

Product Information  
On

**Cavex Bite&White Impact / PVP**

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## 1. Introduction

For the whitening of teeth a strong oxidizing agent is required in order to remove the color stains in the enamel surface layer. Therefore, teeth whitening products contain some form of hydrogen peroxide which can break down into oxygen radicals and water. During the whitening process the high energy of the free radicals attack the double carbon bonds that are the source of most colors (stains) in the teeth. Hydrogen peroxide with fast reaction and thus effectiveness has the disadvantage that it shows poor stability. Therefore, many teeth whitening products use carbamide peroxide which first falls apart into hydrogen peroxide and urea, then the hydrogen peroxide can break down. Carbamide peroxide is stable when stored in a refrigerator.

Cavex Bite&White - PVP contains PVP-peroxide in order to obtain a stable product even at room temperature. PVP is a polymer containing an amide carbonyl group with a strong hydrogen bond acceptor. Therefore, hydrogen peroxide which is a strong hydrogen donor can form a stable complex. Under the influence of moist present in the mouth the PVP-peroxide breaks down rapidly into oxygen radicals and water. This will be even faster when the temperature is elevated due to the mouth temperature of 32°.

As Cavex Bite&White - PVP does not show degradation at room temperature it can be packed in tubes and application pens.

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.

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

## 2. Composition

The basic ingredients of Cavex Bite&White PVP are:

	<b>Tubes</b>	<b>Pen</b>	
Polyethyleneglycol	00,00	61,40	% w/w
Glycerine	00,00	10,00	% w/w
Polyglycerin-3	20,00	00,00	% w/w
Propylene glycol / 1,2 propane diol	50,50	00,00	% w/w
PVP peroxide*	29,20	28,50	% w/w
Potassium Nitrate	00,10	00,00	% w/w
Peppermint oil	00,20	00,10	% w/w

**\*5 – 6 % hydrogen peroxide**

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

	<b>Cavex Bite&amp;White PVP</b>
Appearance	Clear, transparent gel
Hydrogen Peroxide Concentration	5 – 6 %
Surface Microhardness	< 0,2 % reduction (max 10 %)
Surface Erosion:	
- Dentin	< 0,3 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	5 – 25 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 PVP for a period of 3 years, provided the product is stored at room temperature (25 °C) when not in use.

### 6. Quality Control

A batch of Cavex Bite&White PVP, 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 PVP 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.