



Instruction for Use

Trade name: Calcedent enamel+

Description:

Enamel-sealing liquid is intended for deep fluoridation of teeth, mineralization of tooth tissues with fluorine and calcium. Reinforcing method in preventive dentistry.

Indications:

For desensitization of the cervix of the tooth by deep fluoridation of the hard substance, prevention of caries, mineral fissure sealing.

Contraindications and side effects:

Individual intolerance to one of the components of a medical product. Do not use for other purposes.

Can cause irritations as a result of direct contact with a pulp.

Composition of the preparation No. 1: anhydrous magnesium fluoride silicate, anhydrous copper-|| fluoride silicate, sodium fluoride (as a stabilizer), distilled water.

Composition of the preparation No. 2: highly dispersed calcium hydroxide, methylcellulose, distilled water.

Properties: Sequentially applied preparations provide deep fluoridation of the enamel or hard substance of the tooth cervix.

Due to deep fluoridation, microscopic crystals are formed inside the enamel. Fluorine in combination with mineral salts of saliva provides long-term remineralization, enhancing it by almost 100 times.

Application:

Desensitization of the cervix of the tooth, prevention of caries: remove plaque with a toothbrush and dry the teeth with warm air. Then the cervix of the tooth is abundantly moistened with a swab soaked in preparation No. 1 for 1-2 minutes. Then thoroughly moisten with preparation No. 2 (previously shaking). Next, the mouth should be rinsed. The patient can eat immediately. The procedure is recommended to be carried out 1-2 times a year. The effect is provided for more than 1 year.

CAUTION: Warnings

If you accidentally swallow a large amount (more than 5 ml) of Fluid No. 1, you should drink plenty of water or milk. In the doctor's office, use liquid gypsum milk (1 teaspoon per 1 glass of water) as an antidote.

For ease of dosing, the caps on the vials can be replaced with the supplied pipettes.

Content:

Calcedent Enamel+ 5 ml liquid /5 ml suspension containing:

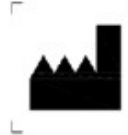
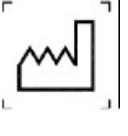

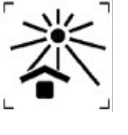
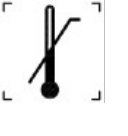





-5 ml liquid




- 5 ml suspension
- instruction

Calcedent Enamel+ 20 ml liquid /20 ml suspension containing:

- 20 ml liquid
- 20 ml suspension
- dropping tube
- instruction

Table Applicable symbols

	<p>Manufacturer</p>
	<p>Date of production</p>
	<p>Protect from moisture</p>
	<p>Avoid exposure to sunlight</p>
	<p>Upper limit of temperature range</p>
	<p>Refer to instruction for use</p>
	<p>Non- sterile product</p>
	<p>Caution! Refer to instruction for use</p>
	<p>European conformity mark to standards and identification number of authorized Authority. The product conforms to the essential requirements of the Medical Devices Directive (93/42/EEC)</p>
	<p>Lot number</p>

	Medical Device
	Do not use if the package is damaged
	Period of validity M- month Y- year

Transportation

All types of the covered transport at a temperature from 5 °C to 25 °C; relative humidity of 10-95%

Storage conditions

Store at a temperature from 5 °C to 25 °C; relative humidity of 10-95%

Avoid exposure to sunlight.

Period of validity:

Period of validity 3 years from the date of production. Do not use after the expiry date.

Utilization

Utilization, according to rules for class A non-hazardous medical waste.

MANUFACTURER (DEVELOPER) OF A MEDICAL DEVICE

Nanoplant-Höchst GmbH by order for Queen Dental GmbH

Neue Straße 67, 99846 Seebach, Germany

Neo Strasse 67, 99846 Seebach, Germany

Phone number: +49 36929 133948

E-mail: sales@queen-dental.de

PLACE OF PRODUCTION OF THE MEDICAL PRODUCT

Neue Straße 67, 99846 Seebach, Germany

Neo Strasse 67, 99846 Zeebakh, Germany