

# Product Information

On

## Cavex Bite&White Shade Correction

Professional shade recovery product

<b>Legal manufacturer:</b>	<b>Cavex Holland BV</b> 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>2022-11</b>

## Table of Contents:

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

## 1. Introduction

Cavex Bite&White Shade Correction is a fast, safe and effective system for restoring the natural tooth color of the patient. It is an In-Office system, so the entire procedure is carried out by the dentist in the dental practice. The revolutionary gel in the system makes it possible to restore the original tooth color with only 2 to 3 applications in 1 treatment.

The Shade Correction System is based on 25% Hydrogen Peroxide Superior (HPS). This revolutionary gel, developed and patented by Cavex, is based on reactive oxygen added in the form of stabilized, encapsulated hydrogen peroxide. Upon contact with saliva, the pure hydrogen peroxide in the HPS gel is rapidly broken down into oxygen and water. This process creates free radicals that attack the carbon double bonds that are the source of most discoloration in teeth.

Due to the unique formula, the HPS gel works extremely fast. This minimizes treatment time and thus the risk of sensitivity. The thermo-reversible properties of the gel ensure that it stays perfectly in place during the treatment which maximizes the final result. The system consists of a unique applicator pen with a brush for maximum control during application and a protective barrier to protect the surrounding soft tissue.

Cavex Bite&White Shade Correction is developed and manufactured by Cavex Holland B.V., a Company that is certified according to the provisions of the Regulation (EU) 2017/745 concerning Medical Devices, against ISO 9001 and ISO13485.

Cavex Bite&White Shade Correction bears the CE-Mark of conformity.

## 2. Composition

The basic composition of Cavex B&W Shade Correction is as follows:

Function	Raw Material	%
Active Peroxide	Hydrogen peroxide 49,5%	25,0
Solvent	PEG	34,8
Solvent	Demiwater (conductivity <10 $\mu$ S)	26,0
Gel former	t-butylalcohol	3,1
Gel stabilizer	Poloxamer	10,5
Peroxide stabilizer	EDTA III	0,10
Peroxide stabilizer	Etidronic acid	0,30
Peroxide stabilizer	Sodium Stannate Trihydrate	0,10
Fragrance	Peppermint oil	0,10

### 3. **Manufacturing**

Basically, the ingredients are carefully weighed, blended in a high-performance mixing device and automatically packed in syringes.

### 4. **Laboratory control**

Every batch Cavex Bite&White Shade Correction is in compliance with ISO28399 Dentistry – Products for external tooth bleaching:

	<b>Cavex Bite&amp;White Shade Correction</b>
Appearance	Clear, transparent gel
Hydrogen Peroxide Concentration	25 % (range +10 % and -30% of the original concentration)
Surface Microhardness	< 0,7 % reduction (max 10 %)
Surface Erosion:	
- Dentin	< 0,1 µm reduction (max 5 µm)
- Enamel	< 0,1 µm reduction (max 4 µm)
Tooth Bleaching Efficacy:	
- 3 – 4 appl. 15-20 min	Delta E > 2
Viscosity	25 – 75 mPas
pH	5 – 6

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

There is no official shelf-life test described for dental whitening products. Based on the results of internal tests, we can guarantee the good qualities of Cavex Bite&White Shade Correction for a period of 3 years, provided the product is stored in at room temperature (25 °C) when not in use.

### 6. **Quality Control**

A batch of Cavex B&W Shade Correction, 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 B&W Shade Correction can be safely used and is non-toxic to the patient as well as to the dental team.

#### **Gingival Irritation**

Cavex B&W Shade Correction Gel that comes into contact with the gingiva may however cause mild to severe soft tissue irritation.