

Product Information

On

**Cavex Bite&White  
Aligner Whitening Pen 3% HPS**

<b>Legal manufacturer:</b>	<b>Cavex Holland BV Fustweg 5 2031CJ Haarlem The Netherlands</b>
<b>Regulatory evaluator:</b>	<b>Danny Stoelinga</b>
<b>Signature:</b>	
<b>Regulatory manager:</b>	<b>Richard Woortman</b>
<b>Signature:</b>	
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## 1. Introduction

Hydrogen peroxide is the bleaching agent in Cavex Bite&White Aligner Whitening Pen. It is added as Hydrogen Peroxide Superior in order to obtain a sufficiently stable product. The hydrogen peroxide breaks down rapidly into oxygen radicals and water. During the whitening process the free radicals attack the double carbon bonds that are the source of most colour (stains) in the tooth.

Cavex Bite&White Aligner whitening is a tooth whitening gel used in combination with an aligner for use in lightening the colour of natural teeth.

Cavex Bite&White Aligner Whitening Pen contains etidronic acid and sodium stannate which provide superior stability to the HPS gel. This results in recommended storage at room temperature.

Cavex Bite&White Aligner Whitening Pen should only be dispensed by or on the order of a dental professional. Before any whitening procedure, a consultation with a qualified dentist is recommended to ensure no underlying oral or health issues.

Cave Bite&White Aligner Whitening Pen is developed and manufactured by Cavex Holland B.V.  
Cavex Bite&White Aligner Whitening Pen is in compliance with the provisions of the Regulation (EC) 1223/2009 Concerning Cosmetic Products.

## 2. Composition

The basic ingredients of Cavex Bite&White Aligner Whitening Pen are:

Function	Raw Material	CAS/CI nr.	% Mass
Solvent	PEG-200	25322-68-3	58.00
Solvent	Water	7732-18-5	30.29
Emulgator	Poloxamer 407	9003-11-6	5,0
Active peroxide	Hydrogen Peroxide	7722-84-1	3,0
Thickener	Aristoflex AVC	335383-60-3	3,0
Chelating	Etidronic acid	2809-21-4	0,3
Fragrance	Mentha Arvensis Extract	90063-97-1	0,2
Chelating	EDTA	6381-92-6	0,1
pH regulator	Potassium hydroxide	1310-58-3	0,06
Stabilising	Sodium stannate	12058-66-1	0,05
			100,00

### 3. **Manufacturing**

The ingredients are carefully weighed, blended in a high-performance mixing device after which the pens are filled.

### 4. **Laboratory control**

There is no standard available for stability testing of whitening gel. Therefore, we have to consider critical parameters based upon our own experiences.

Characteristic	Product specifications	Release specifications	
Appearance	Colourless gel, homogeneous	Colourless gel, homogeneous	
Flavour	Peppermint flavour	Peppermint flavour	
pH	5,4 – 6,4	5,2 – 6,5	
Viscosity	25 – 75	10 – 100	Pas
Peroxide content	5,6 – 6,4	5,6 – 6,4	%

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

Based on all this experience, we are able to guarantee the good quality of Cavex Bite&White Aligner Whitening Pen for a period of 3 years, when kept at room temperature in its original packaging, provided the pen is unopened and stored in a dry place and exposure to direct sunlight is avoided.

### 6. **Quality Control**

A batch of Cavex Bite&White Aligner Whitening Pen, 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**

Adverse effects that may be associated with the use of Cavex Bite&White Aligner Whitening Pen include, but are not limited to:

#### **Sensitivity**

Some patients may experience increased tooth sensitivity to cold during the treatment, while others may have non-specific sensitivity in their teeth, gums, tongue, lips or throat. In general symptoms should disappear within several days after the treatment is stopped. The treatment can be proceeded with shorter, less frequent applications until the desired whitening effect has been achieved. If the discomfort remains, discontinue the treatment.

#### **Gingival irritation**

Trays that extend onto the gingiva may cause mild to severe soft tissue irritation. If the trays fit properly, check if the patient applies the proper quantity in the proper way. The patient may need to reduce the amount of gel in their trays.