

# Product Information

On

## **Cavex Bite&White CP10 / CP16**

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## Table of Contents:

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

## 1. Introduction.

Hydrogen peroxide is the bleaching agent in Cavex Bite&White. It is added as carbamide peroxide in order to obtain a sufficiently stable product. The carbamide 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 colours (stains) in the tooth. Cavex Bite&White is a tooth whitening gel for use in lightening the colour of natural teeth. The ideal consistency is achieved by the mixture of glycerine and water with the addition of a gelling agent Carbopol. This makes Cavex Bite&White easy in handling and is high control on the application obtained.

The addition of sodium fluoride and potassium nitrate ensure the early remineralization after every treatment. This avoids reduction of the tooth hardness, which can result in surface erosion.

Cavex Bite&White 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.

The dentist shall prepare an individual bleaching tray with excellent fit. After instructions, the patient will perform the actual whitening treatment at-home.

After several days the first results will become visible. However, the strongest whitening effects are measured during 9 – 14 days. After two weeks the whitening process can be determined. The treatment can be repeated after some months when necessary.

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

## 2. Composition.

The basic ingredients of Cavex Bite&White are:

	CP10	CP16	
Carbamide peroxide (hydrogen peroxide)	10,00 (3,5%)	16,00 (6%)	% w/w
Potassium nitrate	0,20	0,20	% w/w
Sodium Fluoride	0,10	0,10	% w/w
Carbopol	2,50	2,50	% w/w
Potassium hydroxide	1,30	1,30	% w/w
EDTA (Ethylene Diamine Tetra acetic Acid)	0,05	0,05	% w/w
Peppermint oil	0,05	0,05	% w/w
Glycerine	62,00	59,00	% w/w
Water	23,80	20,80	% w/w

## 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 is in compliance with ISO28399 Dentistry – Products for external tooth bleaching:

	<b>Cavex Bite&amp;White</b>
Appearance	Clear, transparent gel
Carbamide peroxide Concentration	10 - 16 % (range +10 % and -30% of the original concentration)
Surface Microhardness	< 0,7 % reduction (max 10 %)
Surface Erosion:	
- Dentin	< 1,0 µm reduction (max 5 µm)
- Enamel	< 0,1 µm reduction (max 4 µm)
Tooth Bleaching Efficacy:	
- 7 days 1 hour	Delta E > 2
- 14 days 1 hour	Delta E > 2
Viscosity	50 – 200 mPas
pH	5,8 – 6,6

#### 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 for a period of 3 years, provided the product is stored in a refrigerator (8 °C) when not in use.

#### 6. Quality Control.

A batch of Cavex Bite&White, 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 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 gingival 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.