

Product Information
On

Cavex Bite&White R2U (Ready to Use)
Dental Whitening System

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

Hydrogen peroxide is the bleaching agent in Cavex Bite&White R2U. 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 R2U is a tooth whitening system for use in lightening the colour of natural teeth.

Cavex Bite&White R2U 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 R2U 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 R2U is supplied in pre-filled trays – Ready To Use. 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 R2U are:

	Ready to Use	
Hydrogen Peroxide	6,00	% w/w
PEG	28,20	% w/w
Glycerin	25,10	% w/w
Water	30,60	% w/w
Aristoflex	4,00	% w/w
Poloxamer	5,00	% w/w
Silica filler	0,05	% w/w
EDTA	0,10	% w/w
Etidronic acid	0,30	% w/w
Sodium stannate	0,05	% w/w
Peppermint oil	0,20	% 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 R2U is in compliance with ISO28399 Dentistry – Products for external tooth bleaching:

	Cavex Bite&White R2U
Appearance	Clear, transparent gel
Peroxide Concentration	6 % (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	95 – 220 mPas
pH	5,5 – 6,5

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 R2U 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 R2U, 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 R2U 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

The trays may cause mild to severe soft gingival tissue irritation.