Product Information On

Quadrant FiniSense

(Desensitizing Primer)

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1. <u>Introduction</u>

Dental desensitizing primers such as Quadrant FiniSense are used in the dental practice to relieve pain caused by exposed tooth necks or dentine and to prevent or relieve post-operative sensitivity under all restorative materials.

Quadrant FiniSense causes coagulation of the proteins in the dentine liquid. The direct result of this is intradentinal closing of the tubuli, which prevents movement of the liquid in them – the cause of the sensitivity.

Quadrant FiniSense has a permanent effect when underneath restorative materials. Pain at the tooth neck disappears for about 12 months.

Quadrant FiniSense is compatible with all restorative materials and it is available in 5-ml bottles.

The standard application of Quadrant FiniSense is as follows:

- Clean the dentin using, for example, pumice slurry.

(Quadrant FiniSense can be applied without removing the smear layer by etching)

- Carefully dry the dentine surface, the tooth may be somewhat moist.

(Working with rubber dam is recommended)

 Apply the minimum amount of Quadrant FiniSense required for the treatment and allow this to work for 30 seconds.

(It is not necessary to use a polymerisation lamp)

- Gently blow-dry with a stream of air, until the liquid disappears and the surface no longer shines.
- Rinse thoroughly with water.

Quadrant FiniSense is developed and manufactured by Cavex Holland B.V. of Haarlem, The Netherlands, a Company that is certified according to the provisions of the Regulation (EU) 2017/745 concerning Medical Devices, against ISO 9001 and ISO 13485.

Quadrant FiniSense bears the CE marking of conformity.

2. Composition

Function	Raw Material	% Mass
Resin	2-Hydroxyethylmethacrylate	36
Active	Glutardialdehyde	5
Viscosity	Water	59

3. <u>Manufacturing</u>

The manufacturing of Quadrant FiniSense is the result of gradually mixing all raw materials into a clear liquid. Quality controls ensure the good quality of Quadrant FiniSense after the manufacturing process.

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4. Laboratory control

At present, a product standard for desensitizing primers is not available. Therefore, quality control is carried out according to a number of in-house standards.

Characteristic	Internal specifications	Quadrant FiniSense	Unit
Appearance	Clear, colourless liquid	Clear, colourless liquid	
pH	3 – 4,5	3 – 4,5	
Active substance	4 - 6	4 – 6	%
Packaging and marking	Must comply		

5. Shelf-life test

Based on all this experience, we are able to guarantee the good quality of Quadrant FiniSense for a period of 3 years(36 months), when kept in its original packaging, provided the bottle is unopened and stored in a cool and dry place.

6. **Quality Control**

A batch of Quadrant FiniSense, 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 Quadrant FiniSense can be safely used and is non-toxic to the patient as well as to the dental team.

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