

FUSION CRYSTA ADHESIVE PRIMER

LIGHT CURE SELF ETCH ORTHODONTIC PRIMER

PREVESTDenPro®
THE FUTURE OF DENTISTRY

Product Description : Fusion Crysta Adhesive Primer is a light-cured single-component orthodontic primer that combines etching, priming and bonding in one bottle. It is an solvent free dental adhesive containing 10- Methacryloyloxydecyl Dihydrogen Phosphate (10-MDP) a functional monomer which helps in bonding to dentin and enamel.

Composition : BisGMA, Triethylene Glycol Dimethacrylate, Camphorquinone, Dimethyl Amino Ethyl Methacrylate, Ethyl 4-dimethyl Amino Benzoate, 10-Methacryloyloxydecyl Dihydrogen Phosphate, Butylated Hydroxytoluene.

Intended Purpose / Intended use: It is intended to be used as a component for attachment of orthodontic brackets using orthodontic adhesive over the tooth surfaces.

Indications for use : Fusion Crysta Adhesive Primer is indicated for use as a combined etchant and primer in orthodontic treatment and is used only with light curing direct bonding orthodontic adhesive (FUSION CRYSTA ADHESIVE).

Instructions for use :

SELF-ETCHING TECHNIQUE : Wash thoroughly with water spray. Use an absorbent pellet or high volume evacuation (HVE) for 1-2 seconds, to remove excess water (do not desiccate).

a. Dispense 1-2 drops of Fusion Crysta Adhesive Primer into a clean well. Replace the cap onto the bottle promptly to avoid evaporation of solvent.

b. Apply two separate coats of Fusion Crysta Adhesive Primer, scrubbing the preparation with a microbrush for 10-15 seconds per coat.

c. Air-drying using an air syringe for at least 10 seconds till there should be no visible movement of the adhesive. The surface should have a uniform glossy appearance; otherwise, apply an additional coat of FUSION CRYSTA ADHESIVE PRIMER and repeat Step 2 and 3.

d. Light cure for 20 seconds.

e. Continue with placement of the orthodontic adhesive (FUSION CRYSTA ADHESIVE) restorative material according to the manufacturer's instructions.

SELECTIVE-ETCHING TECHNIQUE : Wash thoroughly with water spray. Etch enamel using 37% phosphoric acid (ACTINO GEL) etchant for 15 seconds. Rinse thoroughly. Remove excess water by blotting the surface with an absorbent pellet or high volume evacuation (HVE) for 1-2 seconds, leaving the preparation visibly moist.

a. Dispense 1-2 drops of Fusion Crysta Adhesive Primer into a clean well. Replace the cap onto the bottle promptly to avoid evaporation of solvent.

b. Apply two separate coats of Fusion Crysta Adhesive Primer, scrubbing the preparation with a microbrush for 10-15 seconds per coat.

c. Evaporate excess solvent by thoroughly air-drying with an air syringe for at least 10 seconds, there should be no visible movement of the adhesive. The surface should have a uniform glossy appearance; otherwise, apply an additional coat of FUSION CRYSTA ADHESIVE PRIMER and repeat Step 2 and 3.

d. Light cure for 20 seconds.

e. Continue with placement of the orthodontic adhesive (FUSION CRYSTA ADHESIVE) restorative material according to the manufacturer's instructions. The dispensed material shall not be placed back in container and the dose once applied and used shall not be reused.

Warnings : Fusion Crysta Adhesive Primer adhesive is an irritant. Contact with the skin, mucous membranes or eyes should be avoided. If case of skin contact, immediately wash with soap and water. If the material should come into contact with the eyes, immediately rinse with copious amounts of water for at least 15 minutes and consult a physician or ophthalmologist. In rare cases, contact with the skin may lead to a sensitization towards methacrylates. Commercial medical gloves do not provide protection against the sensitizing effects of methacrylate.

Precautions :

1. Safety Precautions : The material contains certain methacrylates and other ingredients which may cause irritation or sensitivity in some individuals. If contact occurs with skin, immediately wash with soap and water. Improper use may result in allergic reaction or skin and tissue irritation. If this occurs, discontinue use of this product. Protective gloves and eye wear should be worn while handling this product. If contact occurs with eye. Flush immediately with large volumes of water and seek medical attention immediately. Do not expose materials to elevated temperatures or intense light.

2. Material Precautions : FUSION CRYSTA ADHESIVE PRIMER is a light-curable material. Use it immediately once it is dispensed in the mixing well. Prolonged exposure to air and light may lead to solvent evaporation and thickening of the adhesive.

Contraindications : Patients with a history of hypersensitivity to methacrylate monomers.

Storage conditions : Store at temperature between 10°C(50°F) to 24°C(75°F). Close the cap carefully after use. Keep away from moisture. Shelf life not affected after opening if stores in a cool dry place.

Shelf Life : 2 years from the date of manufacturing.

Presentation :

Regular Pack

Ref: 10021

1 x 5ml Bottle, 5 x Mixing Wells, 10 x Micro Brushes, 1 x Instruction manual.

Disposal conditions : To be disposed off based on the prevailing rules of the country in which it is used.

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UDI Symbol for "UNIQUE DEVICE IDENTIFIER"

LOT Symbol for "BATCH CODE" USE-BY DATE Symbol for "USE-BY DATE" NON STERILE Symbol for "NON STERILE" KEEP DRY Symbol for "KEEP DRY"

CAUTION Symbol for "CAUTION" CONSULT INSTRUCTION FOR USE Symbol for "CONSULT INSTRUCTION FOR USE" REF Symbol for "CATALOGUE NUMBER"

EC REP Symbol for "AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY/EUROPEAN UNION"

DO NOT USE IF PACKAGE IS DAMAGE Symbol for "DO NOT USE IF PACKAGE IS DAMAGE" KEEP OUT OF THE REACH OF CHILDREN Symbol for "KEEP OUT OF THE REACH OF CHILDREN" MANUFACTURER Symbol for "MANUFACTURER"

TEMPERATURE LIMIT Symbol for "TEMPERATURE LIMIT" KEEP AWAY FROM SUNLIGHT Symbol for "KEEP AWAY FROM SUNLIGHT" MD Symbol for "MEDICAL DEVICE"

The material has been developed solely for professional dental use. Application should be carried out strictly according to the instruction for use. Liability cannot be accepted for damages resulting from failure to observe the instructions of the stipulated area of applications. The user is responsible for testing the material for its suitability and use for any purpose not explicitly stated in this instruction sheet. Description and data constitute no warranty of attributes and are not binding. For feedback, complaints and reporting of unexpected events contact customer care.