EN (English) INSTRUCTIONS FOR USE

# CAVEX EXSENSE



#### PRODUCT DESCRIPTION

Cavex ExSense is the perfect solution for sensitive teeth. Sensitive teeth often occur as a result of dental erosion or exposed dentin. Cavex ExSense is based on 2% hydroxyapatite that seals the tubules and microcracks in the enamel using a hydro-dispersing sol. In doing so, it completely closes off sensitive areas. The addition of 0.1% potassium nitrate also restores the micro-hardness of the elements. In addition to complete closure, crystallization takes place which supports and accelerates the remineralization process.

Cavex ExSense is available in a tube (42 ml – 50 gram), sufficient for approximately 20 treatments. The product can be applied in various ways, depending on the nature of the sensitivity. The most effective method is to use a custom-made tray that is filled with Cavex ExSense and then allow teeth to 'bathe' for 10 minutes. If the complaint is more localized, Cavex ExSense can also be applied very effectively to the sensitive spot with the tip of a finger. Afterwards tray and excess are removed and the tray is rinsed with water. The procedure should be repeated for 10 days or as instructed by a dental professional.

#### COMPOSITION

Key-ingredients: Hydroxyapatite 2%, Potassium nitrate 0.1%

#### INTENDED LISE

Dental desensitisers such as Cavex ExSense are used in the dental practice to relieve pain caused by exposed tooth necks or dentine and to prevent or relieve post-operative sensitivity.

#### INDICATION FOR USE

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- Prevention and reduction of tooth sensitivity.
- After teeth whitening in dental practice and / or at home.
- After professional cleansing of the teeth.

### **CONTRA-INDICATIONS & WARNINGS**

### Contra-indications:

Do not use if allergic to mint or one of the other ingredients.

# Potential side effects:

Hypersensitivities to the product or its components cannot be excluded in individual cases.

#### **Storage Conditions:**

Store at temperatures between 0 °C (32 °F) to 25 °C (77 °F).

Store in a cool and dry place (frost-free) and protected from direct sunlight.

Always close the tube tightly after use. Keep out of reach of children.

# Warnings:

In case of contact with the eyes, rinse thoroughly with plenty of water and seek medical attention. Do not use the product after expiry date.

# HANDLING

Clean teeth beforehand by brushing and flossing.

### Application without tray:

Wash hands thoroughly with water and soap. Dispense a small amount of Cavex ExSense on a clean finger and apply it on the upper and lower teeth. Leave the gel on for 10 minutes. Spit out any excess gel but do not rinse afterwards.

#### With tray:

Dispense a small amount of Cavex ExSense across the entire tray. Place the tray in the mouth and move the tray a little from left to right to spread the gel on the teeth. Gently bite down on the tray and leave the tray with the gel in place for 10 minutes. Remove the tray and spit out any excess gel but do not rinse afterwards. Rinse tray with cold water.

- Always close the tube with the cap immediately after use.
- For best results: do not drink or eat for at least 30 minutes after application.
- Use Cavex ExSense once a day for a minimum of 10 days or follow the instructions of your dental professional.

## LABELLING:

This information is in compliance with ISO24234 and also with European legislation.

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# INTENDED PATIENT(S)

Cavex ExSense is suitable for patients requiring dental treatment for the following indications with consideration of the contraindications. For pregnant and nursing women, the treatment risks must be weighed carefully against the benefits taking into consideration the unborn child or infant.

#### INTENDED USER(S)

Cavex ExSense will only be used by dental professionals (dentist).

#### **CLINICAL BENEFITS**

Desensitizer based upon biocompatible hydroxyapatite with easy application for in-office and at-home use.

#### **CLAIMS**

- Instant and long-lasting relief from sensitive teeth
- Helps to prevent sensitive teeth
- Accelerates and reinforces the process of remineralization

#### PRODUCT CHARACTERISTICS AND SPECIFICATIONS

At present, a product standard for Cavex ExSense is not available. Therefore, quality control is carried out according to a number of in-house standards.

<u>Characteristic</u>	Internal specifications	Cavex ExSense
Appearance	White gel	White gel
рН	7,5 – 9	8,5 – 9

Viscosity 5-100 5-30 Pa.s

#### **COMBINATION PRODUCTS:**

Cavex ExSense can be used as a single product or applied with a tray (i.e. an individual aligner tray or standard dental tray.

### SPECIAL ADVICE

According to EU Medical Device Regulation users/ patients are obliged to report serious incidents with a medical device to the manufacturer and to the competent authority of the country, the incident occurred.

#### STORAGE ADVICE

Do not store at temperatures higher than 25°C (77°F). Do not use this material beyond its expiry date. Avoid direct exposure to sunlight. Close tube firmly after use and keep out of reach of children.

#### **DISPOSAL INFORMATION**

Dispose of in accordance with local regulations. Do not dispose of contents or partially emptied packaging in household waste or allow them to enter the sewage system.

Our technical advice, whether verbal, in writing or by way of trials, is given in good faith but without warranty, and this also applies where proprietary rights of third parties are involved. It does not release you from the obligation to test the products supplied by us as to their suitability for the intended processes and uses. The application, use and processing of the products are beyond our control and, therefore, entirely your own responsibility. Should, in spite of this liability be established for any damage, it will be limited to the value of the goods delivered by us and used by you. We will, of course, provide consistent quality of our products within the scope of our General Conditions of Sale and Delivery.

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