

Product Information  
On

**Cavex ExSense**  
(Dentinal desensitisers)

<b>Legal manufacturer:</b>	Cavex Holland BV Fustweg 5 2031CJ Haarlem The Netherlands SRN: NL-MF-000000423
<b>Regulatory evaluator:</b>  <b>Signature:</b>	<b>Danny Stoelinga</b> 
<b>Regulatory manager:</b>  <b>Signature:</b>	<b>Richard Woortman</b> 
<b>Version:</b>	<b>2023-08</b>

## Table of Contents:

1. Introduction .....	3
2. Composition .....	4
3. Manufacturing.....	4
4. Laboratory control.....	4
5. Shelf-life test.....	5
6. Quality Control.....	5
7. Statement of non-toxicity.....	5

## 1. Introduction

### **Functional description & intended use**

Cavex ExSense is a water-based gel with mint aroma that contains hydroxyapatite and potassium nitrate. It offers fast relief from sensitive teeth thanks to a blend with a 'hydro-dispersing clay'. This ensures accelerated dispersion that helps the hydroxyapatite penetration into the surface tubules and micro-cracks in the enamel. As a result the areas causing sensitivity are sealed off completely. In addition to the desensitizing properties a process of crystallization helps the re-mineralization process which enhances whiteness of the teeth.

Cavex ExSense is indicated after tooth whitening, professional tooth cleaning or in case prevention and control of sensitivity is required.

### **Device description**

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 mouth is rinsed with water. The procedure should be repeated for 10 days or as instructed by a dental professional.

### **Expected life time and classification**

Cavex ExSense is a gel which is applied in the oral cavity on the teeth for 10 minutes. During the application there will be contact with the teeth and mucosa. The bulk of the hydroxyapatite will remain limited (>24 hrs – 30 days) in the tubules and micro-cracks of the enamel. This will result in an immediately desensitizing effect which will be noticeable for at least 4 weeks after commencing the treatment.

Due to food digestion and oral hygiene (i.e. tooth brushing) there will be a “wash out” effect of the hydroxyapatite. However, small formations of the hydroxyapatite crystals can be present in the mouth for several month (long term > 30 days) As these crystals are not liable to be absorbed by the mucous membrane, the classification is considered Class IIa - Rule 5. Cavex ExSense is a Medical Device and therefore should only be dispensed by or on the order of a dental professional.

Cavex ExSense is developed and manufactured by Cavex Holland B.V. in Haarlem, The Netherlands, a Company that is certified according to the provisions of the Regulation (EU) 2017/745 concerning Medical Devices, against ISO 9001 and ISO 13485.

## 2. Composition

The basic ingredients of Cavex ExSense are:

Function	Art	Raw Material	CAS/CI nr.	% Mass
Solvent	XC527	Aqua	7732-18-5	56,39
Humectant	XA510	Sorbitol	50-70-4 / 68425-17-2	18,50
Humectant	XA403	Glycerin	56-81-5	12,00
Humectant - moisturizing	XA512	Erythritol	149-32-6 / 7541-59-5	5,00
Viscosity controlling	XV112	Lithium magnesium sodium silicate	53320-86-8	4,50
Conditioning	XA515	Hydroxyapatite	1306-06-5	2,50
Oral care - soothing	XA505	Potassium nitrate	7757-79-1	0,03
Preservative	XA511	Phenoxyethanol	122-99-6	0,50
Gel forming	XX502	Xanthan gum	11138-66-2	0,25
Anticaking	XA104	Tetrasodium Pyrophosphate	7722-88-5	0,10
Buffering - masking	XA513	Tartaric acid	87-69-4	0,09
Flavoring	XD106	Spearmint flavor	8008-79-5	0,08
Oral care - flavoring	XA514	Sodium saccharin	128-44-9 / 6155-57-3	0,06
Total				100,00

## 3. Manufacturing

All raw materials are accurately weighed according to the formulation, and the weight of all the raw materials of every single batch is recorded and filed. The components are fed into the blender in a special, fixed order and mixed. A sample is taken for In-Process Control, which comprises viscosity and pH.

Once released the batch is transferred to the filling device and the mixture is filled into tubes. During the filling process the weight and closing of the tubes is carefully controlled. After completion the tubes are packed into the final boxes with labelling. For final inspection and reference, samples are taken.

## 4. Laboratory control

Quality control is carried out according to a number of in-house standards and every batch is in compliance with internal specifications.

Characteristic	Internal specifications	Cavex ExSense	
Appearance	White gel	White gel	
pH	7,5 – 9	8,5 – 9	
Viscosity	5 – 100	5 – 30	Pa.s

## **5. Shelf-life test**

There is no official shelf-life test described for dental desensitizing products. Based on the results of internal tests, we can guarantee the good quality of Cavex ExSense for a period of 37 months (36 months + 1 month In-Use), provided the product is stored at room temperature when not in use.

## **6. Quality Control**

A batch of Cavex ExSense, that has passed all the tests, is released for sales. In case of one or more requirements being not in specification, that batch is withdrawn and not sold.

## **7. Statement of non-toxicity**

We hereby declare, that Cavex ExSense can be safely used and is non-toxic to the patient as well as to the dental team.

Cavex ExSense will also normally not be irritant to oral tissues and does not contain any hazardous ingredients in sufficient concentration to be harmful to human beings when used as directed.