

Instructions For Use

Quadrant FiniSense

CE 0197

Product description

Quadrant FiniSense is a water-based desensitizing primer effective against sensitive teeth. Quadrant FiniSense causes coagulation of the proteins in the dentine liquid. The direct result of this is intra dentinal 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.

Composition

The following materials are used in Quadrant FiniSense:

Function	Raw Material	CAS/CI nr.	% Mass
Resin	2-Hydroxyethylmethacrylate	868-77-9	36
Active	Glutardialdehyde	111-30-8	5
Viscosity	Water	7732-18-5	59
Total			100.0

Indication for use

- Prevention and reduction of tooth sensitivity.
- Pain relief for exposed tooth necks or dentine.
- Relieve post-operative sensitivity under all restorative materials.
- Dental desensitizing primer exclusively for dental professional users.

Intended use

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.

Dental desensitizing primers are exclusively handled by trained professional users.

Contra-indications & Warnings

Contra-indications

Quadrant FiniSense must not be used:

- If the necessary precautions cannot be taken or the specified application technique cannot be used,
- If the patient is allergic to any of the ingredients contained in Quadrant FiniSense
- If the pain is due to pulpitis,
- If the pulp is exposed or the dentine adjacent to the pulp is perforated.

Warnings and precautions

Quadrant FiniSense should only be used in dental practice.

Quadrant FiniSense contains 36% (2-hydroxyethyl) methacrylate (HEMA) and 5% glutaraldehyde.

- It is a local irritant and has toxic effects.
- Vapours from or contact with Quadrant FiniSense can cause irritation and burns to the eyes, respiratory organs, skin and mucous membranes.
- Appropriate precautions should always be taken before using Quadrant FiniSense
- Only dispense the smallest possible amount necessary for the treatment.

Instructions For Use

- Avoid contact with eyes, skin and mucous membranes
- In an emergency, rinse the affected area immediately, with copious amounts of water and apply suction. If symptoms persist consult your Doctor.

Handling

Applications

Quadrant FiniSense is used for the treatment of hypersensitive dentine. It achieves its effects by precipitation of plasma proteins, which reduces dentinal permeability and occludes the peripheral dentinal tubules. This inhibits the flow of fluid through the tubules which is the cause of sensitivity.

Quadrant FiniSense is used:

- to eliminate pain in exposed cervical areas not requiring restoration,
- to alleviate or prevent dentinal sensitivity after preparation of teeth, prior to receiving indirect restorations.

Dosage and Administration

Treatment of hypersensitive dentine

The treatment of hypersensitive dentinal surfaces is only indicated in cases of severe pain in reactions to thermal, osmotic or tactile stimuli. In cases of mild pain, alternative treatments such as desensitising toothpastes should be used.

- Clean the dentine (e.g. with cleansing pumice), under local anaesthesia if necessary, and then rinse off with water.
- Protect gingival and mucous membranes by using a rubber dam. Make sure that Quadrant FiniSense only comes into contact with the area to be treated.
- Apply the smallest possible amount of Quadrant FiniSense required for treatment to the dentinal surface using a Q-Brush and then leave for 30-60 seconds.
- Dry the surface carefully by applying a stream of oil-free compressed air until the fluid film has disappeared and the surface is no longer shiny. Apply suction. Then rinse thoroughly with water.
- Deep cavities and/or areas near the pulp should be covered with a suitable cavity lining before the desensitise is applied.




If a single application of Quadrant FiniSense does not produce sufficient and sustained pain relief, the treatment can be repeated at the same or a subsequent appointment before alternative treatments are used. If the symptoms persist, a bonding procedure for composite restoratives can be performed with or without a layer of composite.

Treatment of dentine prepared to receive complete cast restorations

- Protect gingiva and mucous membranes by using a rubber dam.
- Remove moisture from the prepared dentine by applying a gentle stream of oil-free compressed air.
- Apply Quadrant FiniSense with a Q-Brush and leave for 30-60 sec. Make sure that only the smallest possible amount required is applied and that it only comes into contact with the area to be treated.
- Dry the dentinal surface carefully by applying a stream of oil-free compressed air, rinse off thoroughly with water and apply suction.
- Cover cavities and/or areas near the pulp with a suitable cavity liner before applying Quadrant FiniSense.

Instructions For Use

Labelling:

 <p>GHS05 Corrosion</p>	 <p>GHS07 Irritation</p>	<p>Symbol use explanation:</p>
 <p>GHS08 Health Hazard</p>		<p>GHS05 Eye Dam. 1 H318 Causes serious eye damage.</p> <p>GHS07 Skin Irrit. 2 H315 Causes skin irritation. Skin Sens. 1 H317 May cause an allergic skin reaction. STOT SE 3 H335 May cause respiratory irritation.</p> <p>GHS08 Resp. Sens. 1 H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.</p>

Intended Patient(s)

Quadrant FiniSense is suitable for patients requiring dental treatment for the following indications with consideration of the contraindications. For pregnant and nursing women, the treatment risks must be weighed carefully against the benefits taking into consideration the unborn child or infant.

Intended User(s)

Quadrant FiniSense will only be used by dental professionals (dentist).

Clinical benefits

The following clinical benefits can be considered for Quadrant FiniSense:
Desensitizer based upon two active ingredients 36% (2-hydroxyethyl) methacrylate (HEMA) and 5% glutaraldehyde which results in a direct result for the patient after application.

Claims

- Effective within 30 seconds
- Durable 12-month effect
- Surface covering with film
- Easy to use
- About 150 applications per bottle

Product characteristics and specifications

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

Characteristic	Product specifications	Release Specifications	
Appearance	Free from foreign matter, Homogeneous	Free from foreign matter, Homogeneous	
pH	3 – 4,5	3 – 4,5	
Active substance	4 - 6	4 - 6	%
Packaging and marking		Must comply	

Instructions For Use

Combination products:

Accessories:

Quadrant FiniSense has the following accessory which can be used in combination with the product:

- Quadrant Q-brushes

Combination products:

Quadrant FiniSense can be used in combination with the following product(s):

- Quadrant Total Etch
- Quadrant Uni-1-Bond
- Quadrant Uni-SE-Bond

Special advice

According to EU Medical Device Regulation users/ patients are obliged to report serious incidents with a medical device to the manufacturer and to the competent authority of the country, the incident occurred.

Storage advice

Do not store at temperatures higher than 25°C (77°F) and lower than -10 °C (14°F). Do not use this material beyond its expiry date. Avoid direct exposure to sunlight. Close containers firmly after use and keep out of reach of children.

We recommend that the product is stored in a refrigerator when not in use.

Disposal information

Dispose of in accordance with local waste regulations. Do not dispose of contents or partially emptied packaging in household waste or allow them to enter the sewage system.

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