# **3M** ESPE

# Clinpro™

5% Sodium Fluoride White Varnish

# **INSTRUCTIONS FOR USE**

#### **GENERAL INFORMATION**

3M™ ESPE™ Clinpro™ 5% Sodium Fluoride White Varnish is a 22,600 ppm fluoride-containing varnish for application to enamel and dentin for support in remineralization, support in the prevention of caries and the treatment of hypersensitive teeth. Clinpro White Varnish is moisture and saliva-activated. It will spread on and adhere to moist teeth. Clinpro White Varnish is an alcohol-based solution of modified rosin. The product is sweetened with xylitol. Clinpro White Varnish contains an innovative tri-calcium phosphate (TCP) ingredient exclusively from 3M. The ingredient, TCP, serves as a source of bioavailable calcium and phosphate ions when the varnish is applied to the teeth. Calcium and phosphate ions are naturally occurring components of saliva long associated with maintaining healthy teeth. Clinpro White Varnish exhibits an extended release formula which, releases fluoride, calcium and phosphate for 24 hours after application.

This product is supplied in unit-dose packages containing 0.5 ml (0.5 grams) of varnish coating.

#### INDICATIONS

Clinpro White Varnish is a 5% sodium fluoride varnish which produces mechanical occlusion of the dentinal tubules in the treatment of tooth hypersensitivity. Clinpro White Varnish supports remineralisation and helps to prevent caries.

#### CONTRAINDICATIONS

Ulcerative gingivitis and stomatitis.

# PRECAUTIONARY INFORMATION for patients

To limit ingestion, use only enough varnish to form a thin coating on the desired treatment area. Discontinue use of other prescriptive fluoride preparations (i.e. gels, rinses) for 24 hours following Clinpro White Varnish application. Children taking fluoride supplements should discontinue use of supplements for 2-3 days following treatment. Patients with known sensitivity to colophony/rosin should avoid this product.

PRECAUTIONARY INFORMATION for dental personnel 3M SDS information can be obtained from:

www.3M.com or contact your local subsidiary.

## HAZARD INFORMATION

This product as sold is a flammable material. Once the material has adhered to the teeth, this product is no longer flammable.

# INSTRUCTIONS FOR USE

General application instructions:

- A prophylaxis is not required. For best results teeth should be minimally clean, but Clinpro White Varnish can be applied where plaque is present.
- Open the unit-dose package of Clinpro White Varnish and dispense the entire contents. Use the applicator brush to thoroughly mix the varnish since components of all sodium fluoride varnishes can separate during storage.
- Apply the product to the teeth in a thin layer with the supplied brush. Apply the varnish in sweeping horizontal brush strokes. Avoid excessive contact with soft tissue. It is not necessary to use all of the varnish provided. Use

- only enough varnish to form a thin coating on the desired treatment area.
- 4. After application, instruct the patient to close their mouth to set the varnish. Rinsing or suctioning immediately after application is not recommended. You may see a thin coating on the teeth. The patient may feel the thin coating when rubbing the treated area with their tongue.
- The treatment period for Clinpro White Varnish is minimally 4 hours. Left undisturbed, the durable coating will continue to release fluoride, calcium and phosphate for 24 hours.
- 6. To achieve the maximum benefit after application, please instruct the patient to follow the directions below:
- Do not brush or floss your teeth for at least 4 hours, and preferably up to 24 hours after the treatment.
- · Eat soft foods during the treatment period.
- Do not consume hot drinks or alcohol (mouth rinses) during the treatment period.
- After the treatment period, the patient can remove varnish by brushing and flossing.

#### STORAGE AND USE

This product is designed to be stored and used at room temperature. Shelf life at room temperature is 36 months. Ambient temperatures routinely higher than 27°C/80°F, or lower than 10°C/50°F, may reduce shelf life. See outer package for expiration date.

#### DISPOSAL

See the Safety Data Sheet (available at www.3M.com or through your local subsidiary) for disposal information.

## **CUSTOMER INFORMATION**

by or on the order of a dental professional.

No person is authorized to provide any information which deviates from the information provided in this instruction sheet. **Caution:** U.S. Federal Law restricts this device to sale

#### WARRANTY

3M warrants this product will be free from defects in material and manufacture. 3M 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's sole obligation shall be repair or replacement of the 3M product.

#### LIMITATION OF LIABILITY

Except where prohibited by law, 3M 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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