

Chemically Activated Gel for Remineralization of teeth

Zuremin-CaPF is a two-component oral gel product providing the remineralizing and desensitizing teeth. The product contains a water soluble calcium phosphate salts, potassium nitrate, compounds containing the fluoride ions and some other compounds. When combined upon application to teeth, the Components A and B generates hydroxylapatite and fluoroapatite formation on teeth tissue and provide the desensitizing effect.

•• Outstanding features of the material

- Provides the both remineralizing and desensitizing effects.
- Contains anticaries fluoride compounds which correspond to about 1100 ppm of fluoride ions.
- Possesses the neutral pH excluding the irritation of gingival tissue.
- Sweetened and flavored composition.
- Possesses the antigingivitis activity.
- The remineralization treatment is ideal as a procedure followed by the teeth bleaching.

•• Processing and indications

In the mouth, the chemical processes between hydroxylapatite and other inorganic teeth components and the substances occurring naturally in the saliva are determined by a natural equilibrium. This equilibrium is shifting continuously. Among other factors, it is determined by physical condition of human organism. If the equilibrium is such that hydroxylapatite is dissolved, a cariogenic condition arises which is referred to as demineralization. If the equilibrium is such that hydroxylapatite is being formed in demineralized tooth tissue, this is referred to as remineralization. By remineralization, pre-existing tooth decay and initial caries can be reduced or eliminated by natural means. Zuremin-CaPF is a two-component calcium phosphate fluoride-providing composition which promotes the remineralization process, reduces pre-existing carious condition. When mixed, it produces the amorphous calcium fluorophosphate compounds possessing under physiological conditions the high solubility, high formation rate and high rate of conversion to teeth apatite. Transformation of a monocalcium salt cascading downward to the di-, octa- and then eventually fluoridated hydroxylapatite is facilitated by the presence of the higher pH inside the human teeth. These mechanisms allow the efficacious remineralization of the teeth tissues.

•• Instructions for use**Pre-treatment procedure**

Before remineralization session, a diagnosis should be performed. The calculus and external stains must be removed. If tissue is traumatized, wait some days before the treatment to minimize the soft tissue trauma caused by tray application.

Manufacture the soft vinyl tray using the routine laboratory procedure. Instruct patient on the remineralization procedure. Explain treatment regime: teeth cleaning, tray loading, application of Zuremin-CaPF, and tray care. The time required for complete remineralization treatment depends mainly on the level of demineralization or pre-existing carious condition and its severity. It is recommended to evaluate patients every 4-5 days of treatment to determine the duration of remineralization treatment. The appropriate vitamin and micro-mineral diet applied together with remineralization is recommended.

Procedure

1. Place approximately equal amount of Zuremin-CaPF Components A and B on a mixing pad.
2. Spatulate the two pastes together for approximately 20 seconds. Make certain that the blend is uniform.
3. The slightly opalescent appearance of mixture indicates the presence of active amorphous calcium fluorophosphate compounds – the evidence that mixture is ready to application.
4. Apply a ready-mixed material to the tray, and place the tray into the mouth. Avoid excessive filling of the tray to prevent the "pumping" ejaculation of material from soft tray while placing into mouth or mouth activity.
5. Remove excess material from mouth.
6. Zuremin-CaPF remineralizes actively 4 – 6 hours and alternative remineralization sessions can be used for as few as half of hour to some hours per day, depending on patient's conditions, level of sensitivity, and day-to-day activities. The most preferable is 1 hour remineralization session per a day.

•• Precautions

- Zuremin-CaPF should not be used during pregnancy or when lactating.
- Zuremin-CaPF should not be used if patient has a known allergy or sensitivity to fluorides, nitrates, calcium phosphate salts, glycerin, carbopol, xanthan gum, etc.
- Wait at least one week or more following the remineralization procedure before placing the resin-bonded restoration as the peroxide residuals within dentin and enamel can significantly reduce the strength of resin bond to tooth tissue.

•• Warranty

The manufacturer warrants the quality of manufactured products. The adverse events inflicted by violation of user manual, storage conditions and other events inflicted by non-stipulated usage of the material are not the subjects of warranty. The customer is responsible for determination of suitability of this product for user's application. Warranty conditions: the product does not comply with requirements declared by manufacturer. In this case the manufacturer replaces the defective material within warranty period.

•• Limitation of liability

The manufacturer's liability is limited by only cases stipulated by direct legislation of the country.

•• Storage

- Store at room temperature with the syringe cap tightly closed. Shelf life at room temperature is 3 years.
- DO NOT FREEZE!

•• Recycling

Dispose of the medical device in accordance with local / regional / national / international legal requirements.

•• Presentation

- Set 2 x 5 ml syringes (Component A and Component B).
- Set 2 x 10 ml syringes (Component A and Component B).