

BRILLIANT Lumina

Instructions for use

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Please read the Instructions for Use carefully before using the product. Keep for later reference.

1. PRODUCT DESCRIPTION

BRILLIANT Lumina is a professional tooth whitening product based on two components (gel and activator). The product is designed to be used for a single treatment.

2. INTENDED USE / CLINICAL BENEFIT

BRILLIANT Lumina is intended to externally bleach tooth substance for the purpose of cosmetic enhancement of a patient's smile.

NOTICE

The outcome of the bleaching depends on the clinical situation of the patient. Restorations may have to be replaced after the treatment.

3. COMPOSITON

Gel: Aqua, Phthalimidoperoxicaproic Acid, Glycerin, Xanthan Gum, Monosodium Citrat, Pvm/ma Copolymer, Sodium Hydroxide, C12-15 Pareth-3

Activator: Aqua, Sodium Hydroxide

4. CONTRAINDICATIONS

Do not use in case of known allergies to the ingredients of the product.

The product is not intended to be applied to patients outside of the intended patient group.

5. SAFETY INSTRUCTIONS

Protective goggles and gloves must be worn when preparing the gel.

WARNING

Gel: Avoid contact with the eyes. Rinse your eyes immediately if the product has come into contact with the eyes.

Activator: Do not let it come into direct contact with humans (skin/eyes/mucous membranes). Causes severe skin burns and severe eye damage. Wear protective gloves/protective clothing/eye protection. IF SWALLOWED: rinse out mouth. Do NOT induce vomiting. IF IT COMES INTO CONTACT WITH THE SKIN (or hair): immediately remove all contaminated pieces of clothing. Wash/shower skin with water. IF IT COMES INTO CONTACT WITH THE EYES: rinse carefully with water for several minutes. If possible, remove any contact lenses being worn. Continue rinsing. Immediately phone a POISON CENTRE or a doctor. Absorb any spillages to prevent material damage.

6. SIDE EFFECTS / INTERACTIONS

Irritation of the gingiva and/or oral mucosa may occur if the liquid dental dam is not placed correctly, or the mixed gel comes into contact with soft tissue. Immediately remove the gel from the tissue using a wet gauze and rinse the area thoroughly.

7. USER- / PATIENT GROUP

Application through dental personnel only. Suitable for all patient groups including elderly people, excluding children and pregnant / breastfeeding women, patient with oral disease (e.g. periodontal disease) and/or seriously ill patients.

8. PREPARATION

Prior to the bleaching procedure, a professional tooth cleaning need to be performed (complete removal of biofilm).

Insert the cheek retractor. Insert a dental cotton wool between the lips and the teeth. Dry the tooth surface and gums with a three-way syringe.

① Complete isolation procedure using liquid dental dam according to the manufacturer's instructions for use.

9. PROPER USE

One treatment comprises 4 application cycles of 15 minutes each:

② Add 3 drops of activator to a jar of gel.

③ Mix with a spatula for 60 seconds to form a homogeneous mass.

④ Apply the gel to the teeth with a spatula.

⑤ Let the gel act for 15 minutes.

⑥ Aspirate the gel off the teeth. Wipe off any remaining gel with a dental cotton roll. Do not apply water.

Repeat steps ② to ⑥ three times.

⑦ When the treatment has been completed, rinse the mouth with water for 60 seconds.

⑧ Remove the gingiva barrier completely according to the manufacturer's instructions for use.

NOTICE

Always ensure that the gingival barrier is positioned correctly.

A patient can be treated several times with BRILLIANT Lumina. In between the treatments, a period of 14 day needs to be respected.

10. STORAGE

Expiry date: see secondary packaging

Storage temperature: 15-25 °C / 59-77 °F

Store in a dry place

11. DISPOSAL

Can be disposed together with household waste in compliance with official regulations in contact with approved waste disposal companies and with authorities in charge. Only dispose of completely emptied packages.

12. REPORTING OBLIGATION

All serious incidents occurring in conjunction with this product must be reported immediately to the manufacturer.

COLTENE International Dental Group

Cobea AG
Weiheracherstrasse 8
CH-8114 Dänikon

Customer Center
service@coltene.com

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