

ProGuard™ Fluoride-containing Desensitizing Varnish

Carefully read instructions prior to use



For use in USA

Product Description:

ProGuard™ Fluoride-containing Desensitizing Varnish is a fluoride containing dental varnish for surface application to enamel and dentin. ProGuard Fluoride-containing Desensitizing Varnish will adhere to wet surfaces and is tolerant to moisture and saliva.

ProGuard Fluoride-containing Desensitizing Varnish is an ethanolic suspension of colophony with artificial flavors and sweetened with xylitol.

1 mL of ProGuard Fluoride-containing Desensitizing Varnish contains 50 mg of sodium fluoride equivalent to 22.6 mg of fluoride.

Indications:

ProGuard™ Fluoride-containing Desensitizing Varnish is intended for use as

- Treatment of hypersensitive teeth
- Treatment of sensitive root surfaces

Contraindications:

ProGuard™ Fluoride-containing Desensitizing Varnish is contraindicated in patients with ulcerative gingivitis or stomatitis or known allergies to colophony.

ProGuard Fluoride-containing Desensitizing Varnish is not intended for systemic treatment.

Methods of Use:

Recommended dosage:

- Treatment of patients with primary dentition:
Use approximately 0.25 mL of ProGuard™ Fluoride containing Desensitizing Varnish.
- Treatment of patients with adolescent or permanent dentition:
Use approx. 0.40 mL of ProGuard Fluoride-containing Desensitizing Varnish.

ProGuard Fluoride-containing Desensitizing Varnish should be applied on a complete set of teeth in a very thin film thickness. A thick film thickness is more likely to peel off and does not provide better therapeutic results. A complete set of teeth can be treated between the ranges of 0.25ml and 0.40mL.

Application:

1. Thoroughly clean tartar from treatment areas.
2. For best results, eliminate any excessive moisture saliva from area to be treated.
3. Use brush applicator or foam pellet to uniformly apply ProGuard™ Fluoride-containing Desensitizing Varnish, covering the entire surface to be treated as a thin film.
4. Allow area to become wet (either by gentle rinsing or natural salivary flow) to ensure setting of ProGuard

Fluoride-containing Desensitizing Varnish.

5. Instruct patient to avoid hard food, alcohol, brushing or flossing for the next 4 hours after application.

Precautionary Measures:

Edematous swellings have been reported on rare occasions especially following application to extensive surfaces. Direct ingestion should be avoided. Dyspnea associated with asthmatic children, has been reported for similar preparations in extremely rare cases. Patients having sensitive digestive systems may experience nausea, usually after extensive treatment. In case of adverse reactions, remove varnish with a soft toothbrush and floss, and then rinse with warm water.

No treatment with other fluoride preparations on day of application. Suspend treatment with fluoride tablets for several days after treatment. Do not swallow.

According to its purpose, ProGuard™ Fluoride-containing Desensitizing Varnish has a sticky consistency.

Storage:

Store at temperatures between 39°F - 73°F (4°C - 23°C). Do not use after expiration date.

This material has been developed solely for use in dentistry. Processing should be done strictly according to the instructions for use. Crosstex recognizes its responsibility to replace products if proven to be defective. Crosstex does not accept liability for any damage or loss, directly or indirectly, stemming from the use of or inability to use the products 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.

Descriptions and data constitute no warranty of attributes and are not binding.

CAUTION: U.S. Federal Laws restrict this device to sale by or on the order of a dentist.

No person is authorized to provide any information which deviates from the information provided in the instructions for use.

**Keep this material out of reach of children.
For dental use only.**

CROSSTEX



Manufactured for: Crosstex International, Inc.
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Made in Germany

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ProGuard™ Fluoride-containing Desensitizing Varnish

Leer esmeradamente las instrucciones antes del uso

Para usar en USA



Descripción del Producto:

ProGuard™ Fluoride-containing Desensitizing Varnish es una laca dental que contiene fluoruros para la aplicación superficial a esmalte y dentina. ProGuard Fluoride-containing Desensitizing Varnish se adhiere a superficies mojadas y es tolerante a humedad y saliva.

ProGuard Fluoride-containing Desensitizing Varnish es una suspensión de colofonia con sabor artificial endulzada con xylitol en solución de etanol.

1 mL de ProGuard Fluoride-containing Desensitizing Varnish contiene 50 mg de fluoruro de sodio equivalente a 22.6 mg de ión de flúor.

Indicaciones:

ProGuard™ Fluoride-containing Desensitizing Varnish está indicado para

- el tratamiento de dientes hipersensibles
- el tratamiento de superficies radiculares sensibles

Contraindicaciones:

ProGuard™ Fluoride-containing Desensitizing Varnish está contraindicado para pacientes con gingivitis ulcerante o stomatitis o alergias conocidas en cuanto a colofonia. ProGuard Fluoride-containing Desensitizing Varnish no es para el tratamiento sistemático.

Métodos de uso:

Dosificación recomendada:

- Tratamiento en pacientes con dientes de leche:
Usar aprox. 0.25 ml de ProGuard™ Fluoride-containing Desensitizing Varnish
- Tratamiento de pacientes con dentición mixta o dentadura fija:
Usar aprox. 0.40 ml de ProGuard Fluoride-containing Desensitizing Varnish

ProGuard Fluoride-containing Desensitizing Varnish se aplica como una película fina en el tejido dental duro. Películas gruesas se desprenden más fácil y no mejoran la terapéutica. Por experiencia, la cantidad requerida está entre 0.25 mL y 0.40 mL para un set completo de dientes.

Aplicación:

1. Límpiase bien el sarro de las áreas a tratar.
2. Para mejores resultados, elimínese la humedad/saliva excesiva del área a tratar.
3. Utilícese un aplicador de cepillo o pellets de espuma para aplicar uniformemente ProGuard™ Fluoride-containing Desensitizing Varnish, cubriendo con una película fina la superficie completa a tratar.
4. Permitase que se moje el área (o bien con enjuague suave o flujo de saliva natural) para asegurar

5. un fraguado de ProGuard Fluoride-containing Desensitizing Varnish.

6. Instrúyase al paciente de evitar comida dura, alcohol, cepillado o seda dental durante las próximas 4 horas después de la aplicación.

Información/medidas precautorias:

Inflamación edematosa ha sido reportada en pocas ocasiones especialmente siguiente a la aplicación en superficies extensas. Una ingestión directa debe ser evitada. Disnea en conexión con niños asmáticos ha sido reportada - en casos extremadamente raros - para preparaciones similares.

Pacientes que tienen sistemas digestivos sensibles pueden experimentar náuseas, normalmente después de un tratamiento extenso. En caso de reacciones adversas, eliminar la laca con un cepillo de dientes blando y seda dental, luego lavar con agua caliente.

No realizar tratamiento con otros preparados de fluoruros en el día de la aplicación. Suspender el tratamiento con comprimidos de fluoruro por unos días después del tratamiento. No tragar.

ProGuard™ Fluoride-containing Desensitizing Varnish tiene, correspondientemente a su modo de aplicación una consistencia pegajosa.

Conservación:

Consérvese a temperaturas entre 39°F - 73°F (4°C - 23°C). No usar después de la fecha de caducidad.

Este material se desarrolló exclusivamente para el uso del odontólogo. El proceso debe ser como está indicado en la información de uso. ProGuard™ reconoce su responsabilidad de reemplazar los productos si se muestran que están defectos. ProGuard no acepta la responsabilidad de cualquier perjuicio o pérdida que descenden del uso o de la incapacidad de usar los productos descritos. Antes de usarlo, es la responsabilidad del utilizador de determinar lo adecuado del producto para su uso intentado. El utilizador supone todo el riesgo y la responsabilidad en conexión con eso. Descripciones y datos no constituyen ninguna garantía y no son aglomerantes.

Atención: La legislación americana registre este dispositivo para venderlo o al pedido del dentista.

Ninguna persona está autorizada de proveer ninguna información que desvíe de las informaciones provéidas en estas instrucciones de uso.

**Manténgase fuera del alcance de los niños.
Solamente para el uso odontológico.**

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