

### EMBRACE™ Varnish

The complete varnish with bioavailable calcium, phosphate and fluoride

#### PRODUCT DESCRIPTION AND INTENDED USE

EMBRACE™ Varnish is a resin-based varnish that provides sustained, time-release of fluoride, calcium and phosphate ions over a period of 4 hours or longer. The calcium and phosphate salts are nano-coated with xylitol and are bioavailable. Exposure to saliva dissolves the xylitol and releases the calcium and phosphate ions, which continuously react with fluoride ions the saliva to form protective fluorapatite on the teeth.

EMBRACE™ Varnish contains 5% sodium fluoride, which is equivalent to 22,600 ppm fluoride (22.6 mg fluoride/mL). The material is tooth shade. It dries quickly forming a smooth thin film on the teeth.

#### INDICATIONS

EMBRACE™ Varnish treats hypersensitivity by releasing fluoride, calcium and phosphate ions that precipitate on and occlude dentinal tubules and fill superficial, non-carious enamel lesions.

#### CONTRAINDICATIONS

Ulcerative gingivitis and stomatitis

#### NOTE:

Apply disposable barrier sleeves/wraps over multiple-use dental dispensers before use with each patient. For additional information, refer to: <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DentalProducts/ucm404472.htm>

#### PRECAUTIONS

Limit ingestion by applying only as much varnish as necessary to cover tooth surfaces with a thin film. Adult patients should refrain from taking prescription fluoride supplements for a period

of 24 hours following treatment, and children should refrain for 2-3 days.

#### INSTRUCTIONS FOR USE

1. Use back of cap to pierce seal on the tube.
2. Dry the teeth with a gauze pad. It is best if teeth are at least minimally clean, but it is not necessary to do a prophylaxis.
3. On a pad or mixing well, dispense 0.25 mL varnish for children and 0.4mL for adults.
4. Using a brush, apply a very thin coat of varnish on the desired tooth surfaces. It is not necessary to use all the varnish.
5. It is best if patients refrain from eating hard foods or drinking hot liquids or alcohol for 3-4 hours after treatment. Eating soft foods for the rest of the day is advantageous. Instruct patients not to brush their teeth for at least four hours.
6. EMBRACE Varnish can be removed by brushing and flossing.

#### WARNING

- Federal law restricts this device to sale by or on the order of a dentist or physician.
- EMBRACE Varnish may be irritating to respiratory tract if inhaled or to eyes or skin on contact. May be a sensitizer with prolonged and/or repeated contact. See MSDS for further information.
- Dental practitioners should wear protective eyewear and gloves. Wash hands after use. Emergency eye wash fountain should be available in the office.
- EMBRACE Varnish contains no soy or gluten products. It contains a processed pine tree extract and not an extract of pine nut. Patients with allergies should consult their physician.

#### STORAGE

Store original packages at cool room temperature 5-25°C / 41-77°F. Avoid extremes of temperature.

#### Español

##### EMBRACE™ Varnish

#### INSTRUCCIONES DE USO

1. Utilice la parte trasera de la tapa para romper la junta del tubo.
2. Seque los dientes con una gasa. Es mejor si los dientes están limpios, pero no es necesario hacer una profilaxis.
3. Dispense el barniz en una gasa o superficie de mezclado con 0.25 mL de barniz para niños o 0.4 mL para adultos.
4. Barniz EMBRACE ya viene pre mezclado y no requiere mas manipulación, lo que asegura una dosis consistente y uniforme.
5. Use el cepillo para aplicar una fina capa de barniz en todas las superficies de los dientes. No es necesario utilizar todo el barniz. Deshechar cualquier material no utilizado.
6. Lo mejor es que los pacientes se abstengan de ingerir alimentos duros o beber líquidos calientes o bebidas alcohólicas durante 3-4 horas después del tratamiento. Comer alimentos suaves para el resto del día es una ventaja. Explicar a los pacientes que no deben cepillarse los dientes durante al menos cuatro horas.
7. EMBRACE barniz se puede quitar con el cepillado y el hilo dental.

#### Français

##### EMBRACE™ Varnish

#### MODE D'UTILISATION

1. Utiliser l'envers du bouchon pour percer l'opercule du tube.
2. Sécher les dents à l'aide d'une compresse de gaze. Les dents doivent être propres, mais il n'est pas nécessaire de procéder à une prophylaxie.
3. Sur une compresse ou dans un mini godet, sortir 0,25 ml de vernis pour un enfant et 0,4 ml pour un adulte.
4. Le vernis EMBRACE est pré-mélangé et ne requiert aucun mélange, ce qui assure d'un dosage uniforme constant.
5. Utiliser le pinceau afin d'appliquer une mince pellicule de vernis sur toutes les surfaces des dents. Il n'est pas nécessaire d'utiliser tout le vernis. Jeter la quantité inutilisée.
6. Il est préférable que le patient évite de manger des nourritures solides ou de boire des liquides chauds ou de l'alcool durant 3 à 4 heures après le traitement. Manger de la nourriture molle le reste de la journée procure un avantage. Et, dire au patient de ne pas se brosser les dents durant au moins les quatre heures suivantes.
7. Le vernis EMBRACE peut être enlevé par le brossage ou du fil dentaire.

Rx only



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