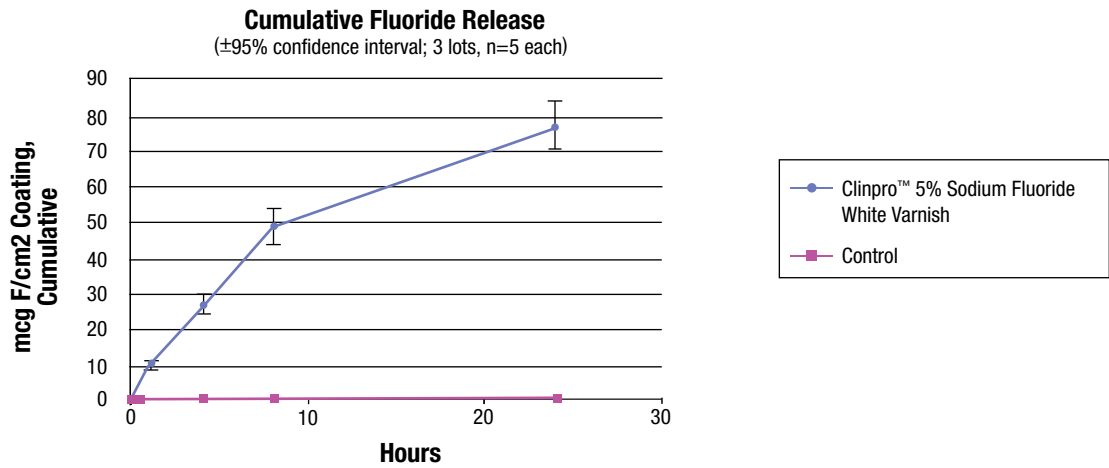
Fluoride release

Methodology

A thin coating of Clinpro White Varnish from 3 lots was applied to plastic slides (n=5 per lot). The varnish-coated slides and non-varnish-coated control slides were placed into separate vials of deionized water at 37°C. After 1 hour, the water was collected and replaced with fresh deionized water. This procedure was repeated at 4, 8 and 24 hours. Buffered samples were evaluated using a calibrated fluoride ion selective electrode. Fluoride concentrations observed were converted to micrograms of fluoride per area applied to the slide.

Results

Clinpro White Varnish continues to release fluoride over at least 24 hours in vitro. The fluoride in Clinpro White Varnish is not bound in the formulation by calcium.



Source:
3M ESPE internal data

Salivary fluoride levels

While laboratory studies can predict clinical outcome, in vivo tests remain the gold standard for product performance. Measuring salivary fluoride levels after application of a fluoride varnish is an effective way to measure the potential effect of a varnish.

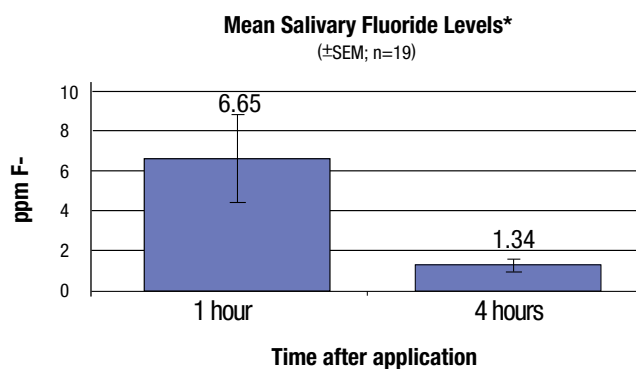
Methodology

Salivary fluoride was measured in 19 volunteer subjects. Clinpro™ 5% Sodium Fluoride White Varnish was applied to the 8 anterior maxillary teeth of each subject.

In vivo salivary fluoride measurements were taken before application of the varnish, and at 1 hour and 4 hours after application. The difference between baseline measurements and the 1 and 4 hour measurements represents the fluoride released from the varnish into the saliva.

Results

Elevated salivary fluoride levels at 1 hour and 4 hours after application of Clinpro White Varnish show that Clinpro White Varnish delivers fluoride in the mouth.



*One and four hour measurements minus baseline

Salivary fluoride levels of Clinpro™ 5% Sodium Fluoride White Varnish

*Source:
3M ESPE internal data*

Calcium and phosphorus availability

Calcium and phosphate are naturally occurring components of saliva long associated with maintaining healthy teeth. Clinpro™ 5% Sodium Fluoride White Varnish contains an innovative tri-calcium phosphate ingredient sold exclusively by 3M ESPE. The tri-calcium phosphate in Clinpro White Varnish is milled with fumaric acid in a ball-mill to achieve fumaric acid-protected calcium components.²² When the tri-calcium phosphate ingredient is added to Clinpro White Varnish, the fumaric acid protection remains, ensuring undesired interactions between calcium and phosphate and calcium and fluoride do not occur throughout the shelf-life of the varnish. After varnish application to the tooth surface, the fumaric acid is slowly dissolved, allowing the protected calcium component to be released in parallel with fluoride ions.

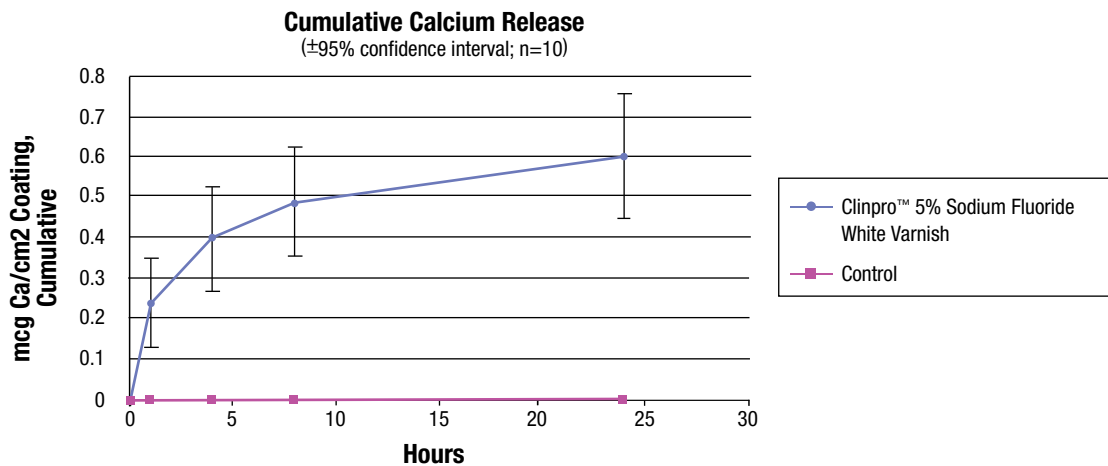
Methodology

Clinpro White Varnish with Tri-Calcium Phosphate (TCP) was applied in a thin layer to frosted glass slides coated with 3M™ ESPE™ Filtek™ Z250 Universal Restorative, (n=10). Filtek Z250 restorative-coated, frosted slides without a layer of varnish were used as a control. The varnish-coated and control slides were placed into deionized water at 37°C. Calcium and phosphorus concentrations in the aqueous solution were measured at 1 hour. The water was replaced with fresh deionized water and the concentration of calcium and phosphorus was measured at 4 hours. This procedure was repeated at 8 and 24 hours. Calcium and phosphorus concentrations from the water were determined by ICP-AES (inductively coupled plasma-atomic emission spectroscopy).

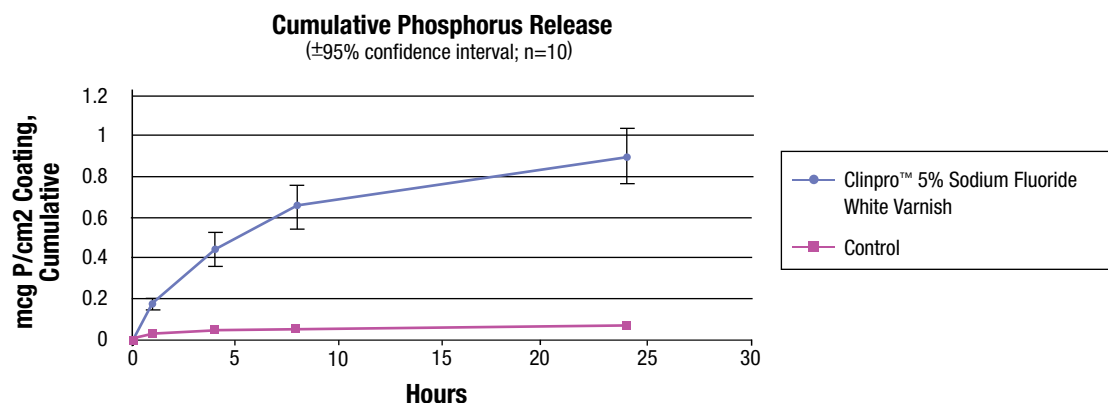
Results

Clinpro White Varnish with tri-calcium phosphate continues to release calcium and phosphorus ions over at least 24 hours.

Source:
3M ESPE internal data



Source:
3M ESPE internal data



Patient acceptance

Dental professionals will appreciate that fluoride varnishes are easy to apply and require less chair time for treatment. In one study, varnish application took only 1-4 minutes, depending on the number of teeth treated.²⁶ While ease of application and time savings are important to the dental professional, patient acceptance of dental treatments is equally important. Patients find fluoride varnishes to be an acceptable and convenient method for fluoride delivery.^{27,28} Patients that are satisfied with their dental care are more likely to adhere to medical recommendations.²⁹

Methodology

To measure the acceptability of Clinpro™ 5% Sodium Fluoride White Varnish, 19 volunteer subjects evaluated their satisfaction with the product when applied to 8 anterior maxillary teeth.

Results

95% of subjects found the appearance of Clinpro White Varnish to be acceptable. Subjects were satisfied with the esthetics of Clinpro White Varnish.

Instructions For Use

For instructions on the use of Clinpro™ 5% Sodium Fluoride White Varnish, please refer to the “Instructions for Use” enclosed with the product, or available at www.3MESPE.com/PreventiveCare.

Storage

Refer to packaging of Clinpro White Varnish for storage information.

Questions and Answers

Q. What advantages does Clinpro White Varnish offer over other fluoride varnishes?

A. Clinpro White Varnish contains 22,600 ppm fluoride and an innovative tri-calcium phosphate ingredient, available exclusively from 3M ESPE. The tri-calcium phosphate in Clinpro White Varnish is milled with fumaric acid during manufacturing. This creates a protective layer around the calcium to keep it separate from the fluoride in the varnish. After Clinpro White Varnish is applied to the tooth surface, the rosin slowly dissolves and releases fluoride, calcium and phosphorus ions into the saliva. Fluoride and calcium react to form calcium fluoride which aids in sensitivity reduction.

Clinpro White Varnish adheres to teeth and also migrates to additional tooth surfaces. The varnish contains a modified rosin in an alcohol-based solution that allows Clinpro White Varnish to adhere to teeth to which it has been applied, but also to migrate to additional tooth surfaces, including spaces that may be difficult to reach.

Clinpro White Varnish is virtually invisible on the tooth. The product is white in color when applied to the tooth. 95% of subjects rated the appearance of Clinpro White Varnish to be acceptable.

Clinpro White Varnish can be applied to moist tooth surfaces. Saliva activates the varnish, forming a lacquer-like coating on the tooth surface. This coating adheres to the tooth surface to which it was applied, but also migrates to additional tooth surfaces.

Q. What is the role of calcium in Clinpro White Varnish?

A. The calcium in Clinpro White Varnish increases the likelihood of forming calcium fluoride globules on tooth surfaces. The presence of calcium fluoride can occlude dentinal tubules to reduce dentinal hypersensitivity.

Q. How is Clinpro White Varnish packaged?

A. Clinpro White Varnish is supplied in a single unit-dose package to eliminate the problems of phase separation and inter-patient contamination which are possible with bulk tube-type packaging. Fluoride varnishes packaged in bulk tubes have been shown to separate during shipment and storage, introducing problems of sodium fluoride and rosin uniformity.³⁰ Unit dose formulations, however, contain the correct amount of rosin and fluoride in an individual package. Although some phase separation may occur during shipment and storage, the unit dose is easily mixed just prior to application to ensure proper amounts of both rosin and sodium fluoride.

Q. How often should I apply Clinpro™ 5% Sodium Fluoride White Varnish?

A. Clinpro White Varnish can be applied as needed for the relief of hypersensitivity. Many dental professionals apply Clinpro White Varnish twice a year, but the product can be applied more frequently if needed.

Q. Will my patients notice Clinpro White Varnish on their teeth?

A. Patients may feel a thin coating of varnish on their teeth when rubbing the treated area with the tongue. Patients may see a thin coating when looking at the teeth, but for most patients Clinpro White Varnish is not noticeable in appearance.

Q. How long should my patients leave Clinpro White Varnish on the teeth?

A. The minimum recommended treatment period for Clinpro White Varnish is 4 hours. Preferably, patients should leave the varnish on the teeth overnight and brush it off in the morning. The coating will naturally wear off in approximately 24 hours.

Q. Can my patients eat after application of Clinpro White Varnish?

A. Patients can eat immediately after application of Clinpro White Varnish. They should avoid eating foods that are hard or sticky, or drinking beverages that are hot or that contain alcohol. This includes the use of mouth rinses containing alcohol.

Q. Should patients stop using fluoride rinses or supplements after application of Clinpro White Varnish?

A. Patients should not use prescriptive fluoride preparations such as gels or rinses for 24 hours after application of Clinpro White Varnish. Children who are taking fluoride supplements should discontinue use of these supplements for 2-3 days following treatment with Clinpro White Varnish.

Q. Are there any contraindications to the use of Clinpro White Varnish?

A. As with other fluoride varnishes, Clinpro White Varnish should not be applied to patients with ulcerative gingivitis or stomatitis.

Summary

Clinpro™ 5% Sodium Fluoride White Varnish:

- is indicated for use as a fluoride-containing coating that treats hypersensitive teeth and exposed dentin and root surface sensitivity
- contains 22,600 ppm fluoride in a unique solvent system
- contains an innovative tri-calcium phosphate ingredient
- is saliva and moisture tolerant, as well as saliva and moisture activated
- creates a physical barrier by covering and occluding dentinal tubules
- creates a chemical barrier by forming insoluble minerals within dentinal tubules
- releases fluoride, calcium and phosphate
- adheres to teeth to which it has been applied
- migrates to tooth surfaces, including hard-to-reach spaces
- contains xylitol
- available in mint flavor; melon flavor is also available in the 500-pack
- has acceptable appearance, taste and texture
- is supplied in unit-dose packaging that assures convenience and dosage consistency

Warranty

3M ESPE warrants this product will be free from defects in material and manufacture. 3M ESPE MAKES NO OTHER WARRANTIES INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. 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 3M ESPE's sole obligation shall be repair or replacement of the 3M ESPE product.

Limitation of Liability

Except where prohibited by law, 3M ESPE 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.

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